# LabChip® XT/XTe

**User Manual** 







#### **Preface**

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#### Content

The information in this manual may contain typographical errors or technical inaccuracies and is subject to change without notice. Modifications may also be made to the product described in this manual at any time.

#### **Proper Equipment Operation**

#### **WARNINGS**





- To reduce the risk of electric shock, do not remove the cover. No user serviceable parts inside. Refer to qualified service personnel if help is required.
- Use this product only in the manner described in this manual. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

#### **AVERTISSEMENTS**





- Pour réduire le risque de choc électrique, ne pas retirer le couvercle. Ce produit ne contient aucune pièce pouvant être réparée par l'utilisateur. Au besoin, confier l'appareil à un réparateur qualifié.
- Ce produit ne doit être utilisé que comme décrit dans ce manuel. Si cet appareil est utilisé d'une manière autre que celle spécifiée par le fabricant, la protection fournie par l'appareil peut être entravée.

#### **Contact Us**

If you have a question about a product that is not answered in this manual or online Help, or if you need assistance with this product, contact the Caliper Technical Support Center from 8:00 A.M. to 8:00 P.M., Eastern Time, Monday through Friday:

Phone: (508) 435-9761;

(877) LabChip for LabChip products only

Fax: (508) 435-0950

Email: technical.support@caliperLS.com

Internet: www.caliperLS.com

For support in Europe contact Caliper Life Sciences LTD, Runcorn, UK +44-1928-711448 or fax +44-1928-791228. For more information contact your local Caliper representative.

Before you call, have the following information available:

- Product serial number
- Software version (found by choosing About from the main Help menu)
- If applicable, the error number shown in the software, or in the log file.

#### **Product Service and Customer Support Plans**

Caliper offers a full range of services to ensure your success. From our original factory warranty through a comprehensive line of customer support plans, Caliper offers you Field Service Engineers and in-house Specialists who are dedicated to supporting your hardware, software, and application development needs.

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Our programs can include such useful services as:

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- Diagnostic servicing performed on-site by Caliper field service engineers or remotely via Technical Support
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- · Software updates
- Parts, labor, and travel expense coverage
- · Other customized services upon request

#### **Training For Your Product**

Contact the Caliper Center for Training and Development for information about the availability of training courses for your product:

Call: **(508) 497-2634** Fax: **(508) 435-3439** 

#### **FCC**

This device complies with part 15 of the FCC (United States Federal Communications Commission) Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

#### CE

This device complies with all CE rules and requirements.

#### **NOTE**



Changes or modifications to this equipment not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

#### **REMARQUE**



Tout changement ou modification apporté à cet instrument non expressément approuvé par l'entité responsable de la conformité peut annuler l'autorisation d'opérer l'appareil accordée à l'utilisateur.

### **Table of Symbols**

Table 1 contains symbols that identify particularly important information and alert you to the presence of hazards. These symbols may appear in this manual and/or on the product it describes.

**Table 1. Important Symbols** 

Symbol Symbole	Description Description
(1)	<b>DANGER:</b> An imminently hazardous situation, which, if not avoided, will result in death or serious injury.
	<b>DANGER:</b> Situation présentant un danger imminent qui, s'il n'est pas éliminé, peut entraîner des blessures graves, voire la mort.
$\triangle$	<b>WARNING:</b> Caution, risk of danger. Refer to the User's documentation.
	<b>AVERTISSEMENT:</b> Attention, danger potentiel. Se reporter à la documentation de l'utilisateur.
!	NOTE: A cautionary statement; an operating tip or maintenance suggestion; may result in instrument damage if not followed.  REMARQUE: Énoncé indiquant une précaution à prendre, un conseil de fonctionnement ou une suggestion d'entretien; son non-respect peut provoquer des dommages à l'instrument.
A	Hazardous voltage; risk of shock injury. Tension dangereuse; risque de blessure par électrocution.
	Crush hazard. Risk of body parts, hair, jewelry, or clothing getting caught in a moving part.  Danger d'écrasement. Faire attention que les parties corporelles,
	les cheveux, les bijoux ou les vêtements ne soient pas pris dans une pièce mobile.
	Risk of puncture injury. Risque de blessure par piqûre.
	Risk of exposure to biohazards.

**Table 1. Important Symbols (Continued)** 

Symbol Symbole	Description Description
	Risk of eye injury; wear safety glasses. Risque de lésion oculaire; porter des lunettes de sécurité.
<u> </u>	Risk of fire. Risque d'incendie.
	Risk of poison. Risque d'empoisonnement.
	Risk of explosion. Risque d'explosion.
	Hazardous fumes. Émanations dangereuses.
	Laser light; avoid exposure. Risk of eye injury. Rayonnement laser; éviter toute exposition. Risque de lésion oculaire.
A	Lifting hazard. May result in injury. Levage dangereux. Peut entraîner des blessures.
<b>(</b>	Protective ground symbol. Symbole de terre de protection.
Ī	Ground symbol. Symbole de terre.
-	Fuse. Fusible.
$\sim$	Alternating current. Courant alternatif.
	On (supply). Marche (alimentation).
0	Off (supply). Arrêt (alimentation).
<b>(€</b>	CE compliance mark.  Marque de conformité CE.
HI-POT	Signifies that the unit has passed safety tests for grounding, power line transience, and current leakage.  Signifie que l'appareil a réussi les tests de sécurité pour la mise à la terre, le courant transitoire de ligne d'alimentation et la perte de courant.
<b>—</b>	Input. Entrée.

**Table 1. Important Symbols (Continued)** 

Symbol Symbole	Description Description
<u></u>	Output. Sortie.
Equipment labels are color coded:	Yellow Caution, risk of danger Red Stop Blue Mandatory action
Les étiquettes de l'appareil sont codées couleur:	Green Safe condition or information  Jaune Attention, danger potentiel  Rouge Arrêter  Bleu Intervention obligatoire  Vert Condition sûre ou informations de sécurité
	Helpful hints, additional information Conseils utiles, informations supplémentaires

# **Instrument Safety**

The following safety information about the LabChip XT/XTe is included in this documentation. Read and review all safety information before operating the LabChip XT/XTe.

- Required Training
- "Chemical Safety" on page 8
- "Laser Safety" on page 9
- "Electrical Safety" on page 10

# **Required Training**

Ensure that all personnel involved with the operation of the instrument have:

- Received instruction in general safety practices for laboratories.
- Received instruction in specific safety practices for the instrument.
- Read and understood all related MSDSs.

#### **WARNING**



Use this product only in the manner described in this manual. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

# **Chemical Safety**

#### WARNING



Some chemicals used with the LabChip XT/XTe are potentially hazardous and can cause illness.

- Read and understand the material safety data sheet (MSDS) provided by the chemical manufacturer before you store, handle, or work with any chemical or hazardous material.
- Minimize contact with and inhalation of chemicals and chemical wastes. Wear appropriate personal protective equipment when handling chemicals (e.g., safety glasses, gloves, or clothing).
   For additional safety guidelines consult the MSDS.
- Do not leave chemical containers open. Use only with adequate ventilation, including a fume hood, if necessary.
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the chemical manufacturer's cleanup procedures as recommended on the MSDS.
- Dispose of waste in accordance with good laboratory practices and local, state/provincial, or national environmental and health regulations.
- After emptying waste containers, seal them appropriately.
- Comply with all local, state/provincial, or national laws and regulations related to chemical storage, handling, and disposal.

# **Laser Safety**

#### WARNING



- The Red Barcode LED is a Laser Class 1M device safe under reasonably foreseeable conditions of operation with the naked eye. Looking directly into the source of radiation by employing optics within the beam such as a magnifying glass, telescope or microscope can be potentially hazardous.
- Caliper LabChip XT/XTe Instruments contain Class 3R
   Excitation laser diodes. The LabChip XT/XTe is classified as a Class 1M device because the lasers are appropriately enclosed (embedded) and indicated with Warning labels.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- This instrument is not intended to be serviced at the customer site.
- NEVER remove instrument covers while the laser is powered. The laser block assembly is marked with the label shown below:



#### **CAUTION**

Class 1M Laser Product
Viewing the LED barcode scanning output with
certain optical instruments such as eye loupes,
magnifiers and microscopes within a distance of
100mm may pose an eye hazard.

Barcode LED (Red): 625nm wavelength, 4.5 mW maximum continuous (CW) in box

Excitation Laser (Green): 532nm (visible green) laser source, 5 mW maximum continuous (CW)

Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated 6/24/2007 & IEC/EN60825-1:2007

# **Electrical Safety**

The LabChip XT/XTe is powered by a UL/CSA/VDE/CE approved 100-240 VAC, 50/60 Hz input, 24 VDC output external power supply. Users should observe the following:

#### **WARNING**





Do not open the instrument enclosure. There are no user serviceable parts inside.

The wall outlet or the power cable connector on the back of the instrument should be accessible after the system's installation to allow personnel to safely disconnect power from the system.

The computer supplied with the LabChip XT/XTe instrument has internal lithium batteries. Batteries should not be incinerated.

#### WARNING







Danger of explosion if battery is incorrectly replaced. Replace only with the same or equivalent type recommended by the manufacturer's instructions.

#### **Power Cord Selection**

The LabChip XT/XTe is powered by the same power supply for 100, 120, and 230VAC operation. Use the correct power supply cord for the region where the instrument will be installed as described below.

#### **United States and Canada**

When using the LabChip XT/XTe instrument in the United States or Canada, use the North American power supply cord shipped with the instrument. The cord is intended to be plugged into a standard NEMA 5-15R receptacle in the wall. If the power cord needs to be replaced, contact Caliper for a replacement cord.

#### International

All power supply cords must be approved by an acceptable, accredited agency responsible for evaluation in the country where the power cords and system will be used. Power cords for international use must have an IEC 60320-1, C7 female connector to be compatible with the power supply. For additional information, contact your local Caliper representative.

### **Fuses**

The LabChip XT/XTe instrument does not contain any user replaceable fuses. Contact Caliper Technical Support (see "Contact Us" on page 2) if blown fuses are suspected.

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### Introduction

The **LabChip XTe** fractionation system performs fast, automated nucleic acid fractionation accurately and reproducibly. The resulting sample is tightly sized and is delivered in a sequencing-compatible buffer. The XTe improves laboratory efficiency and provides sizing that is difficult to obtain using manual methods. Data is displayed digitally and non-fractionated sample can be recollected and used at another time.

The LabChip XTe software can be used to run standard Caliper methods to perform extractions and to view the analyzed data after the run.

The **LabChip XT** Instrument has all the functionalities of the XTe with added features for sample tracking and data analysis. The quantitation feature allows for each sample's total input concentration to be determined. Additionally, the estimated concentration of the extraction region is automatically calculated using Smear analysis. Sample Names can be imported and data can be automatically exported for LIMs compatibility.

The LabChip XT software includes additional features for data analysis, sample tracking, data filtering, and data export to reports or LIMS. The following additional extraction modes are also available in the LabChip XT software: Fluorescence, Peak Max, Smear Max, Skip Extraction, and Separation Only. A 21 CFR Part 11 Security option is available for the LabChip XT software. Features that are only available in the LabChip XT software are identified in this manual.

Chip and Reagent Kits, which include the required reagents and consumables, are available to run specific assays on the LabChip XT/XTe. Contact Caliper to order Assay Kits.

This manual includes general instructions for using the LabChip XT and XTe hardware and software. It includes general procedures for operating the system, analyzing the data, using software security to comply with 21 CFR Part 11 requirements, instrument maintenance, and hardware and software troubleshooting.

#### **Assay User Guides**

Assay User Guides provide information about the assay. Instructions for preparing the chip and the sample are included in the LabChip XT Assay User Guide for the specific assay that you are running. Detailed information about the assay, including Specifications, Safety Warnings, Preparation Procedures, Expected Results, Troubleshooting, LabChip Kit Essential Practices, and Reordering Information is also located in the LabChip XT Assay User Guide for the assay.

#### **Assay Quick Guides**

Assay Quick Guides are included with each Assay Kit and include instructions for preparing the chip to run an assay.

The current version of the Assay User Guides and Assay Quick Guides can be accessed on the Caliper web site at: http://www.caliperls.com/support/reference-library/data-sheets/labchip\_systems\_data\_sheets.htm.

# **Principles of Operation**

The LabChip XT/XTe assays are based on traditional gel electrophoresis principles that have been transferred to a chip format. The chip format dramatically reduces separation time and provides automated sizing and quantitation information in a digital format. The additional collection well on the chip allows a specified range of nucleic acid sizes to be separated from the rest of the sample.

Fractionation is the separation of a small range of DNA strand lengths from a sample of DNA containing a broad mixture of DNA strands. The LabChip XT/XTe uses a microfluidic chip to separate the DNA strands by length in a gel contained in the chip. The sample is directed into a waste well on the chip until the specified size range is detected. The desired portion of the sample is then diverted into a collection well on the chip. At the end of the extraction, the run can be paused automatically and the extracted sample can be removed from the collection well. Multiple extractions can be performed during the same run to collect multiple sizes from the same sample. Options are also available to skip specific sizes or regions. The run can stop automatically when all extractions are complete or the run can continue to the end of the supported range and the remainder of the sample is diverted into the waste well.



Figure 1. LabChip XT Chip

When the channels in the chip are filled with sieving gel and buffer, the chip functions as an integrated electrical circuit. The circuit is driven by the electrodes in the lid that contact the chip's electrodes when the lid is closed.

The polymer filling the channels in the chip is designed to sieve DNA fragments by size as they are driven through the chip channels by electrophoresis, similar to using agarose or polyacrylamide gels.

# **Principles of Operation (Continued)**

The sample is loaded into the sample well on the chip. A fluorescent dye is added to, or already contained in the waste well at the opposite end of the separation channel. The sample then moves electrophoretically into the separation channel. The dye migrates in the opposite direction toward the sample well. As the DNA fragments move down the separation channel, they separate by size and bind with the dye. The dye increases in fluorescence when bound to the DNA in the separation channel. The complex then moves past the laser, which excites the fluorescent dye bound to the DNA. The software plots fluorescence intensity versus time and produces electropherograms for each sample (see Figure 2).

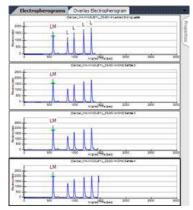


Figure 2. Electropherogram

The data can also be viewed in a gel-like format on the Gel Tab to achieve the appearance of a slab gel. (The colors of the gel can be changed.)

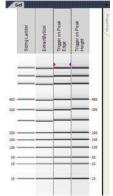


Figure 3. Gel View

# **Principles of Operation (Continued)**

Quantitating the concentration and accurately sizing each fragment are achieved by comparing against a sizing ladder. An internal standard or "marker" is added to each sample to adjust for channel to channel variations. The internal standard of known concentration is mixed with the sample to aid in quantitation and sizing. The marker lies slightly outside the assay range so it does not interfere with analysis.

The LabChip XT/XTe can use either a virtual software ladder or a ladder that runs in one channel of the chip at the same time as the samples for real-time sizing of the separated nucleic acids.

The following ladder options are available in the LabChip XT/XTe software:

- A virtual Caliper software ladder
- A Caliper ladder included in the reagent kit
- A customer-supplied ladder (LabChip XT only)

# **Operation**

This section includes general instructions for using the LabChip XT or XTe hardware and software to run an assay.

For assay-specific information, see the *LabChip XT Assay User Guide* for the specific assay that you are running. The current version of the Assay User Guides can be accessed on the Caliper web site at:

http://www.caliperls.com/support/reference-library/data-sheets/labchip\_systems\_data\_sheets.htm.

To run a chip in the LabChip XT or XTe:

- 1 Open the LabChip XT or XTe software (see page 24).
- 2 Create a Run File (see page 24).
- **3** If necessary, clean the electrodes (see page 221).
- **4** Prepare the chip for the method as directed in the *LabChip XT* Assay Quick Guide or Assay User Guide.
- **5** Run the chip (see page 33).
- 6 Monitor the run (see page 35).
- 7 If Extract and Pause is selected for any channels, remove the extracted material from the collection well when the run pauses and then continue the run (see page 35).
- 8 To manually pause a run, see page 37.
- **9** To stop a run before it ends, see page 38.

This section also includes the following procedures:

- Creating a new method (See page 39)
- Saving data files (See page 40)
- Saving workspace files (See page 42) (LabChip XT only)

# **Opening the LabChip XT or XTe Software**

To open the LabChip XT or XTe software:

- 1 Double-click on the LabChip XT or XTe icon on the Windows desktop.
- 2 If 21 CFR Part 11 Security is installed, the Login Window opens.
  - a Type a valid LabChip XT user name and password into the text boxes and click the OK button. (For instructions on creating LabChip XT user names, see "Adding New Users" on page 80.)
- 3 The LabChip XT/XTe Main Window opens. Do not use any other software applications while running the LabChip XT/XTe software.
- 4 If the run file has not been created, see "Creating a Run File" on page 24. If the run file exists, see "Running a Chip" on page 33. To analyze data from a previous run, see "Data Analysis" on page 43.

# Creating a Run File

Before running a chip, you should create a Run File. The Run File specifies the extraction or separation settings for the samples on the chip. Specifying the settings in a run file enables you to import the desired settings into the Start Fractionation Window after the chip has been prepared to minimize the time between preparing the chip and starting the run.

To create a run file:

- On the LabChip XT/XTe Main Window, select Tools → Run File Editor. The Run File Editor Window opens.
- 2 Select the Method to run from the Fractionation Method drop down list.
- **3** Select the options on the Run File Editor window:
  - Select the Extraction Parameters on the Setup Tab
  - Check the Buffer Utilization
  - Enter the User Info
  - Specify the Ladder Settings
  - Select the Output File Locations
  - Select the Auto Export Settings (LabChip XT only)

### Select the Extraction Parameters on the Setup Tab

The Setup tab displays the selected options for the run. The icon for each channel indicates the Operation mode and the Extraction mode.

To change the settings for a channel:

- 1 Click the Setup Tab in the Run File Editor Window.
- **2** For each channel, select the desired Operation for the channel by clicking the down arrow next to the channel icon:
  - Disabled
  - Ladder
  - eXtract and Stop
  - eXtract and Continue
  - eXcLuDe Region (LabChip XT only)
  - Separation (LabChip XT only)
  - eXtract and Pause
  - Skip Extraction (LabChip XT only)
  - Flush Sample

For descriptions of each option, see "Setup Tab" on page 188.

- 3 For each channel where eXtract and Stop, eXtract and Continue, eXcLuDe Region, eXtract and Pause, or Skip Extraction is selected, go to step 4 to select the desired extraction mode.
- **4** Select the desired Mode:
  - Size The extraction is specified by the size of the fragments.
  - **Trigger** The extraction is specified by searching for the specified trigger in the search region.
- **5** If the Mode is **Size**, select the desired Extraction Region. Either:
  - Click and drag the slider to the desired range.
  - Type the desired values in the Extraction Region text boxes.
  - Type the size (in BP) of the fragments to be collected in the Size text box and type the desired percent of size before and after to collect in the Percent (%) text box. Collection will start at the specified size minus the percent and will stop at the specified size plus the percent.

### Select the Extraction Parameters on the Setup Tab (Continued)

- 6 If the desired extraction region is larger than the assay Maximum Extraction Width, select the **Auto MultiStep Cut** check box and enter the desired extraction region in the text boxes. (Click the Review Setup button to see the actual steps that will be executed.)
- 7 If the Mode is **Trigger**, select the desired extraction mode:
  - Fluorescence The extraction trigger point is the point where the RFU exceeds the specified Threshold. (LabChip XT only)
  - Peak Start The extraction trigger point is the point where the signal slope meets or exceeds the specified Threshold value.
  - Peak Max The signal slope within the search region must exceed the specified slope threshold (RFU/min) to arm this trigger. The extraction is triggered when the signal has switched to a negative slope which meets or exceeds the specified threshold in magnitude. If the end of the search region is reached after the trigger has been armed but before the negative slope threshold has been achieved, the extraction will trigger at the end of the search region. (LabChip XT only)
  - **Collect On Click** Collection is triggered by the user. The target region displays in green on the graph. Click on the word **CLICK** in the Run Setup section on the left side of the LabChip XT/XTe Main Window to open the Fractionation Pending window. The target region continues to update until the extraction is triggered. Click the **Start Now** button when the green region is over the region to be extracted. When manual mode is selected in the width setting, click on the word **STOP** in the Run Setup section to end the collection or exclusion. Note that for some width settings, the target region may extend beyond the last visible data point on the graph. In this case, the highlighted region ends at the last visible data point and the dialog box indicates the time when the target region ends. When manual mode is selected in the width setting, click on the word STOP in the Run Setup section to end the collection or exclusion.

### Select the Extraction Parameters on the Setup Tab (Continued)

 Smear Max - The signal must exceed the Threshold value (RFU) within the search region to arm this trigger. The extraction triggers at the point when the signal decreases after averaging over three consecutive data points. If the trigger is armed but the signal decrease has not been detected by the end of the search region, the extraction triggers at this endpoint. (LabChip XT only)

(See "Setup Tab" on page 188 for details on each option.)

- 8 If Fluorescence, Peak Start, Peak Max, Collect on Click, or Smear Max is selected, select the desired **Collection Width**:
  - Percent (%) Specifies the Collection Width as a percent of the size at which the extraction is triggered. The extracted range is centered at the trigger point, and the collection width is from (size - %) to (size + %).
  - BP Specifies the number of base pairs (BP) to collect, starting at the specified trigger point. For Smear Max or Peak Max, the collection is centered on the peak or smear maximum.
  - If the extraction size is too large or exceeds the assay range limit, the extraction size is automatically adjusted to a valid range. For example, if the collection width is set to 400 BP triggered by Smear Max starting at 100 BP, then the extraction of 100 to 500 would be too large (beyond 20% which is the assay limit of XT DNA 750 assay) Theextraction range will be automatically adjusted and limited to 100 to 150. For Collect on Click, the Fractionation Pending dialog will show that the collection is limited to 150 BP to meet the assay limit constraint.
  - Manual For Peak Start, Collect on Click, and
    Fluorescence, the collection begins at the trigger point and
    ends when the user clicks STOP in the Run Setup. For Peak
    Max and Smear Max, collection begins at the specified
    percent before the trigger point (size %) and ends when the
    user clicks STOP. If the user has not stopped the extraction
    when the end of the search region has been reached, the
    extraction ends there automatically.
- If the start point of the collection width has already passed the switch point when the trigger point is detected, collection begins immediately and continues for the entire collection width.
- Fluorescence, Peak Max, and Smear Max are not supported in the LabChip XTe software.

### Select the Extraction Parameters on the Setup Tab (Continued)

- **9** Specify the desired name for each channel:
  - Type the desired name for each channel in the Sample Name text box.
  - Click the Import Names button at the bottom of the window and select the Sample Name File that contains the desired names. (LabChip XT only.)
- **10** To add another step to a channel, click the **New** button. The **Step** text box displays the step number of the new step. Repeat steps 2 through 8 to select the settings for the current step.
  - To add a new step between existing steps, go to the step before the desired location for the new step and click the New button. For example, to insert a step between steps 2 and 3, go to step 2 and click New. The new step is numbered step 3 and the step that was step 3 is now numbered step 4.
- 11 If desired, use the Copy and Paste buttons to copy settings between channels. The Copy function selects the source channel, not the actual settings. If the settings of the copied channel are edited before clicking Paste, the edited settings are pasted.
- **12** When the settings on the Setup tab are correct, go to "Check the Buffer Utilization" on page 29.

#### **Check the Buffer Utilization**

Before the run, verify that the buffer will not run out during the run. The buffer cannot be refreshed. The Buffer capacity is an estimation. The run can be started even if the run is over the buffer limit, but be aware that if the buffer capacity runs out, the current will drop and the DNA will not continue to migrate into the collection well. Exceeding the buffer capacity will cause undesired results.

- 1 Check the buffer icons on the Setup Tab and verify all the icons are green, indicating the buffer is sufficient for the run. If the icons are not green, click the Buffer Utilization Tab. to view the estimated extraction time and buffer limit.
- 2 Using the estimated extraction time, select extraction parameters on the Setup Tab that either complete the extraction before the buffer time limit is exceeded or select the manual collection width and end the collection before the buffer runs out.

#### **Enter the User Info**

- 1 Click the User Info Tab in the Run File Editor Window.
- 2 Type the operator's name and a comment, if desired. If the 21 CFR Part 11 Security option is installed in the LabChip XT software, the current logged in user name is automatically displayed.

### Specify the Ladder Settings

Custom Ladder settings are only supported in the LabChip XT software. To change the ladder settings:

- 1 Click the Sizing Table Tab in the Run File Editor Window.
- 2 To use the default Caliper ladder, select the **Method Ladder** option.
- 3 To use a custom ladder by specifying the sizes of the peaks in the ladder, select the **Custom Ladder** option and type the ladder peak sizes into the Size column of the ladder table.
- 4 To reset the ladder table back to the settings saved in the method file, click the **Copy Table from Method** button.

### **Select the Output File Locations**

- 1 Click the Output Tab in the Run File Editor Window.
- 2 To change the **Data Path**, click the Browse (...) button and select the desired location for the data files. Clicking the Default button restores the default data path.

#### **NOTE**



Data files should be saved to a local folder on the computer's hard drive. Saving data files to a network drive may cause loss of data if the network connection is slow or interrupted.

- 3 If desired, select the **Create Daily Sub-Directory** check box to create a new sub-directory for data files each day.
- 4 If the 21 CFR Part 11 option is installed and you want to save a copy of the data files to a folder outside of the CDR or if the 21 CFR Part 11 option is not installed and you want to save a second copy of the data files:
  - a Select the Copy To check box.
  - **b** Click the **Browse (...)** button. The Browse for Folder Window opens.
  - **c** Navigate to the folder where you want to save the exported copies of the data files.
  - **d** Click the **OK** button to choose the selected folder. The path displays in the Copy To text box on the Output Tab.
- 5 In the File Prefix text box, type the desired prefix for all data files. (The File Name Example text box displays the selected format for the data files.)
- To add the Computer Name, Project Name, Chip ID (LabChip XT only), Date, and/or Time to the data file name, select or clear the desired check boxes or type the desired project name.
- 7 To automatically export data tables, graphs, or gels in the LabChip XT software, select the **Automatic Export** check box, click the **Settings** button, and then select the desired Auto Export settings (see page 31). Auto Export is not supported in the LabChip XTe software.
- **8** See "Save the Run File" on page 32.

### **Select the Auto Export Settings**

The Auto Export settings in the LabChip XT software specify which views to automatically export at the end of each run and specifies the format for each view. Click the **Settings** button located after the **Automatic Export** check box in the Output Tab on the Run File Editor Window to open the Export Window. Auto Export is not supported in the LabChip XTe software.

To select the desired views to export:

- 1 Select the check boxes next to the views to export. Selecting **Export All** selects all check boxes.
- **2** For each selected view, to change the location for the files, click the **Browse** (...) button and select the desired location.
- 3 If Raw Data is selected, click the AIA Format check box to export in Chromatography Data Interchange Format or clear the check box to export in .CSV format. If .CSV is selected:
  - Select Include Size Data to align the data to the channel's ladder (for one file per channel) or to the first channel (for a single data file) and include the size data in the exported data.
  - Select Export Single Table to export the data for all channels in the chip to one .CSV file. If not selected, the data from each channel is exported to a separate .CSV file.

#### 4 If Gel is selected:

- a Select either **Single File** to include gels for all channels in the run in the same image file, or select **Separate Files** to export each gel to a separate image file.
- **b** If desired, change the height, in pixels, of the exported gel graphics in the Height text box.
- 5 If either **Electropherogram** or **Gel** is selected, choose the desired format for the image files.
- 6 Click **OK** to save the Export settings. The specified files will be exported at the end of the run.

#### Save the Run File

After the desired settings are entered in the Run File Editor Window, save the Run File so it can be imported into the Start Fractionation Window.

To save the run file:

- 1 Click the Save button at the bottom of the Run File Editor Window. The Export Fractionation Setup to XML File window opens.
- 2 Navigate to the desired location to save the run file (\*.xml). You should save the run file in the default location if it will be used to run chips.
- 3 Type the desired name for the run file in the File Name text box.
- 4 Click the **Save** button to save the run file.
- **5** Click the **Close** button on the Run File Editor window to close the window or modify the settings to create another run file.

# Running a Chip

Before starting a run, make sure the desired run settings have been selected in the Run File Editor Window and saved as a run file (see page 24).

To start a run to read a chip:

- 1 Prepare and Load the Chip
- 2 Select the Run File
- 3 Start the Run
- 4 Monitor the Run

### Prepare and Load the Chip

1 Prepare the chip as directed in the LabChip XT Assay Quick Guide or Assay User Guide.

#### **WARNING**









Some chemicals or samples used with the LabChip XT/XTe are potentially hazardous and can cause illness. Follow the precautions in "Chemical Safety" on page 8 and the precautions in the Assay User Guide.

- 2 Lift the latch on the front of the instrument to open the lid.
- 3 Place the prepared chip in the instrument with the notched corner of the chip aligned with the notch in the chip locator.
- 4 Close the lid.
- **5** See "Select the Run File" on page 34.

#### Select the Run File

After the chip is prepared, open the run file that contains the settings for the run:

- 1 On the LabChip XT/XTe Main Window, move the cursor over the image of the LabChip XT instrument to display the Run button. Click the Run button or select Instrument → Start Run to open the Start Fractionation Window.
- 2 Click the **Import Setup** button at the bottom of the window. The Import Fractionation Setup from XML File window opens.
- **3** Click the name of the run file that contains the settings for the run.
- 4 Click the **Open** button to display the saved settings in the **Start** Fractionation Window.
- **5** Edit the settings if required. If desired, click the Export Setup button to save the modified settings to a run file.
- **6** When the settings are correct, go to Start the Run.

#### Start the Run

1 Click the **Start** button in the **Start** Fractionation Window to start the run. A new workspace opens to display the data.

See "Monitor the Run" on page 35 for information about viewing data during the run.

### Monitor the Run

The following occurs after a run is started:

- 1 The Run button on the LabChip XT/XTe main window changes to Pause/Stop.
- 2 The software performs a Connectivity Test to verify that correct voltage and current is achieved in both separation and collection modes.
- 3 If all four channels are enabled, performs a Current Leakage Test to verify there is no current leaking between the channels. All four channels are tested at full current, then each channel is switched off one at a time and the currents are tested.
- **4** Data collection begins. Data is saved to a file with the name shown above the chip diagram.
- 5 The Graph View displays the electropherograms of the channels being read.
- 6 If any channels are set to Collect on Click, watch the data and click on the word **CLICK** in the Run Setup section when the green collection area shown on the graph is near the desired point. The Fractionation Pending window opens. Click Start Now when the green collection region is over the desired area.



- 7 During the run, each extracted region is highlighted in the Graph View and in the Gel View. The color of the highlight indicates the type of region:
  - Red Normal extraction region
  - Yellow Exclusion region
  - Green Target region for Collect on Click. Changes to red during collection.
  - Gray Skip extraction region
  - Red changes to Purple Buffer capacity exceeded during the extraction

# Monitor the Run (Continued)

- 8 The highlighted regions correspond to Smears created automatically by the software. The smears are included in the Smear Analysis Tab on the Method Window after the run is complete.
- 9 If any channels are set to eXtract and Pause, the run automatically pauses after the extraction is complete, the Run Paused window displays, and any channels that have completed the extraction display COLLECT in the Run Settings.
- 10 While the run is paused, remove the sample from the collection well, replace the chip in the instrument, close the lid, and resume the run by clicking the Resume button on the Run Paused window. See the Assay Guide and Run File Guide for important information about using Extract and Pause.
  - While the run is paused, you can also edit or stop the run.
- 11 To select a single channel as data is acquired or after the run is finished, click a channel in the Chip View or List View (LabChip XT only), a sample name in the Channel Table View, or a lane in the Gel View.
- **12** To manually pause a run in progress, see "Pause a Run" on page 37.
- 13 To stop the run before it is complete, see "Stop a Run" on page 38.
- 14 When the assay is complete, **Run Successful** displays in the Status line. For information on data analysis, see "Data Analysis" on page 43.
- **15** If desired, remove the chip.

#### To save the Workspace in the LabChip XT software:

- Select File → Save Workspace. The Save Workspace File As Window opens with the data file name as the default name of the workspace.
- 2 If desired, change the location and/or the name of the workspace file and click the **Save** button. (Workspace files have an .xtw file extension.) The workspace file should be saved in the default location, which is the same directory that contains the data file. The data file is automatically saved at the end of the run. To view or re-analyze the data, see "Data Analysis" on page 43.

## Pause a Run

The run in progress can be manually paused to remove material from the collection wells or to edit certain extraction parameters. While the run is paused, the voltage for each channel is set to zero, the lasers are turned off, and the samples stop moving through the channels. The run will automatically pause if the lid is opened during the run, but using the software Pause feature ensures that all of the extracted material has entered the collection well before the run is paused.

To manually pause a run in progress:

Move the cursor over the instrument icon on the upper left side of the LabChip XT/XTe Main Window. The Pause/Stop button displays as shown in Figure 4.

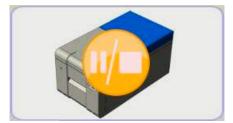


Figure 4. Pause/Stop Button

- 2 Click the Pause/Stop button. The Modify Run Settings Window opens, the voltage in each channel is set to zero, and the lasers turn off.
- While the run is paused, the settings on the Setup Tab and User Info Tab can be edited. On the Setup Tab, the Operation mode for a channel cannot be changed, only the Search Region, Extraction Region, and Extraction Mode can be edited. It is the operator's responsibility to select valid settings while the run is paused.
- 4 If the lid is opened while the run is paused, the chip can be removed and the material can be collected from the appropriate Collection wells. The channels in which the extraction is complete display COLLECT in the Run Setup area on the LabChip XT/XTe Main Window. When the lid is closed, any channels that have finished all of the extractions display DONE. Channels that have not completed display information about the next step.
- 5 To stop a run while the run is paused, see "Stop a Run" on page 38.

# Stop a Run

If you need to stop the run before it is complete, click the **Pause/Stop** button. After a run is stopped, it cannot be restarted and the channel cannot be reused.



The Modify Run Settings Window opens, the voltage in each channel is set to zero, and the lasers turn off. Click the **Stop Run** button.

A message box confirms that you want to stop the run in progress.



Click **Yes** to stop the run. The Run Status line displays **Run stopped by user**.



The data that has been collected up to the time the run was stopped displays in the LabChip XT/XTe Main Window. Save the workspace (see page 42) if desired in the LabChip XT software. In the LabChip XTe software, the data file is saved automatically.

## **Create a New Method**

The LabChip XT software enables you to create a new method by opening and editing an existing method and then saving the method with a new name. Only the pre-defined Caliper method files are available in the LabChip XTe software.

To create a new method:

- 1 On the LabChip XT/XTe Main Window, select Tools → Method Editor. The Select Method To Edit window opens.
- 2 Select the name of the Method file that you want to edit and click the OK button. The Method Window opens and displays the settings for the open method.
- 3 Modify the settings as necessary for the new method. (See Modifying Analysis Parameters or Reanalyzing a Data File for information on setting or changing analysis parameters.)
- 4 Click the **Save Method** button at the bottom of the Method window, specify the desired name for the new method file, and click the **Save** button.

#### **NOTE**



All method files must be saved in the C:\Program Files\Caliper Life Sciences\LabChip XT\Assay folder. Only the methods saved in this folder are available in the Fractionation Method list in the Start Fractionation Window and the Run File Editor Window.

# **Saving Data Files**

While running a method, the raw data received from the instrument is automatically saved to the data file (.xtd for LabChip XT, or .xte for LabChip XTe). If a run is stopped before it is complete, the data that has already been collected for the run is saved in the data file. The name of the data file is specified in the Output Tab on the Start Fractionation Window.

The analysis settings for a chip are saved at the end of the data file. If analysis settings are changed in the Method Window in the LabChip XT software and the data file is saved, the new settings are added to the end of the data file, but the previous settings are not overwritten. This enables a chip to be restored to previous analysis settings using the **Restore Chip** button in the Method window in the LabChip XT software. Changing analysis settings is not supported in the LabChip XTe software.

If the 21 CFR Part 11 option is installed with the LabChip XT software, data files are saved in the Centralized Data Repository (CDR). The CDR is a secure folder that can only be accessed by the LabChip XT software. The location of the CDR is specified in the CDR Utility Window.

Updated analysis settings are saved when the chip data file is saved. To save the data file, either:

- select Workspace → Save Chip on the Menu Bar,
- right-click on the chip name in the Chip View and select Save Chip, or
- select File → Save Workspace or File → Save Workspace As on the Menu Bar. See Saving Workspace Files for more information. (LabChip XT software only.)

If the 21 CFR Part 11 option is installed with the LabChip XT software and Require Signature on File Update is selected in the Set Policies tab on the User Administration Window, the user must have signature rights to save an updated data file.

To save the data file when the 21 CFR Part 11 option is installed and Require Signature on File Update is selected:

- 1 The Perform Signature Window opens when you save a data file
- 2 Select the name of the user who is signing the data file in the Username drop-down list.
- **3** Type a **Comment** that meets the requirements of the compliance policies.

# **Saving Data Files (Continued)**

- 4 If desired or required by compliance policies, select the **Approval State** of the data file.
- 5 If desired or required by compliance policies, select the **Lock** check box to lock the data file and prevent any changes until the data file is unlocked. To lock a data file, the Approval State must be either Accepted or Rejected.
- 6 Type the **User Password** for the signing user.
- 7 Click the Sign button. The Signature Performed window confirms that the signature has been performed.
- **8** Click the **OK** button. The signature is recorded in the data file.

#### **NOTE**



Changing the analysis settings in the LabChip XT software and saving the chip data file does not change the raw data from the run. Only the display of the data is changed.

If you change the analysis settings in the LabChip XT software without saving the new settings, and then try to close the workspace, exit the software, or acquire new data, you are prompted to save the changes. Selecting Yes opens the Save Workspace File As Window.

# **Saving Workspace Files**

When viewing chip data in the LabChip XT/XTe main window, you view the selected data files in a Workspace. When a new run starts, a new blank workspace opens, which contains the data file for the chip in the run. After the run is complete, saving the workspace in the LabChip XT software saves the data file with the current analysis settings. (See Saving Data Files for more information on the contents of the data files.) The LabChip XTe software does not support saving workspace files.

The Data Files are not saved in the Workspace file. In the LabChip XT software, the saved workspace file contains links to the revision of the data file that was last open in the collection. If a Workspace file is moved to another folder or computer, the data files must be moved with the Workspace file. The data files must be in the same location relative to the Workspace file as they were, otherwise you are prompted to find the missing data files when you open the Workspace file. It is a good practice to save the workspace files in the same location as the data files that are included in the workspace.

Saving a Workspace file in the LabChip XT software automatically saves any changes to the data files that are open in the workspace, and saves the settings for each collection in the workspace.

If the 21 CFR Part 11 option is installed, saving Workspace files does not require permission to save data files unless the data files in the workspace have been modified.

# **Data Analysis**

After a run is complete, use the LabChip XT or XTe software to view and analyze the chip data. The LabChip XT and XTe software can open multiple data files in the same workspace to compare the data from different chips. In the LabChip XT software, analysis settings can be changed for single channels, entire chips, or all chips in the workspace.

This section contains the following information:

- How the Software Analyzes DNA Data
- Organizing, Retrieving, and Backing Up Data Files
- Opening a New Workspace (LabChip XT only)
- Opening a Data File
- Adding a Collection to a Workspace (LabChip XT only)
- Using Expected Fragments (LabChip XT only)
- Modifying Analysis Parameters (LabChip XT only)
- Reverting to a Specific Data File Revision (LabChip XT only)
- Changing the View of the Results
- Copying Information
- Reanalyzing a Data File (LabChip XT only)
- Printing Workspace Information
- Exporting Data (LabChip XT only)

# **How the Software Analyzes DNA Data**

The LabChip XT and XTe DNA Assay Analysis calculates the size of nucleic acid fragments during the run to provide accurate extraction of the desired fragment sizes. Three options are available for calculating the fragment sizes:

- using the default Caliper Sizing Ladder while running up to four samples in the chip,
- using the default Caliper ladder while running one ladder and up to three samples in the chip, or
- using a custom ladder while running up to four samples in the chip (LabChip XT only).

In its simplest form, the sizing is performed with only the sizing ladder. A generic ladder is provided by Caliper as part of the fractionation method designed for the chip and size range. The ladder times of the sizing ladder are used to map migration time to size. The collection start time and collection end times are determined at the start of the run and do not change as the run progresses. It is essential for each sample to include a lower marker. The ladder and sample markers are aligned, resulting in an adjustment of the sample migration times relative to the ladder. The collection times are corrected using the aligned sample migration times after the sample lower marker passes the detector.

To improve sizing accuracy, a ladder can run in one of the channels and the channel can be designated as the real time ladder. The real time ladder runs parallel to the samples. The ladder peaks that are smaller than the extraction region pass the detector before the collection time. The software uses the sizing lookups from the sizing ladder to estimate the times for sizes larger than the collection region. Often the sample DNA of the desired size reaches the switch point before a real time ladder peak of greater size has passed the detector. In this scenario, the DNA size is calculated from previously observed real time ladder peaks of smaller sizes and the sizing ladder points of greater size.

After the run is complete, additional data analysis can be performed in the LabChip XT software to filter the data, change peak find settings, or change the view of the data in the software. See the procedures in this section for details.

# Organizing, Retrieving, and Backing Up Data Files

As you work in the LabChip XT or XTe software, it's a good practice to organize the files generated by the software.

- Create a folder in which to save the data files or use the default \Data folder. If desired, each person can save data files to their own subfolder to organize the data files.
- Save Workspace files in the LabChip XT software in the same directory as the data files to prevent missing data files in the workspaces.
- Review the files periodically, even if only one person uses the software. If you are not using the 21 CFR Part 11 option, archive files you are no longer using but want to save to a backup disk, and discard unneeded files. If you are using the 21 CFR Part 11 option, see "Software Security" on page 78 for backup options. Verify there is enough free space on the hard drive to save new chip data files.
- Each user in the laboratory can specify a particular data file name prefix to easily differentiate data files.
- A new folder can be created each day to store the data from all runs. To automatically create the folders, select the Create
   Daily Sub-Directory check box on the Output Tab in the Start Fractionation Window.

# **Opening a New Workspace**

A workspace displays data from one or more chip data files from the same type of assay. Each workspace can contain one or more Collections to display the data. In the LabChip XTe software, open a data file to automatically open a new workspace.

To open a new workspace:

On the menu bar, select File → New Workspace. If changes have been made to an open workspace, you are prompted to save any unsaved changes. A blank workspace opens in the LabChip XT/XTe Main Window.

To view data, see:

- Opening a Data File
- Adding a Collection to a Workspace
- Using Expected Fragments
- Modifying Analysis Parameters

# **Opening a Data File**

Open a data file to view the data, to compare the data to other data files in the same workspace, or to change analysis settings and view the reanalyzed data. Data files generated by the LabChip XT software have an .xtd file extension. Data files generated by the LabChip XTe software have an .xte file extension.

#### To open a data file:

- 1 Open a new workspace (see page 45) or a workspace that already contains compatible data files. (In the LabChip XTe software, the workspace opens automatically when the data file is imported.)
- 2 On the menu bar, select File → Import Data File. If the 21 CFR Part 11 option is not installed, the Select a Data File Window opens. If the 21 CFR Part 11 option is installed, the CDR Manager Window opens.
- 3 Select the name of the data file to open and click the Open button. The selected data file is imported into the open workspace. Use Ctrl+click or Shift+click to select multiple files.
- 4 If desired, right-click on the Chip Name in the Chip View (see Chip View or List View) and select **Rename Chip** to change the name of the chip in the display. (If the Rename File to Match check box is selected, the data file is also renamed to the same name as the chip. The data file cannot be renamed if the 21 CFR Security option is installed.)
- 5 Select the desired channels to view in each collection in the workspace. (The LabChip XTe software does not support multiple collections in one workspace.)
- 6 See "Modifying Analysis Parameters" on page 53 for information about changing analysis parameters in the LabChip XT software.

# Adding a Collection to a Workspace

Collections are used to specify the channels selected for view in each chip data file, the layout of the views in the Collection tab, and the display properties for each view in each collection. Only the LabChip XT software supports multiple collections in a workspace.

To add a new collection to an open workspace:

- 1 On the menu bar, select Collection → New Collection. The New Collection Window opens.
- **2** Select the desired option for creating the new collection:
  - Template Opens a new collection with the same settings as a saved collection template file.
  - Blank Collection Opens a new template using the default collection settings.
  - **Current Collection** Opens a new template based on the current settings in the currently open collection.
- 3 If no chips are open in the collection, choose the desired Assay Type for the collection: DNA. Only data files from the selected assay type can be imported into the workspace.
- 4 If desired, type a new name for the collection in the **Name** text box.
- **5** Click the **OK** button to open the new collection.

# **Using Expected Fragments**

You can track expected DNA fragments (EFs) for the samples in a DNA assay in the LabChip XT software. The LabChip XTe software does not support defining Expected Fragments.

## **Entering EFs in the Method Window**

Only supported in LabChip XT software.

- Select Analysis → Analysis Settings on the Menu Bar. The Method Window opens.
- 2 Click on the Expected Fragments Tab.
- **3** Click in the bottom (empty) row in the table.
- 4 In the column labeled **Size**, enter the size of the expected fragment in **bp**.
- 5 In the **Window** (%) column, if desired, change the tolerance value to allow for variations in the expected fragment size. This value is specified as a percent of the expected size for that fragment. The default is 10% for DNA.
  - **Note**: If there are multiple peaks in the tolerance range, the largest peak is labeled as the expected peak, even if it is not the exact size specified. To change the peak identified as an expected peak, see "Forcing Expected Peaks" on page 50.
- **6** A default color is automatically assigned. To change the color, click on the color block in the **Color** column and select the desired color in the Color window.
- 7 If desired, change the name shown in the **Name** column.
- If desired, change the **Property Displayed in the Channel Table**. This setting specifies the property that will be displayed in the Expected Peak column for each expected peak listed in the Channel Table View.
- 9 To apply the expected peak only to specific channels, double-click in the Apply to Channels column. The Select Channels window opens. Click to select the channels that you want to apply the expected peaks to, and then click the OK button.
- **10** To apply the EFs to the active chip, click the **Apply** button.
- 11 To apply the EFs to all chips in the workspace, click the **Apply Global** button.

## **Exporting EFs**

Only supported in LabChip XT software.

- 1 After the EFs are entered in the Expected Fragments Tab, click the Export button at the bottom of the window. The Export Expected Fragments Window opens.
- 2 Navigate to the desired location for the file, type the desired name for the file in the File Name text box, and then click the Save button. A .GEP file is created to save the expected peak settings.

## **Importing EFs**

Only supported in LabChip XT software.

After an Expected Peak file (\*.GEP) has been exported, you can import the settings into another chip or workspace.

- 1 With the chip open in a workspace, in the Expected Fragments Tab, click the **Import** button at the bottom of the window. The Import Expected Fragments Table window opens.
- 2 Navigate to the location of the file, select the name of the file to import, and then click the **Open** button. The expected peak settings are imported into the tab.
- **3** To apply the EFs to the active chip, click the **Apply** button.
- To apply the EFs to all chips in the workspace, click the **Apply Global** button.

## **Forcing Expected Peaks**

Only supported in LabChip XT software.

If there are multiple peaks in the tolerance range, the largest peak is labeled as the expected peak, even if it is not the exact size specified. If a different nearby peak should have been selected as the expected peak, you can specify which peak is labeled the expected peak.

- 1 In the Graph View, right-click on the peak that should be labeled as the expected peak.
- 2 On the shortcut menu, select **Force Expected Fragment** and then select the desired fragment from the menu.

To clear a forced peak and revert to the default expected peak, right-click on the forced expected peak and select **Clear Forced EP**.

# Viewing the EFs in the Graph View

**Expected Fragments** are identified in the electropherogram in the LabChip XT software by solid triangles over the peaks. The triangles are the same color as specified in the Expected Fragments Tab.

To display the expected peak indicators in the Graph view:

- 1 Click the **Properties** tab on the right side of the **Graph view** to open the **Graph View Properties**.
- 2 To view the size of all expected peaks, select **Expected Fragments** in one of the Annotation list boxes.

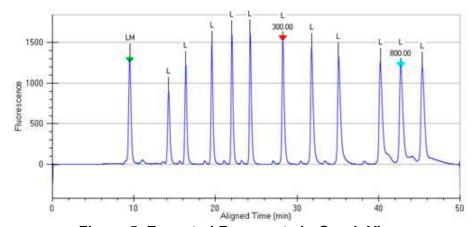


Figure 5. Expected Fragments in Graph View

## Viewing the EFs in the Gel View

**Expected Fragments** are indicated in the Gel View by colored lines in the LabChip XT software. The color of the line matches the color specified in the Expected Fragments Tab.

To display the expected peaks in the Gel View:

- 1 Click the **Properties** tab on the right side of the Gel View to open the Gel View Properties.
- 2 Select the **Show EPs and Smears** check box.

To display the legend that identifies the colors and sizes of the expected peaks and smears:

- 1 Click the **Properties** tab on the right side of the Gel View to open the Gel View Properties.
- 2 Select the Show EP/Smear Legend check box.

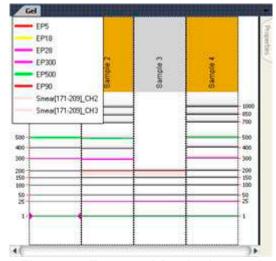


Figure 6. Expected Peaks Legend

## Viewing the EFs in the Channel Table

A column is added to the Channel Table in the LabChip XT software for each Expected Peak entered in the Expected Fragments Tab. The column displays the property selected in the **Property Displayed in Channel Table** list in the Method Window.

# Viewing the EFs in the Peak Table

**Expected Fragments** are identified in the Peak Table in the LabChip XT software with the peak name displayed in the **Type** column.



Figure 7. DNA Assay Peak Table

# **Modifying Analysis Parameters**

Some analysis parameters can be changed in the software to modify the data evaluation for sample analysis. The following procedures are included in this section:

- Changing the Peak Find Parameters
- Adding a Peak
- Excluding a Peak
- Merging Two Peaks
- Changing the Time Window for Analysis
- Aligning or Unaligning the Marker Peaks

These settings can be changed after the run is complete or when reanalyzing a previously saved data file.

**NOTE:** Only expert users should change analysis settings while the run is in progress, since changes can affect extractions.

## Changing the Peak Find Parameters

After data filtering, the peak find algorithm locates the peaks and calculates the local peak baselines. The algorithm begins by finding all the peaks above the noise threshold to determine the baseline, after which any peaks below the noise threshold are rejected. A local baseline is calculated for each peak to allow for baseline drift.

The following Peak Find parameters can be changed in the LabChip XT software:

- Min Peak Height
- Min Peak Width
- Slope Threshold
- Inflection Threshold
- Start Time
- End Time
- Filter Width
- · Baseline Plateau

The LabChip XTe software does not support changing analysis parameters.

#### To change the Peak Find parameters for all channels:

- 1 Select Analysis → Analysis Settings to open the Method Window, and then click the Peak Find Tab.
- 2 Change the parameters as necessary at the top of the window under Chip Peak Find Settings.
- 3 Click the **OK** button to save the setting, reanalyze the data, and close the window.
  - Click the **Apply** button to apply the changes and reanalyze the data, but keep the Method window open.
  - Click the **Apply Global** button the apply the settings to all chips in the workspace and reanalyze the data, but keep the Method window open.

#### To change peak find settings for individual channels:

- 1 Select Analysis → Analysis Settings to open the Method Window, and then click the Peak Find Tab.
- 2 In the **Channel** drop-down list, select the channel number that you want to change the settings for.

- 3 Change the settings at the bottom of the window under Channel Peak Find Settings to change the settings for the selected channel.
- 4 Click the **OK** button to save the setting, reanalyze the data, and close the window.
  Click the **Apply** button to apply the changes and reanalyze the data, but keep the Method window open.

## **Adding a Peak**

You can manually add a peak in a region where a peak has not been identified in the LabChip XT software.

- 1 In the Graph View, right-click near the top of the area where the peak is to be added. The area must be outside any previously identified peak and the cursor must be an up arrow.
- 2 Select **Add Manual Peak** from the shortcut menu. A new peak of type MP is created.
- 3 If necessary, adjust the Peak Baseline.

# **Excluding a Peak**

You can exclude any peak or fragment from being used in the analysis.

To exclude a peak:

- 1 In the Peak Table View, right-click on the peak to be excluded.
- 2 Select **Exclude Peak** from the shortcut menu. The Type for the peak changes to X (excluded), and the value is not used in the analysis.
- 3 Right-click on an Excluded Peak in the peak table and select **Include Peak** to include the peak in the data analysis.

OR

- 1 In the Graph View, right-click near the top of the peak to be excluded.
- 2 Select Exclude Peak from the shortcut menu. The Type for the peak changes to X (excluded), and the value is not used in the analysis.
- 3 Right-click on an Excluded Peak in the Graph view and select **Include Peak** to include the peak in the data analysis.

## **Merging Two Peaks**

If the analysis has defined two separate peaks, the two distinct adjacent peaks can now be merged into one peak in the LabChip XT or XTe software. This will include the area of both peaks in the total concentration and percent purity calculations.

To merge two adjacent peaks:

- 1 Exclude one of the peaks from the analysis, following the procedure "Excluding a Peak" on page 55.
- 2 Verify that Show Peak Baselines is selected in the Graph View Properties.
- 3 Click and drag the baseline of the remaining peak to include the area under the excluded peak.

# **Changing the Time Window for Analysis**

The **Start Time** and **End Time** parameters in the **Peak Find tab** define the time window within which peaks are found. These settings can only be changed in the LabChip XT software.

To change the Start Time and End Time parameters for all channels in the open assay:

- 1 Select Analysis → Analysis Settings to open the Method Window, and then click the Peak Find Tab.
- **2** Change the **Start Time** and **End Time** parameters as necessary.
- 3 Click the **OK** button to save the setting, reanalyze the data, and close the window.

OR

Click the **Apply** button to apply the changes and reanalyze the data, but keep the Method window open.

## Aligning or Unaligning the Marker Peaks

To perform data analysis for DNA assays, the LabChip XT software aligns marker peaks included in the sample channels with markers from the ladder. (LabChip XT only.)

- To view the raw data without analysis, choose Analysis → Turn
   Off Analysis. (LabChip XT only.)
- To re-enable analysis, choose Analysis → Turn On Analysis. (LabChip XT only.)

The default setting for this function is enabled. Turning off the analysis displays the data without aligning the markers in the channels and without displaying peak labels or smears.

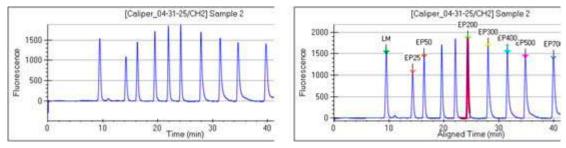


Figure 8. Data Before and After Analysis

#### Lower Marker Peaks for DNA Assays

For each DNA sample, the lower marker peak is assigned first and then the data is aligned so that the channel markers match the ladder markers in time, allowing the size and concentration of the sample peaks to be determined.

For DNA assays, the peak in a sample channel that meets the lower marker criteria specified in the method file is assigned to be the lower marker and is then offset to match the lower marker in the ladder. The Sample Lower Marker is aligned to the ladder marker by resampling the channel data in a linear stretch or compression using a point-to-point fit.

If there are unexpected peaks in the ladder analysis or the markers have been set incorrectly, you can manually exclude peaks or set a peak to be used as a lower marker.

## **Aligning or Unaligning the Marker Peaks (Continued)**

#### **NOTES**



- Excluding a peak or manually setting a peak to be an lower marker for a DNA assay can cause errors with analysis.
- You can move the boundary between the Peak Table and the Graph view up or down to increase or decrease the size of the Peak Table, making it possible to see all of the results at once.

Right-clicking in the Peak Table View (LabChip XT only) of a channel opens a shortcut menu with the following commands:

- Include Peak (only for peak type "?")
- Exclude Peak
- Force Lower Marker
- Add Expected Peak

#### **NOTE**



You can also right-click on a peak in the Graph View to view the same menu.

# Reverting to a Specific Data File Revision

Each time a LabChip XT data file is changed, a new version of the data file is created and saved. The LabChip XT software enables you to revert to a previous version of a data file. This option is not supported in the LabChip XTe software.

To revert to a previous data file version:

- 1 On the LabChip XT/XTe Main Window, select Analysis → Analysis Settings on the main menu. The Method Window opens.
- 2 Click the **Restore Chip** button at the bottom of the window. The Restore Chip Settings to Version window opens.
- **3** Select the data file version that you want to restore to.
- **4** Click the **OK** button. The Method Window displays the settings for the selected data file version.
- **5** Click the **OK** button to display the data file with the selected settings.

# **Changing the View of the Results**

The views in the LabChip XT/XTe Main Window can be customized to display data according to the preferences of the user. These options do not change the *raw* data but provide different means of displaying the data.

To change the view in the main window, see:

- "Viewing Gels" on page 60
- "Viewing Zero Baselines" on page 61
- "Adjust Pane Widths" on page 61
- "Show or Hide Views" on page 62
- "Zoom In and Zoom Out" on page 62
- "Viewing Graphs in the Overlay Electropherograms Tab" on page 63
- "Viewing Graphs in the Electropherograms Tab" on page 64
- "Viewing Multiple Properties in the Channel Table View" on page 65

## Viewing Gels

To compare the gels generated by the instrument, view the gels in the Gel View.

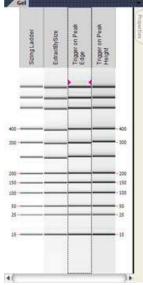


Figure 9. Gel Tab

The color, width, and contrast of the gels can be changed using the Gel View Properties.

To rearrange gels, click on the column header (channel name) and drag the channel to the desired location. To hide a channel, select the channel and then click the (X) button on the column header, or right-click on the channel in the Chip View or List View and select **Remove Channel**.

## Viewing Zero Baselines

All electropherograms produced with the instrument show some amount of background fluorescence. By default, the LabChip XT and XTe software enables the Zero Baseline function (see page 258). In the LabChip XT software, to remove the zeroing, select Analysis → Analysis Settings to open the Method Window, click the Peak Find Tab, and select the None check box under Baseline Algorithm.

## **Adjust Pane Widths**

The LabChip XT/XTe Main Window displays several different views of the data files open in the workspace. You can change the height and width of the views to make the views smaller or larger.

To adjust panes:

- 1 Place the cursor over the edge of the pane that you want to adjust. The cursor changes to a line with arrows on each end.
- 2 Click and drag up, down, left, or right. The pane is resized after you release the mouse button. The layout setting is saved as part of the collection.
- 3 In the LabChip XT software, to save the settings, save the workspace. To create new collections in the LabChip XT software with the same settings, the collection can be saved as a collection template (see "Collection Menu" on page 105).

#### **Show or Hide Views**

The views displayed in the LabChip XT Main Window can be hidden to maximize other views in the main window. The Layout of the LabChip XTe Main Window cannot be changed.

#### To hide a view:

- 1 Select Collection → Layout on the LabChip XT Main window. The Layout Options Window opens.
- **2** Click on the location that is selected for the view to clear the selection. The view is hidden.
- 3 If a location (Left, Right, or Bottom) does not contain any views, the pane closes and the remaining panes enlarge to fill the space.

Note: The Gel View is always displayed and cannot be hidden.

#### To display a hidden view:

- 1 Select Collection → Layout on the LabChip XT Main window. The Layout Options Window opens.
- 2 Click on the desired location for the hidden view (Left, Right, or Bottom). If multiple views are displayed in the same location, use the tabs at the top of the location to switch between views.

#### **Zoom In and Zoom Out**

You can zoom in and out on data displayed in the Gel View and the Graph View. The Graph View and the Gel view both zoom to the same levels when either view is zoomed in. If Synchronized Zoom is selected, all graphs zoom to the same level.

#### To zoom in:

- Click and drag to enclose the region of interest. When you
  release the mouse button, the selected area enlarges to fill the
  view. In the Gel view, all lanes in the collection zoom to the
  same level.
- You can continue zooming in until you reach the maximum magnification (the graph will not zoom in any closer).

#### To zoom out:

 Right-click in the Graph view or Gel view and select Unzoom to go to the previous zoom setting or select Unzoom All to zoom out to the default view.

For more information, see Viewing Graphs in the Overlay Electropherograms Tab.

## Viewing Graphs in the Overlay Electropherograms Tab

If the Overlay Electropherograms Tab is not open, select Collection → Layout on the LabChip XT/XTe Main Window, select the location where you want to display the Overlay Electropherograms tab, and click the Apply button. The Overlay Electropherograms tab opens.

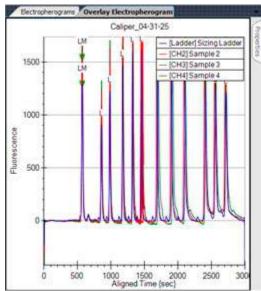


Figure 10. Overlay Electropherograms Tab with Multiple Graphs

Data from multiple channels can be overlaid in the same graph for visual comparison. Each peak graph is shown in a different color and line style with a legend at the top of the window.

<u>To add samples</u> to the Overlay Electropherograms Tab, **Ctrl + click** on the sample that you want to add in the Chip View, List View, Gel View, Channel Table View, or Peak Table View. Selected channels are identified by: dashed outlines around the selected gel lanes in the Gel view, black outlines around the selected wells in the Chip view, and light blue text in the List view.

<u>To remove a specific sample</u> from the graph, **Ctrl + click** on the sample that you want to remove in the Chip View, List View, Gel View, Channel Table View, or Peak Table View.

**Note**: The list view is not displayed in the LabChip XTe software.

## Viewing Graphs in the Electropherograms Tab

If the Electropherograms Tab is not open, select Collection → Layout on the LabChip XT/XTe Main Window, select the location where you want to display the Electropherograms tab, and click the Apply button. The Electropherograms tab opens.

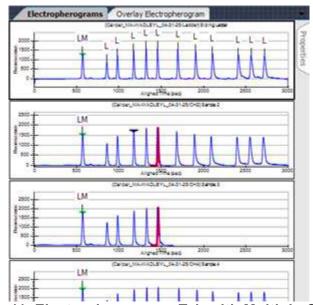


Figure 11. Electropherograms Tab with Multiple Graphs

Data from multiple channels can be displayed in the same tab for visual comparison. A separate graph for each channel in the collection is displayed in the Electropherograms tab. The data file name and channel name display at the top of each graph.

To only display the channels selected in the Gel View or Channel Table View, select the **Graph Selected Gels Only** check box in the Graph View Properties.

To move the graphs in the tab, in the Gel View click and drag the channel to the desired position.

To change the number of graphs displayed in the tab, select the desired Maximum Graphs per Page value in the Graph View Properties.

To view the point coordinates and size at the position of the cursor, hold down <CTRL> or <Shift> and move the cursor over the graph.

To view the point coordinates and slope of a point on the trace, hold down <ALT> + <CTRL> and move the cursor over the trace.

## Viewing Multiple Properties in the Channel Table View

Properties for Expected Peaks and Smears display in the Channel Table View. When entering the settings in the Expected Fragments Tab or the Smear Analysis Tab on the Method Window, the property to display in the Channel Table is specified in the Property Displayed in Channel Table column.

To display multiple properties for the same Expected Peak or Smear in the Channel Table:

- 1 In the Expected Fragments tab, or the Smear Analysis tab, enter the properties for the expected peak or smear, selecting one of the desired properties in the Property Displayed in Channel Table column.
- 2 Click in the next row and type the same name as an existing EP or smear in the Name field of the table. The row will automatically update with the same entries as the original row. The only field that can be changed is the Property Displayed in Channel Table column.
- 3 Change the **Property** to the desired selection.
- 4 Repeat until all desired properties have been added to the table.
- 5 Click the **Apply** button to display the new columns in the Channel Table. Duplicate properties in the table will be removed when the settings are applied to the chip.

# **Copying Information**

Some of the right-click pop-up menus offer the following choices for copying information from the LabChip XT/XTe software for use with other applications, depending on the selection:

- Copy Gel
- Copy Lane
- Copy
- Copy Rows to Clipboard
- Copy Column to Clipboard

Choosing any of these commands places a copy of the selected item on the computer's clipboard. You can then paste the item into a word processing, graphics, or other program.

Choosing **Copy Gel** copies all of the channels displayed in the Gel View with the labels as part of the graphic. To copy a gel, right-click in the Gel View and choose **Copy Gel**.

Choosing **Copy Lane** copies the selected channel in the Gel View with the labels as part of the graphic. To copy a gel, right-click in the Gel View and choose **Copy Lane**.

Right-clicking in the Electropherograms Tab and selecting **Copy** places a graphic of all the channels displayed in the Electropherograms tab on the clipboard.

Right-clicking in the Overlay Electropherograms Tab and selecting **Copy** places a graphic of the entire Overlay Electropherograms tab on the clipboard.

Copying rows from the Channel Table View places selected channels on the clipboard. To copy a row or multiple rows, select the desired rows in the table, right-click on one of the selected rows, and select Copy Rows to Clipboard.

Copying columns from the Channel Table View is only available for certain columns in the table. To copy a column, select a single cell in the column, right-click on the cell, and select Copy Column to Clipboard.

# Reanalyzing a Data File

Occasionally you may need to open and view or reanalyze a data file that was run and saved previously. The raw data values are saved in the chip data file, along with the original analysis settings that were chosen for the run and any changed analysis settings. This enables you to reanalyze the data with new settings or to view previously saved settings.

The following analysis parameters can be changed:

- Chip peak find settings and channel peak find settings (see "Changing the Peak Find Parameters" on page 54)
- Add a Peak (see "Adding a Peak" on page 55)
- Exclude peaks from analysis (see "Excluding a Peak" on page 55)
- Reassign lower markers (see "Lower Marker Peaks for DNA Assays" on page 57)
- Alignment or no alignment with ladder peaks (see "Aligning or Unaligning the Marker Peaks" on page 57)

To reanalyze a data file:

- 1 Open the workspace that contains the chip data (see page 45).
- **2** Change the analysis parameters (see list above) as needed.
- When you click the Apply, Apply Global, or OK buttons in the Method Window, the data is automatically re-analyzed and the updated information is displayed.
- 4 To view previous analysis settings, click the **Restore Chip** button at the bottom of the Method window and select the version to view.

# **Printing Workspace Information**

Choosing **File** → **Print** opens the Print Window to select the information to print from the open workspace. The selected information can be printed to a printer or to a PDF file. If the workspace contains multiple collections, information from the active (selected) collection is printed.

The header of each printout contains the workspace name, the collection name, and the page number. The Footer of each printout contains the LabChip XT/XTe software version, the date that the workspace was modified, and the print date.

The following information can be printed for the open workspace:

- Print All
- Gel
- · Electropherogram
- Overlay Electropherogram
- Channel Table
- Peak Table (LabChip XT only)
- Run Report (LabChip XT only)

See below for descriptions of each option.

#### **Print All**

This option prints the results of the method in all of the available formats. The page layout depends on the options selected in Print Settings.

#### Gel

Choosing this option prints a gel image with the lanes marked by the channel name.

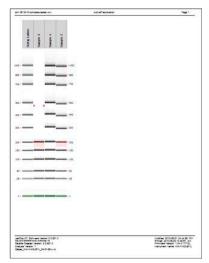


Figure 12. Printed Gel

#### Electropherogram

Choosing this option prints an individual electropherogram of each of the selected channels, with one graph on each page.

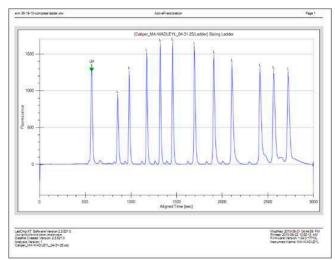


Figure 13. Printed Electropherogram

## **Overlay Electropherogram**

Choosing this option prints one graph with the electropherograms for all of the selected channels overlaid onto a single graph.

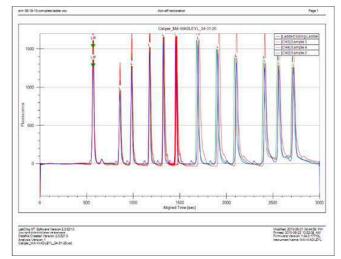


Figure 14. Printed Overlay Electropherogram

#### **Channel Table**

Choosing this option prints the columns displayed in the Channel Table View. To change the columns that are printed or the order of the columns, change the columns in the Channel Table View.

- Selecting the Add Border check box prints the table with a border around each cell in the table.
- Selecting both the Channel Table and the Peak Table prints each channel on a separate page with the Channel Table row at the top of the page and the Peak Table for the channel below it.

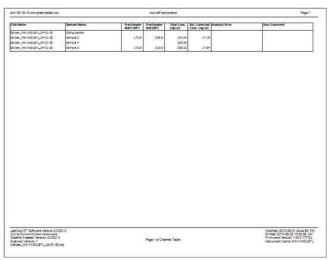


Figure 15. Printed Channel Table

#### **Peak Table**

(LabChip XT only) Choosing this option prints the columns displayed in the Peak Table View. To change the columns that are printed or the order of the columns, change the columns in the Peak Table View.

- Selecting the Exclude Marker check box removes all markers from the printout.
- Selecting the Add Border check box prints the table with a border around each cell in the table.
- Selecting the Add Channel Name as Header check box prints a channel header (chip name and channel name) before the peaks in each channel.
- Selecting the Per Page or Per Channel option for the Column Header specifies whether the Peak Table column headers are printed only at the top of each page (default), or if the headers are also printed at the beginning of each new channel table.
- Selecting both the Channel Table and the Peak Table prints
  each channel on a separate page with the Channel Table row at
  the top of the page and the Peak Table for the channel below it.

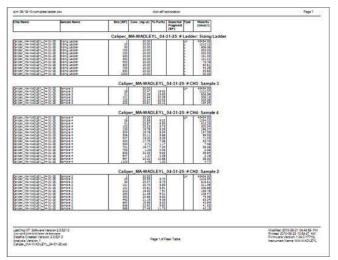


Figure 16. Printed Peak Table

### **Run Report**

(LabChip XT only) Choosing this option prints a one page summary of the run, which includes the gel for each channel, the Electropherogram for each channel, Run Information, and the columns displayed in the Channel Table View. To change the columns that are printed or the order of the columns, change the columns in the Channel Table View.

 Selecting the Add Border check box prints the table with a border around each cell in the table.

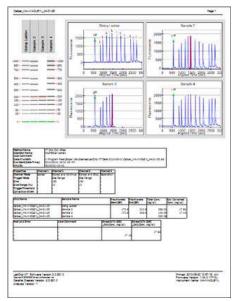


Figure 17. Printed Run Report

# **Exporting Data**

Data from a Peak Table, Channel Table, Gel, or Graph can be exported automatically and/or manually in the LabChip XT software. Options selected for automatic export do not affect manual export options, and vice versa.

- To automatically export data during the run, select the desired settings in the Start Fractionation Window as described in "Select the Auto Export Settings" on page 31.
- To manually export data, see "Exporting Data Manually" on page 77.

The LabChip XTe software does not support exporting analyzed data.

Peak Tables, Channel Tables, and Raw Data are exported to .CSV files, which can be imported into a spreadsheet program such as Microsoft Excel.

Gel and Graph data is exported to the selected image format.

This section shows export examples for the following:

- Peak Table
- Raw Data
- Gel

### **Peak Table**

ASCII text file that contains the data in all columns in the Peak Table. Figure 18 is an example of part of an exported Peak Table file (data truncated for this example):

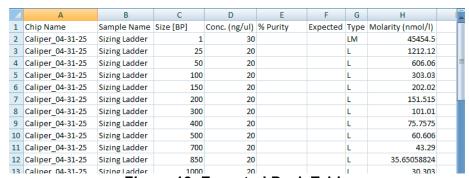


Figure 18. Exported Peak Table

Peaks that are excluded are not exported and are missing in the exported file. For example, if peaks 3, 5, and 7 are excluded when the data is exported, peaks 3, 5, and 7 are not included in the .csv file.

### **Raw Data**

ASCII text file that contains the signal data from the run as one file per channel or multiple channels in the same file. Note that data that is exported has been smoothed using the polynomial filter.

In addition to exporting time and value information, you can choose to export Size information. This information is determined based on aligned data and is used to correlate the peaks across different runs or from one row to another.

When **Include Size Data** is not checked and only time and values are exported, the state of the analysis function (peaks aligned or not aligned with the ladder data) determines whether or not data that is exported is or is not aligned. The same is true for the Zero Baseline function: if enabled, data that is exported is also zeroed to the baseline.

Below is an example of part of a raw data file exported from a DNA assay (header not included and data truncated in this example):

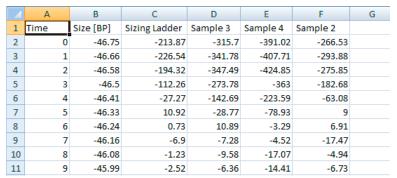


Figure 19. Exported Raw Data

Raw data can also be exported in a **Chromatography Data Interchange Format** (formerly AIA format), which is used by some graphical analysis software tools. The Include Size Data and Export Single Table options are not available with Chromatography Data Interchange Format.

### Gel

Exports the selected gel(s) in the selected image format. Options are available to export the entire collection or only the selected gels. Gels can be exported into the same image file or into separate files for each gel.

Figure 20 shows multiple selected gels exported to the same image file

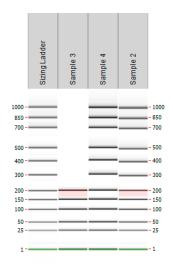


Figure 20. Exported Gel

# **Exporting Data Manually**

If the workspace contains multiple collections, the data exported is from the active/selected collection. Exporting data is not supported in the LabChip XTe software.

- **1** Open the file that you want to export the data from.
- 2 Select File → Export. The Export Window opens.
- 3 Select the check boxes next to the views to export. Selecting **Export All** selects all check boxes.
- **4** For each selected view, to change the location for the files, click the **Browse** (...) button and select the desired location.
- **5** If **Raw Data** is selected, choose the desired export options:
  - Select AIA Format to export in Chromatography Data Interchange Format, used by some graphical analysis software. The Include Size Data and Export Single Table options are not available with AIA Format.
  - Select Include Size Data to align the data to the channel's ladder (for one file per channel) or to the first channel (for a single data file) and include the size data in the exported data.
  - Select Export Single Table to export the data for all channels in the chip to one .CSV file. If not selected, the data from each channel is exported to a separate .CSV file.
- 6 If Electropherogram is selected, select either Entire Collection to export a graph for each channel in the collection or select Selected Channels to export a graph for each selected channel.
- 7 If **Gel** is selected, choose the desired export options:
  - Select **Entire Collection** to export all of the channels in the collection or select **Selected Channels** to export only the channels that are selected in the Gel view.
  - Select Single File to include gels for all channels in the same image file, or select Separate Files to export each gel to a separate image file.
  - If desired, change the height of the exported graphic in the Height text box.
- 8 If either **Electropherogram** or **Gel** is selected, choose the desired format for the image files.
- **9** Click **OK** to export the data to the specified location.

# **Software Security**

A 21 CFR Part 11 Compliance option is available for the LabChip XT software. This option ensures that methods, output data, analysis settings, event data, and backup data files are not available for editing or tampering. Data is stored in a secure folder on the local computer. To create and maintain the Audit Log and LabChip XT user accounts, Microsoft SQL Server 2005 Express is provided with the LabChip XT 21 CFR Part 11 option.

The following procedures are included in this section:

- "Locking and Unlocking the Software" on page 79
- "Managing User Accounts" on page 80
  - "Adding New Users" on page 80
  - "Changing User Information" on page 81
  - "Changing User Information" on page 81
  - "Printing User Information" on page 82
  - "Activating and Deactivating User Accounts" on page 82
  - "Changing Access Rights" on page 83
  - "Printing Access Rights" on page 84
  - "Setting Policies for User Accounts" on page 84
  - "Printing User Policies" on page 85
- "Electronic Signatures" on page 86
- "Automatically Exporting Copies of Data Files" on page 87
- "Audit Trail" on page 88
  - "Viewing the Audit Trail" on page 89
  - "Exporting the Audit Trail" on page 89
- "Central Data Repository (CDR)" on page 90
  - "CDR Security Suggestions" on page 90
  - "Creating New Data Folders" on page 91
  - "Moving Data Files into Folders" on page 91
  - "Deleting Data Folders" on page 91
  - "Hiding Data Files in the CDR Manager Window" on page 92
  - "Showing Hidden Data Files in the CDR Manager Window" on page 92
- "Remote CDR Server Backup" on page 93
  - "Setting Up the Remote CDR Server" on page 93
  - "Backing Up Data Files to the Remote CDR" on page 95

- "Restoring Data Files from the Remote CDR" on page 96
- "Manually Backing Up and Restoring the CFR Files" on page 97
  - "Backing Up CFR Files" on page 97
  - "Restoring CFR Files" on page 99

# Locking and Unlocking the Software

The LabChip XT software with the CFR option installed allows you to lock the LabChip XT software. This prevents unauthorized users from accessing the software while you are away from the computer. After the software is locked, only the logged in user or a LabChip XT Administrator can unlock the software.

To lock the LabChip XT software:

1 On the LabChip XT/XTe Main Window, click Security → Lock Application. The Unlock Application Window opens on top of the LabChip XT Main Window and displays the Username of the current user.



Figure 21. Unlock Application Window

To unlock the LabChip XT software:

- On the Unlock Application Window, type the user password for the logged in user in the Password text box and click the OK button.
- 2 If the password for the current user is not available, type a LabChip XT Administrator username and password in the Unlock Application Window and click the **OK** button. The Administrator is logged into the LabChip XT software.
- 3 To change the user to a non-administrator user, close and restart the LabChip XT software and then log in as the desired user.

# **Managing User Accounts**

Access to the LabChip XT software is controlled by user names when the 21 CFR Part 11 Security option is installed. Each user must sign into the LabChip XT software. The user's Access Level controls which options are available for each user name.

The following procedures are included in this section:

- "Adding New Users" on page 80
- "Changing User Information" on page 81
- "Printing User Information" on page 82
- "Activating and Deactivating User Accounts" on page 82
- "Changing Access Rights" on page 83
- "Printing Access Rights" on page 84
- "Setting Policies for User Accounts" on page 84
- "Printing User Policies" on page 85

### **Adding New Users**

Each person who uses the LabChip XT software should have a unique LabChip XT user account.

To add a new user:

- 1 On the LabChip XT/XTe Main Window, select Security → User and System Administration. The User Administration Window opens.
- 2 Click the Create User button.
- 3 Type the desired **Username**.
- 4 Type the First, Middle, and Last Name for user.
- **5** Type the user's **Position** if desired.
- 6 Select the **Access Level** for the user. The Access Level controls which rights the user has. The following access levels are available:
  - Restricted User
  - Operator
  - Supervisor
  - Administrator
  - Service
- 7 Type the desired User Password\*.

# **Adding New Users (Continued)**

- 8 Type the **User Password** again.
- **9** Select whether the user can perform a signature.
- 10 Select whether the user can Accept/Reject/Lock data files.
- 11 Select whether the user can Unlock data Files.
- 12 Click the Save button.
- \* Passwords must be at least 5 characters long and must contain at least one uppercase letter and at least one number.

# **Changing User Information**

After a user account is created in the LabChip XT software, the user details can be edited.

To change the user information:

- 1 On the LabChip XT/XTe Main Window, select Security → User and System Administration. The User Administration Window opens.
- 2 Click the Edit Users button.
- 3 Select the user to edit from the **User** drop-down list.
- **4** Change the User Information as necessary:
  - First Name
  - Middle Name
  - Last Name
  - Position
  - Access Level
  - User Can Perform Signature
  - Accept/Reject/Lock data files
  - Unlock data file
  - User Password
- **5** Click the **Save** button to save the updated user information.

# **Printing User Information**

After editing a user account in the LabChip XT software, the user details can be printed for record-keeping purposes.

To print the user information:

- 1 On the LabChip XT/XTe Main Window, select Security → User and System Administration. The User Administration Window opens.
- 2 Click the Show User Info button.
- 3 To print the information for a single user, select the user name in the **Select User to Display** list box.
- 4 To print the information for all users, select the **Print All Users** check box.
- **5** To preview the printout, click the **Print Preview** button.
- **6** To print the selected information, click the **Print** button.

### **Activating and Deactivating User Accounts**

If a user name is not going to be used, the user account can be deactivated in the LabChip XT software. The user name is not removed from the system, but cannot be used to log into the LabChip XT software. User names cannot be deleted. A deactivated user name can be activated to continue to be used.

- 1 On the LabChip XT/XTe Main Window, select Security → User and System Administration. The User Administration Window opens.
- 2 Click the **De/Activate User** button.
- 3 Select the Username in the **Select User** drop-down list.
- 4 Click the **Deactivate** button.

To reactivate a user name, select the deactivated user and click the **Activate** button to return the user to active status. The user name can now log into the LabChip XT software.

# **Changing Access Rights**

The rights assigned to each Access Level control the actions that a user is allowed to perform in the LabChip XT software. The rights apply to any user name assigned to the access level. Rights cannot be assigned to an individual user name. The Define Access tab is not available while an assay is running.

To change the rights for an Access Level:

- On the LabChip XT/XTe Main Window, select Security → User and System Administration. The User Administration Window opens.
- 2 Click the **Define Access** button.
- 3 Enable or Disable the desired rights for each Access Level:
  - User Administration Allows users to create, edit, activate and deactivate users, or to change policies.
  - Run Method Allows users to run methods and save the new data files that are created by the run. Users are not permitted to save changes to existing data files.
  - Save Existing Data File Allows users to save changes to existing data files.
  - Save Workspace Allows users to save new and existing workspaces. If Save Existing Data Files is not selected, users can only save workspaces where the data files have not changed.
  - Hide/Show in CDR Allows users to hide and show data files in the CDR.
  - Manage CDR Folders Allows users to create, rename, and delete folders in the CDR Manager window. This permission is not required for automatically creating daily subdirectories or to move data files in the CDR.
  - Perform Validation Allows users to perform IQ (Installation Qualifications) and OQ (Operation Qualifications).
  - Print/Export Analysis Results Allows users to print or export analysis results.
  - Audit Trail Access Allows users to view the Audit Trail in the Audit Trail Window.
  - Method Editor Allows users to edit and save methods.
- 4 Click the Save button.

# **Printing Access Rights**

After changing the user rights in the LabChip XT software, the access rights can be printed for record-keeping purposes.

To print the access rights:

- On the LabChip XT/XTe Main Window, select Security → User and System Administration. The User Administration Window opens.
- 2 Click the **Define Access** button.
- 3 To preview the printout, click the **Print Preview** button.
- **4** To print the access rights, click the **Print** button.

# **Setting Policies for User Accounts**

User Account Policies specify properties such as password options and whether to require a signature when updating data files in the LabChip XT software.

- 1 On the LabChip XT/XTe Main Window, select Security → User and System Administration. The User Administration Window opens.
- 2 Click the Set Policies button.
- **3** Set the options as desired:
  - Password Expires After The number of days until each password expires. Range is 1 to 1000 days.
  - Number of Retired Passwords to Remember User cannot reuse the specified number of old passwords. Range is from 0 to 5.
  - **Minimum Password Length** The minimum length of each password. Range is from 5 to 30 characters.
  - Maximum Login Attempts The maximum number of times
    the user can attempt to log in before being locked out of the
    LabChip XT software. Range is from 3 to 20. This option can
    be disabled to allow unlimited retries without locking the user
    out.
  - Minutes to Automatic Lock The number of minutes that
    the software is inactive until the LabChip XT software locks
    automatically. Range is from 5 to 4320 minutes (3 days). To
    disable this option, clear the check box. To unlock the
    software, see "Locking and Unlocking the Software" on
    page 79.

# **Setting Policies for User Accounts (Continued)**

- Require Signature on File Update If selected, an
  electronic signature is required to save modified data files.
  Signatures can be performed by any user who has the
  Perform Signature option selected in the User Administration
  Window.
- 4 Click the Save button.

# **Printing User Policies**

After changing the LabChip XT user policies, the user policies can be printed for record-keeping purposes.

To print the user policies:

- 1 On the LabChip XT/XTe Main Window, select Security → User and System Administration. The User Administration Window opens.
- 2 Click the **Set Policies** button.
- **3** To preview the printout, click the **Print Preview** button.
- **4** To print the selected information, click the **Print** button.

# **Electronic Signatures**

Based on a company's procedural requirements, creating and saving LabChip XT data files may require a superior's signature. If so, a user with signature permissions must enter a valid username, password, and comment to explain the purpose of the signature. The authorized user also has the option to mark the file as Accepted or Rejected and to Lock the data file to prevent changes. The data file can be signed, approved, and locked any time, except while the assay is running.

Electronic signatures are not supported for LabChip XTe.

### NOTE



To change user signature permissions, see "Changing User Information" on page 81.

To electronically sign a data file:

- On the LabChip XT/XTe Main Window, click Security → Perform Signature. The Perform Signature Window opens on top of the LabChip XT Main Window.
- 2 Select the username of the user that is signing the data file in the **Username** drop-down list.
- 3 Type a comment describing the reason for the signature in the **Enter Comment** text box.
- 4 If desired, select Accepted or Rejected as the **Approval State**.
- 5 If desired, select the **Lock** check box to lock the data file and prevent any changes. Unreviewed data files cannot be locked.
- 6 Type the User Password for the signing user in the **User Password** text box.
- 7 Click the **Sign** button. The Signature Performed window opens to confirm the signature was performed.
- 8 Click the **OK** button in the Signature Performed window. The Perform Signature window closes. Signature information is embedded in the data file and the signature is logged in the Audit Trail.

# **Automatically Exporting Copies of Data Files**

The LabChip XT software provides the option of automatically exporting a copy of the data file (.xtd) to a folder outside the CDR when the 21 CFR Part 11 Security option is installed. The data file is copied to the specified folder after the run is complete.

To automatically export a copy of each data file:

- 1 On the Output Tab on the Run File Editor Window, select the Copy To check box.
- 2 Click the Browse (...) button. The Browse for Folder Window opens.
- 3 Navigate to the folder where you want to save the exported copies of the data files.
- **4** Click the **OK** button to choose the selected folder. The path displays in the Copy To text box on the Output Tab.
- 5 To continue setting the assay options in the Run File Editor Window, see "Select the Output File Locations" on page 30.

# Reverting to a Specific Data File Revision

Each time a LabChip XT data file is changed, a new version of the data file is created and saved. The LabChip XT software enables you to revert to a previous version of a data file.

To revert to a previous LabChip XT data file version:

- 1 On the LabChip XT/XTe Main Window, select Analysis → Analysis Settings on the main menu. The Method Window opens.
- 2 Click the **Restore Chip** button at the bottom of the window. The Restore Chip Settings to Version window opens.
- **3** Select the data file version that you want to restore to.
- **4** Click the **OK** button. The Method Window displays the settings for the selected data file version.
- 5 Click the **OK** button to display the data file with the selected settings.

# **Audit Trail**

LabChip XT software uses secured, computer-generated, timestamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. The audit trails can be printed for documentation purposes. The audit trail documents can be made available for agency review and copying.

The audit trail is a log of all of the following events that have occurred in the LabChip XT software:

- Administration and user management (create/ edit / deactivate user, policy settings, access level modifications, login and lock events)
- Data file run events (run started, run finished, run stopped, run aborted)
- · Data file signing events
- Data file hide/show events
- Instrument error events
- Data file version changes
- IQ events
- Application errors related to main database failures

In Windows XP, the "Computer User Role" records the Windows role of the user logged in to the LabChip XT software.

In Windows 7, the "Computer User Role" records either User or Administrator, depending on how the LabChip XT software is started. If the LabChip XT software is started by right-clicking on the icon and selecting Run as Administrator, the Computer User Role is Administrator. If the software is started by double-clicking on the icon, the Computer User Role is User. The Computer User Role reflects the privilege that was used to start the LabChip XT software.

This section includes the following Audit Trail procedures:

- "Viewing the Audit Trail" on page 89
- "Exporting the Audit Trail" on page 89

### Viewing the Audit Trail

To view LabChip XT events in the Audit Trail Log:

- 1 On the LabChip XT/XTe Main Window, select Security → Audit Trail Log. The Audit Trail Window opens.
- 2 Select the desired data range:
  - Select whether to view most recent entries, entries between specific dates, or the entire database.
  - Select the number of entries or dates to search if Entire Database is not selected.
- **3** To view only events performed by a specific user, select a user name.
- **4** To view events for a specific data file, select the name of the data file.
- 5 To search only specific types of events select the desired Event Category in the Event Category drop-down list. Default shows all events.
- 6 To change the columns that are displayed, click the green arrow button next to Event Category and select or hide the desired columns.
- 7 Click the **Search** button to search the database.

# **Exporting the Audit Trail**

The LabChip XT events displayed in the Audit Trail Window can be exported to a file. To export the events:

- 1 On the LabChip XT/XTe Main Window, select Security → Audit Trail Log. The Audit Trail Window opens.
- 2 Click the Export button in the Audit Trail Window. The Audit Trail Export Window opens.
- 3 Select the desired export file format.
  - Text
  - XML
  - Excel
- 4 Click the **Export** button. The Save As window opens.
- 5 Choose the desired location for the file, type the desired file name, and click the Save button. By default, the file name is ATexport\_<date>\_<time>, where <date> and <time> are the current date and time.

# **Central Data Repository (CDR)**

The Central Data Repository (CDR) is a protected folder located on the local computer. All LabChip XT data files (.xtd) are saved in the default CDR folder on the local computer. The CDR folder is protected from changes by unauthorized users. The CDR is only used when the 21 CFR Part 11 option is installed with the LabChip XT software.

The CDR Manager Window enables you to organize data files into virtual folders. The folders are not actually created in the CDR folder on the local computer, but are displayed in the CDR Manager Window to organize the data files. The CDR Manager Window enables you to create new folders, rename existing folder, and delete empty folders.

The following procedures are included in this section:

- "CDR Security Suggestions" on page 90
- "Creating New Data Folders" on page 91
- "Moving Data Files into Folders" on page 91
- · "Deleting Data Folders" on page 91
- "Hiding Data Files in the CDR Manager Window" on page 92
- "Showing Hidden Data Files in the CDR Manager Window" on page 92

# **CDR Security Suggestions**

To ensure proper security of data files, the LabChip XT Administrator should:

- 1 Change the LabChip XT Administrator password. Make sure to keep a copy of the password in a safe place. This password cannot be reset if forgotten. To change the administrator password:
  - Log into the LabChip XT software as the administrator.
  - Select Security → Change Password.
  - Type the current password.
  - Type the new password in both the New Password and Confirm Password text boxes.
  - Click the **OK** button.
- 2 To enable remote CDR, install and set up the Remote CDR Server (see page 93), then start the CDR Utility and enable remote CDR Backup (see page 95).

### **Creating New Data Folders**

To create a new CDR data folder for LabChip XT data files:

- Select File → Import Data File. The CDR Manager Window opens.
- 2 Click on the upper-level CDR folder.
- 3 Click the New Folder button on the left side of the window. A new folder named New Folder is created and the name is selected for update.
- **4** Type the desired name for the folder and then press the Enter key.
- **5** Close the CDR Manager Window.

### **Moving Data Files into Folders**

To move a LabChip XT data file into a CDR data folder:

- Select File → Import Data File. The CDR Manager Window opens.
- 2 Click on the name of the data file.
- 3 Drag and drop the file into the desired folder.
- 4 Close the CDR Manager Window.

# **Deleting Data Folders**

Only CDR Data folders that are empty can be deleted. Move the LabChip XT data files out of the folder before deleting the folder.

To delete a CDR data folder:

- 1 Select File → Import Data File. The CDR Manager Window opens.
- 2 Verify the folder is empty.
- 3 Click on the folder name.
- 4 Click the **Delete** button on the left side of the window or at the top of the window.
- 5 Close the CDR Manager Window.

# Hiding Data Files in the CDR Manager Window

The CDR Manager window enables users to hide or show specific LabChip XT data files or folders in the CDR Manager window. This functionality can be used to reduce the number of data files displayed in the CDR Manager window when certain files or folders are not used. The user must have Hide/Show in CDR rights in the Define Access tab in the User Administration Window.

Hiding data files or folders does not change the data file or folder, they are just not displayed in the CDR Manager Window.

To hide data files or folders:

- Select File → Import Data File. The CDR Manager Window opens.
- 2 Select the name of the data file or folder that you want to hide. If you select a folder name, all data files and folders in the selected folder will also be hidden.
- 3 Click the Hide button on the left side of the CDR Manager Window.
- 4 Close the CDR Manager Window.

# **Showing Hidden Data Files in the CDR Manager Window**

To set hidden LabChip XT data files back to unhidden (show):

- 1 Click the Show Hidden Files button at the top right of the CDR Manager Window. All hidden files and folders show in the CDR Manager window. The file or folder icon indicates if the file or folder is hidden.
- 2 Click the name of the file or folder that you want to show and click the Show button on the right side of the CDR Manager Window.

### NOTE



Files and folders in a hidden folder do not show in the CDR Manager Window, even if the files are not set to hidden. To show files, the folder cannot be set to hidden.

- 3 Click the Hide Hidden Files button at the top right of the CDR Manager Window.
- 4 Close the CDR Manager Window.

# Remote CDR Server Backup

The LabChip XT software with the 21 CFR Part 11 option installed supports backing up data files to a remote server using Subversion (SVN). Subversion is a third-party database application used to copy data files to a remote server within the intranet. To use remote backup, Subversion must be installed on the remote server using the CDRServerUtilitySetup.exe included on the LabChip XT Installation CD.

The LabChip XT software can be set up to automatically back up all new and modified data files to the Remote CDR Server. Automatic backup ensures that secure versions of all data files are available and synchronized, even in the event of failure of the instrument computer.

The following procedures are included in this section:

- "Setting Up the Remote CDR Server" on page 93
- "Backing Up Data Files to the Remote CDR" on page 95
- "Restoring Data Files from the Remote CDR" on page 96

To back up the Remote CDR Server, either back up the entire C:\ drive on the remote server, or back up the C:\RemoteCDR folder.

The LabChip XT software also contains an option to copy the data files to an unsecured location on the local hard drive. These data files do not meet 21 CFR Part 11 security requirements after they are copied out of the CDR. To copy data files to a non-secure location, use the Copy button on the CDR Manager Window.

# **Setting Up the Remote CDR Server**

To back up copies of LabChip XT data files on 21 CFR Part 11 compliant systems, and keep the copies of the data files secure, back up the files to a Remote CDR Server. The Remote CDR Server must be running Windows 7. To set up the Remote CDR Server:

- 1 If the CDR Server Utility is not already installed on the remote server, see the Readme.htm file on the LabChip XT Installation CD for instructions on running CDRServerUtilitySetup.exe.
- 2 On the Remote computer, double-click on the CDR Server Utility icon on the Windows desktop. The CDR Server Utility Window opens.

### **Setting Up the Remote CDR Server (Continued)**

3 If the Server has not been created on the computer yet, click the Create Server button to create the server. The default folder name and location (C:\RemoteCDR) cannot be changed. Wait for the Create Server button to be disabled and the text boxes to be active.

### **NOTE**



Server name, folder name, username, and password are case sensitive.

- **4** A folder must be created on the server to store the database. To create a new folder on the remote server:
  - Type the desired folder name in the Folder Name text box.
  - Type a Username for the folder in the Username text box. (This is a separate username from the user names created in the LabChip XT software. This username is only used to access the data folder on the Remote CDR Server.)
  - Type the desired password in the Password and Confirm Password text boxes.
  - If Get Folder Details is checked, a text file specifying the folder details is created and saved in C:\Program Files\ Caliper Life Sciences\ LabChip XT\ CDRServer\ ServerDetails\.
  - Click the Apply button to create the folder.
- **5** Close the CDR Server Utility Window after the desired folders have been created.

### **Backing Up Data Files to the Remote CDR**

Remote CDR Backup copies each data file in the LabChip XT software to the Remote CDR server and stores a copy of the data file in a database. Each time a data file is created or modified, the changes are copied into the remote database.

Remote CDR Backup can only be enabled by the LabChip XT default Administrator.

To set up Remote CDR Backup:

- 1 Verify that the Remote CDR Server is set up on an accessible network server.
- 2 Log into the LabChip XT software using the default administrator user name and password.
- 3 Select Tools → CDR Utility. The CDR Utility Window opens.
- 4 Select the Enable Remote CDR Backup check box.

### NOTE



Server name, folder name, username, and password are case sensitive.

- 5 Type the computer name of the Remote CDR server in the Remote Computer Name/IP Address text box. If the remote computer and the local computer are not in the same Windows workgroup, type the IP address of the remote computer.
- 6 In the **Folder** text box, type the name of the folder to use in the remote CDR server to store the LabChip XT data. (The folder must have already been created using the CDR Server Utility on the remote computer.)
- 7 Type the folder username in the **User Name** text box. This username is the same username that was used to create the CDR Server folder.
- 8 Type the folder password in the **Password** text box. This is the same password that was used to create the CDR Server folder.
- 9 Click the **Apply** button.
- **10** Click the **Close** button to close the CDR Utility Window.

### Restoring Data Files from the Remote CDR

The last backed up copies of LabChip XT data files can be restored from the backup database on the remote CDR Server if the LabChip XT computer is replaced.

To restore the data files from the backup database:

- 1 Verify that the Remote CDR Server is accessible on the network.
- 2 Log into the LabChip XT software using the default administrator user name and password.
- 3 Select **Tools** → **CDR Utility**. The **CDR Utility** Window opens.
- 4 Select the Enable Remote CDR Backup check box.

### **NOTE**



Server name, folder name, username, and password are case sensitive.

- 5 Type the computer name of the Remote CDR server in the Remote Computer Name/IP Address text box. If the remote computer and the local computer are not in the same Windows workgroup, type the IP address of the remote computer.
- 6 In the **Folder** text box, type the name of the folder in the remote CDR server that you want to restore the LabChip XT data from. (Make sure to select the same folder to which the data was backed up.)
- 7 Type the folder username in the **User Name** text box. This username is the same username that was used to create the CDR Server folder.
- **8** Type the folder password in the **Password** text box. This is the same password that was used to create the CDR Server folder.
- 9 Click the Apply button. The progress bar display the status of the restoration process and a confirmation displays when the restore is complete.
- **10** Click the **Close** button to close the CDR Utility Window.

# Manually Backing Up and Restoring the CFR Files

The LabChip XT software with the 21 CFR Part 11 option installed supports backing up data files to a remote server (see "Remote CDR Server Backup" on page 93). The CDR data files and the Audit Trail database can also be backed up manually to another secure location. Manual backup does not update the backup copies with any changes to the files. The backup copies can be stored on another computer or on a removable storage drive. The data files and Audit Trail database can only be restored to the point when the files were backed up.

# **Backing Up CFR Files**

To manually back up the CFR Files in the LabChip XT software, you must back up both the CDR data files and the Audit Trail database.

### Setting the CDR folder as accessible

- 1 Log in to the computer with a User Name in the Administrator group.
- **2** For Windows 7: Right-click on the LabChip XT icon on the Windows desktop and select Run as Administrator.
  - **For Windows XP**: Double-click on the LabChip XT icon on the Windows desktop
- 3 Log in to the LabChip XT CFR software as the Administrator user.
- 4 On the LabChip XT/XTe Main Window, select Tools → CDR Utility. The CDR Utility Window opens.
- 5 Select the Accessible by Windows Administrator Level Users check box and then click the Apply button.
- 6 Click **OK** in the Confirmation window.
- 7 Click the **Close** button on the CDR Utility Window.
- **8** Close the LabChip XT software.

### Copying the CDR Folder

- 1 In Windows Explorer, navigate to C:\Program Files\Caliper Life Sciences.
- 2 Copy the entire \CDR\ folder to the desired location for the backup files.

### Setting the CDR folder back to not accessible

- 1 For Windows 7: Right-click on the LabChip XT icon on the Windows desktop and select Run as Administrator.
  - **For Windows XP**: Double-click on the LabChip XT icon on the Windows desktop
- 2 Log in to the LabChip XT CFR software as the Administrator user.
- 3 On the LabChip XT/XTe Main Window, select Tools → CDR Utility. The CDR Utility Window opens.
- 4 Clear the Accessible by Windows Administrator Level Users check box and then click the Apply button.
- 5 Click **OK** in the Confirmation window.
- 6 Click the Close button on the CDR Utility Window.
- **7** Close the LabChip XT software.

### **Backing up the Audit Trail Database**

- 1 In Windows Explorer, navigate to C:\Program Files\Caliper Life Sciences\ LabChip XT.
- 2 Double-click the **BackupDB.bat** file. A backup copy of the database, named DBback.bak, is created.
- 3 In Windows Explorer, navigate to C:\Program Files\Caliper Life Sciences\ LabChip XT\Database\.
- **4** Copy the DBback.bak file to the desired location for the backup files.

# **Restoring CFR Files**

To restore the CFR files from a manual backup point, you must restore both the CDR data files and the Audit Trail database. If restoring the files to a new computer, install the LabChip XT software and then restore the CFR files.

### Setting the CDR folder as accessible

- 1 Log in to the computer with a User Name in the Administrator group.
- **2** For Windows 7: Right-click on the LabChip XT icon on the Windows desktop and select Run as Administrator.
  - **For Windows XP**: Double-click on the LabChip XT icon on the Windows desktop
- 3 Log in to the LabChip XT CFR software as the Administrator user.
- 4 On the LabChip XT main window, select Tools → CDR Utility. The CDR Utility Window opens.
- 5 Select the Accessible by Windows Administrator Level Users check box and then click the Apply button.
- 6 Click **OK** in the Confirmation window.
- 7 Click the **Close** button on the CDR Utility Window.
- **8** Close the LabChip XT software.

### **Restoring the CDR Folder**

- 1 In Windows Explorer, navigate to C:\Program Files\Caliper Life Sciences.
- 2 Delete the existing \CDR\ folder.
- 3 Copy the backed up \CDR\ folder into the folder. (See "Backing Up CFR Files" on page 97.)

### Setting the CDR folder back to not accessible

- 1 For Windows 7: Right-click on the LabChip XT icon on the Windows desktop and select Run as Administrator.
  - For Windows XP: Double-click on the LabChip XT icon on the Windows desktop
- 2 Log in to the LabChip XT CFR software as the Administrator user.
- 3 On the LabChip XT main window, select **Tools** → **CDR Utility**. The CDR Utility Window opens.
- 4 Clear the Accessible by Windows Administrator Level Users check box and then click the Apply button.
- 5 Click **OK** in the Confirmation window.
- 6 Click the Close button on the CDR Utility Window.
- **7** Close the LabChip XT software.

### **Restoring the Audit Trail Database**

- 1 In Windows Explorer, navigate to C:\Program Files\Caliper Life Sciences\ LabChip XT\Database\.
- **2** Copy the backed up database (DBback.bak) into the folder.
- 3 In Windows Explorer, navigate to C:\Program Files\Caliper Life Sciences\ LabChip XT\.
- 4 Double-click the **RestoreDB.bat** file. The Audit Trail database is restored to the backup point.

# **Software Reference**

This section describes each of the windows in the LabChip XT and XTe software. Each window description describes the options and buttons on the window, and how to open the window. This section describes the following windows:

- "LabChip XT/XTe Main Window" on page 102
- "About LabChip XT/XTe Window" on page 138
- "Add New Expected Peak Window" on page 139
- "Audit Trail Window" on page 140
- "Audit Trail Export Window" on page 141
- "Audit Trail Manage Columns Window" on page 142
- "CDR Manager Window" on page 143
- "CDR Server Utility Window" on page 145
- "CDR Utility Window" on page 146
- "Change Password Window" on page 148
- "Data File Version Window" on page 149
- "Event Viewer Window" on page 150
- "Export Window" on page 151
- "Flush Chip Window" on page 154
- "Layout Options Window" on page 155
- "Login Window" on page 156
- "Method Window" on page 157
- "Modify Run Settings Window" on page 173
- "New Collection Window" on page 174
- "Perform Signature Window" on page 175
- "Print Window" on page 176
- "Print Validation Reports Window" on page 178
- "Rename Collection Window" on page 179
- "Run File Editor Window" on page 180
- "Run Info Window" on page 181
- "Save Workspace File As Window" on page 183
- "Select a Data File Window" on page 184
- "Software Installation Qualification Window" on page 185
- "Start Fractionation Window" on page 186
- "System Diagnostics Window" on page 199
- "Unlock Application Window" on page 201
- "Unlock Data File Window" on page 202
- "User Administration Window" on page 203

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# LabChip XT/XTe Main Window

Figure 22. LabChip XT Main Window

The main window of the LabChip XT/XTe software includes:

- "Menu Bar" on page 103
- "Run Status and Chip Info" on page 109
- "Error Message Area" on page 110
- "Run Setup" on page 111
- "Chip View or List View" on page 113
- "Collection Pane" on page 116
- "Graph View" on page 117
- "Graph View Properties" on page 122
- "Filter View" on page 124 (LabChip XT only)
- "Gel View" on page 128
- "Gel View Properties" on page 131
- "Channel Table View" on page 133
- "Peak Table View" on page 135 (LabChip XT only)
- "Peak Table Properties" on page 137 (LabChip XT only)

Clicking and dragging the borders between the views changes the size of the views in the collection. To change the location of the views, see "Changing the View of the Results" on page 60.

### Menu Bar

The menu bar is directly below the title bar on the LabChip XT/XTe Main Window. Clicking a menu name displays a list of commands to access software functions.

The LabChip XT/XTe software contains the following menus:

- "File Menu" on page 104
- "Workspace Menu" on page 104
- "Collection Menu" on page 105 (LabChip XT only.)
- "Analysis Menu" on page 105 (LabChip XT only.)
- "Instrument Menu" on page 106 (Instrument mode only.)
- "Tools Menu" on page 106
- "Security Menu" on page 107 (Only displays if the 21 CFR Part 11 option is installed with the LabChip XT software.)
- "View Menu" on page 107
- "Validation Menu" on page 107
- "Window Menu" on page 108
- "Help Menu" on page 108

### File Menu

The File menu contains the following commands:

**New Workspace** - Creates a new, blank workspace. (LabChip XT only.)

Open Workspace - Opens a saved workspace. All data files in a workspace must be the same type. (LabChip XT only.)

Import Data File - Opens a saved LabChip XT/XTe data file for a specific chip. If the 21 CFR Part 11 option is installed, opens the CDR Manager Window. A graphical representation of the chip displays. Data files are file type .xtd (LabChip XT) or .xte (LabChip XTe).

**Export** - Opens the Export Window to choose the type of data to export. Exports a Peak Table, Channel Table, Gel, Single Graph, or all open graphs in the current Collection to a file, depending on the options selected. (LabChip XT only.)

**Print** - Opens the Print Window to choose the data to print.

Save Workspace - Saves the current workspace. (LabChip XT only.)

Save Workspace As - Saves the current workspace with a new filename. (LabChip XT only.)

**Exit** - Closes the LabChip XT/XTe software.

### Workspace Menu

The Workspace menu contains the following commands:

**Remove Chip** - Removes the selected chip data file from the workspace.

Save Chip - Saves the chip data file (\*.xtd for LabChip XT or .xte for LabChip XTe). Changes to the analysis settings (in the Method Window) are saved at the end of the chip data file. Previous analysis settings are not overwritten, enabling you to use the Restore Chip button on the Method Window to go back to any previously saved settings. Chip data files are automatically saved when the Workspace is saved. The LabChip XTe software does not support changing analysis settings or saving workspaces.

### **Collection Menu**

The Collection menu in the LabChip XT software contains the following commands:

**Undo** - Undoes changes to the collection view settings and filter settings. Changes made in pop-up windows, such as analysis settings, export settings, etc, are not affected by this Undo.

**New Collection** - Opens the New Collection Window where you choose whether to create a new Collection from a saved Collection Template, a Blank Collection, or the Current Collection.

**Rename Collection** - Opens the Rename Collection Window to rename the currently selected Collection.

**Delete Collection** - Deletes the current Collection.

**Save As Template** - Opens the Save Template As window to save the display and filter settings currently displayed in the Collection tab as a collection template.

**Apply Template** - Opens the Apply Template window to open a saved collection template and apply the settings to the current Collection.

**Layout** - Opens the Layout Options Window to change where tabs are displayed by default on the main window.

The Collection menu is not available in the LabChip XTe software.

### **Analysis Menu**

The Analysis menu in the LabChip XT software contains the following commands:

**Turn On/Off Analysis** - Toggles analysis on and off. When analysis is on, the data displayed in the main window uses the analysis settings in the Method Window. When analysis is off, the raw (unanalyzed) data displays.

**Scale to All Peaks** - Scales the view to the minimum and maximum X values of the current sample peaks. Marker and/or system peaks are ignored.

**Analysis Settings** - Opens the Method Window to choose analysis parameters for the chip. Use these settings to change the analysis and peak finding parameters to help resolve hard-to-decipher data.

**Standard Curve** - Opens the Standard Curve Window to view the ladder as a curve with a point-to-point fit.

The Analysis menu is not available in the LabChip XTe software.

### **Instrument Menu**

The Instrument menu contains the following commands:

**Start Run** - Opens the Start Fractionation Window to begin running a sample chip. See the *Assay User Guide* for chip and sample prep instructions. Changes to Stop Run while a chip is running.

**Stop Run** - Displays a Stop Run window to stop the run. Click the **Yes** button to stop the run. Click the **No** button to continue the run.

**Flush Chip** - Opens the Flush Chip Window to flush the selected channels on a chip.

### NOTE



The Instrument menu does not display if the software was installed in Reviewer mode.

### **Tools Menu**

The Tools menu contains the following commands:

**Run File Editor –** Opens the Run File Editor Window to create Run files. Run files contain all of the settings in the Start Fractionation Window.

**Method Editor** - Opens the Select Method To Edit window to select the name of the method to edit. The selected method opens for editing in the Method Window. (LabChip XT only.)

**CDR Utility** - Opens the CDR Utility Window to set or change the CDR options or Remote CDR Backup options. This command is only available when the 21 CFR Part 11 option is installed and the default Administrator is logged into the LabChip XT software.

### Security Menu

The Security menu only displays if the **21 CFR Support** option is installed with the LabChip XT software.

**User and System Administration** - Opens the User Administration Window to create, edit, and view user login information, activate or deactivate users, define user access, and set user policies.

Change Password - Opens the Change Password Window to change the Login Password for the current user.

**Perform Signature** - Opens the Perform Signature Window to sign a data file, change the approval state, or lock the data file.

Unlock Data File - Opens the Unlock Data File Window to unlock a locked data file.

Audit Trail Log - Opens the Audit Trail Window to view, search, export, and print the audit trail.

**Lock Application** - Opens the Unlock Application Window to lock the LabChip XT software and prevent other users from using the software until the software is unlocked by the current user or an Administrator.

### View Menu

The View menu contains the following commands:

**Event Viewer** - Opens the Event Viewer Window to view events and errors that occur during the current run or during a previous run.

Run Info - Opens the Run Info Window to view information about the run.

Version Change Details - Displays the Data File Version Window to view changed versions of the selected open data file. (LabChip XT only.)

### Validation Menu

The Validation menu contains the following commands:

**Software IQ** - Opens the Software Installation Qualification Window to perform the IQ.

**Diagnostics** - Opens the System Diagnostics Window to run diagnostic tests to verify system operation and performance.

Reports - Opens the Print Validation Reports Window to view or print IQ/OQ results.

### Window Menu

The Window menu contains the following commands:

**Cascade** - Displays each Collection in a separate, cascading window in the Collection Pane.

**Tile Vertical** - Displays each Collection in separate side by side windows in the Collection Pane. (LabChip XT only.)

**Tile Horizontal** - Displays each Collection in separate top to bottom windows in the Collection Pane. (LabChip XT only.)

**Tabbed** - Displays each Collection in a separate tab in the Collection Pane.

### Help Menu

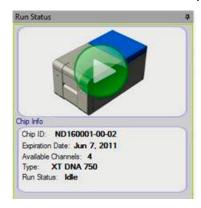
The Help menu contains the following commands:

**LabChip XT/XTe Help** - Opens the Contents/Index page for the LabChip XT/XTe Help file.

**About LabChip XT/XTe** - Opens the About LabChip XT/XTe Window, showing the software and firmware version numbers.

### **Run Status and Chip Info**

The Run Status and Chip Info areas on the LabChip XT/XTe Main Window display the instrument status, chip status, chip information, and information about the current run. If the software was installed in Reviewer mode, this status area does not display.



**Run Button** - Opens the Start Fractionation Window to begin a run. The Run button only displays when the cursor is positioned over the instrument image. See the *LabChip XT Assay User Guide* for chip preparation instructions. While an assay is running, the Run button changes to a **Pause/Stop** button.

Pause/Stop Button - Opens the Modify Run Settings Window to edit the method, resume the run, or stop the run. The Pause/Stop button only displays when the cursor is positioned over the instrument image while a method is running. The method settings can be changed before resuming the run. Clicking the Stop Run button immediately stops the run. Runs that have been stopped cannot be continued or resumed.

#### Chip Info

**Chip ID** - The ID number of the chip, read from the barcode on the chip.

**Expiration Date** - Displays the date when the chip will expire. If the chip is expired, the date displays in red. Starting a run with an expired chip displays a warning, but allows the run to continue if desired.

**Available Channels**- Displays the number of unused channels on the chip. Used channels are automatically disabled in the software.

**Type** - Displays the type of assay that the chip will run.

**Run Status** - Displays the current system activity and the time until the next collection time. When all collections are complete, displays the time until the end of the run.

## **Error Message Area**



Figure 23. Error Messages Displayed

Chip errors can display on top of the instrument image or in the Chip Info section. Errors in the Chip Info area are indicated by red text as shown in Figure 23.

Connectivity and hardware error messages are displayed at the bottom of the Run Status and Chip Info area on the LabChip XT/XTe Main Window. Figure 23 shows a barcode reader error at the bottom of the Run Status area.

See "Error Messages" on page 226 for a list of errors and tips on preventing or resolving errors.

# **Run Setup**

The Run Setup area displays information about the run currently in progress. This section only displays during the run.



Figure 24. Run Setup

The Run Setup displays the following information:

Column	Description
С	Displays the channel number on the chip.
S	Displays the number of the step currently executing. Single step extractions display 1 in this column.
Mode	Displays the Extraction Mode for the current step.
	Lddr = Ladder
	Off = Disabled
	X&S = eXtract and Stop
	X&C = eXtract and Continue
	XId = eXcLuDe region (XT only)
	Sep = Separation (XT only)
	X&P = eXtract and Pause
	Skip = Skip extraction (XT only)
	See "Setup Tab" on page 188 for descriptions of
	each extraction mode.
Size Range (BP)	Displays the Size range or Search region for each step.

Column	Description
Trigger At	Displays the trigger point for the current step in each channel.
	<ul> <li>For Collect on Click Extraction Mode or Manual Collection Width, click on the word CLICK to begin or end the extraction. The sample in the channel is within the specified search region when a pink background displays behind the text.</li> <li>Displays COLLECT on a green background when the extraction for a channel is complete and the run is paused, either automatically or manually. Pausing the run and then opening and closing the lid to remove the sample from the Collection well changes the display to the trigger for the next step in the channel or to DONE if the extraction is complete in that channel. If the run is paused but the lid is not opened, the channel continues to display COLLECT.</li> </ul>
	Displays <b>DONE</b> when the extraction is complete in each channel.

### Chip View or List View

The Chip View or List View displays on the lower left side of the LabChip XT/XTe Main Window in the LabChip XT software. The List View is not available in the LabChip XTe software.

The Chip View or List View displays the data files in the open collection and enables you to select specific channels of chip data. Click the tabs at the bottom of the view to switch between Chip View and List View.

#### **Chip View**

#### Chip View Right-Click Menu

Right-clicking on the chip name in the Chip view displays the following options in the shortcut menu:

Save Chip - Saves the current data file.

**Copy Chip** - Saves a copy of the chip data file (.xtd for LabChip XT, or .xte for LabChip XTe) to the selected folder.

**Rename Chip** - Renames the chip in the workspace. If the Rename File to Match check box is selected, the data file is also renamed. If the Rename File to Match check box is cleared (not selected) the data file name remains the same. The data file cannot be renamed if the 21 CFR Security option is installed.

**Remove Chip** - Removes the chip data file from the workspace. The data file is not deleted, only the workspace view changes.

**Analysis Settings** - Displays the Method Window to change the analysis settings for the data file. (This option is not available in the LabChip XTe software.)

**Version Change Details** - Displays the Data File Version Window to change the version of the data file displayed in the workspace. (This option is not available in the LabChip XTe software.)

**Run Info** - Displays the Run Info Window to view the run information and Event Log.

#### **Chip Channel Color Code**



**Green** - Channels are running.

**Blue** - Channels are included in the open collection (channel 1 above).

**Blue with Black Ring** - Channels are selected for analysis (channel 2 above).

**White** - Channels are not included in the open collection but have data.

Grey - Channels do not contain any data.

White with Red Ring - An analysis error has occurred in the channel.

White with Green Ring - The channel is not analyzed.

**Any Other Color** - Channels are selected by a Filter. See the Filter View to determine which color represents each filter. If a channel is selected by multiple filters, the colors are combined in the channel.

#### **List View**

The List View in the LabChip XT software displays a list of all the channels in the currently open data files. Select the List tab at the bottom of the Workspace pane to see the List view. (The List View is not displayed in the LabChip XTe software.)

- Black channels are not included in the open collection.
- Dark Blue channels are included in the open collection.
- Light Blue channels are selected in the Gel View and Channel Table View.
- Channels outlined in black are selected by a filter.
- Red channels have an analysis error.



Figure 25. List View

#### **Collection Pane**

The Collection Pane in the LabChip XT/XTe Main Window displays a tab for each collection in the workspace. Each collection displays the information from the data files that are open in the Chip View or List View. (Multiple collections are not supported in the LabChip XTe software.)

The Collection Tabs each contain the following views:

- **Graph View**
- **Gel View**
- **Channel Table View**
- **Peak Table View**
- Filter View

The views in the Collection pane are synchronized with each other.

- Selecting a graph on the Graph tab automatically selects the same channel on the Gel tab.
- Selecting a peak in the Peak Table automatically selects the same peak in the Graph tab and the Gel tab.
- Closing a gel on the Gel tab closes the graph for the channel and removes the channel data from the Peak Table and Channel Table tabs.

### **Graph View**

The Graph view in the Collection Pane is a visual representation of the data from each channel as an electropherogram.

The Graph view contains the Overlay Electropherograms Tab and the Electropherograms Tab to view data while a run is in progress or after the run is complete. For information on changing the view in the Overlay Electropherograms tab, see "Viewing Graphs in the Overlay Electropherograms Tab" on page 63. For information on changing the view in the Electropherograms tab, see "Viewing Graphs in the Electropherograms Tab" on page 64.

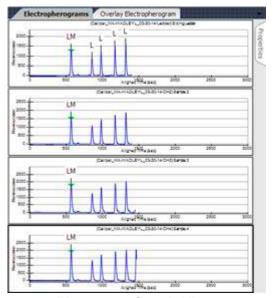


Figure 26. Graph View

If Type is selected as an annotation, the lower markers are displayed in the graph view with green arrows labeled LM. The currently selected peak in the Gel view or Peak Table displays a blue arrow above the peak.

You can zoom in and zoom out the Graph View of the channels. Zoom in by clicking and dragging over a region of an electropherogram. Zoom out by right clicking on a graph, and selecting either Unzoom or Unzoom All from the shortcut menu. Double-clicking in the graph will zoom out to the previous zoom level.

Graph data in the LabChip XT software can be exported to a graphic file by choosing **Export** on the File menu. (See "Exporting Data" on page 74 for details.) If the workspace contains multiple collections, the data exported is from the active/selected collection.

### **Graph View (Continued)**

To show or change the labels on the peaks in the graph, show the data points on the graph, show peak baselines, or change the graph colors, see "Graph View Properties" on page 122.

To select a peak on the graph, move the cursor near the peak. A blue arrow above the peak shows that the peak is selected, and the cursor changes to an arrow that points straight up. The Gel View and Peak Table View also select the corresponding entry.

You can adjust the peak baselines from the graph view after the run is complete, if desired. Select **Show Peak Baselines** in the Graph View Properties to display the baseline for each peak. To change the baseline, click at either end of the peak baseline and drag to the desired location. To reset the baseline back to the original position, right-click near the baseline end point and choose Reset to Defaults.

While a run is in progress, the graphs initially display the raw (unanalyzed) data as it is being read from the chip. As data is acquired, the analysis aligns the baselines and lower markers, and the aligned data displays in real time.

#### **Graph View Shortcut Menus**

#### Right-Click Menu (not near a peak)

Right-click away from a peak in the graph to display a shortcut menu containing the following commands:

**Synchronize Zoom** - If checked, all open graphs will zoom to the same level when one graph is zoomed.

**Unzoom** - Zooms out to the previous zoom level.

**Unzoom All** - Zooms out completely and returns to the standard view.

**Set Scale** - Opens the Set Graph Scales window to specify the X and Y ranges to show on the graph.

**Scale to Sample Peaks/Scale to All Peaks** - Scales the view to the minimum and maximum X values of the all peaks, including marker peaks and system peaks.

**Remove -** Removes selected graph from the view.

**Copy** - Copies the selected graph to the clipboard in a .bmp format.

**Analysis Settings** - Opens the Method Window to change the analysis settings. (LabChip XT only.)

## **Graph View (Continued)**

#### Right-Click Menu (near a peak)

Right-click above or below a peak in the graph to display a shortcut menu containing the following commands:

**Exclude Peak** - Excludes the peak from the analysis. (The Peak Type label displays X.)

Force Lower Marker - Defines the selected peak as the Lower Marker. (The Peak Type label displays LM\*.)

Add Expected Peak - Opens the Add New Expected Peak Window to add a new Expected Peak to the specified channels. (LabChip XT only)

#### **Overlay Electropherograms Tab**

Use the Overlay Electropherograms tab on the Graph View to view a single graph or multiple graphs overlaid on top of each other.

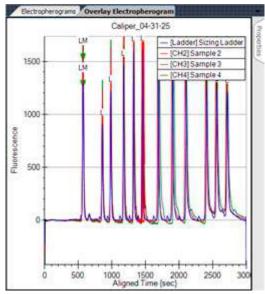


Figure 27. Overlay Electropherograms Tab

The sample list at the upper right displays the name of each sample and the color assigned to the graph for each sample. If only one graph is displayed, the Gel View, Channel Table View, and Chip View or List View all show the same selected channel.

The gel lanes selected in the Gel View are synchronized with the graphs displayed in the Overlay Electropherograms tab.

For information on changing the view in the Overlay Electropherograms tab, see "Viewing Graphs in the Overlay Electropherograms Tab" on page 63.

See "Graph View Properties" on page 122 for descriptions of the properties that can be set for the Overlay Electropherograms tab.

### **Electropherograms Tab**

Use the Electropherograms tab on the Graph View to view a single graph or multiple graphs in the same tab.

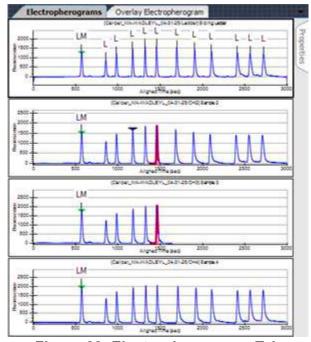


Figure 28. Electropherograms Tab

Each graph displays the data file name and channel name at the top of the graph.

For information on changing the view properties in the Electropherograms tab, see "Viewing Graphs in the Electropherograms Tab" on page 64.

See "Graph View Properties" on page 122 for descriptions of the properties that can be set for the Electropherograms tab.

## **Graph View Properties**

To view the Properties for the Electropherograms Tab or the Overlay Electropherograms Tab, click the **Properties** tab on the right side of the Graph View.

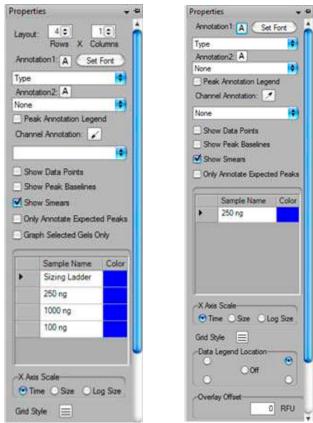


Figure 29. XT Electropherograms Properties and XT Overlay **Electropherograms Properties** 

This window contains the following options:

Option	Function
Layout (Rows x Columns)	Specifies the number of rows and columns of graphs displayed on the Electropherograms Tab. (Only displayed when the Electropherograms tab is selected.)
Annotation 1	Labels each peak in the graph with the peak property selected from the drop down list. Default is Type. The Annotations available depend on the columns selected in the Peak Table View. (LabChip XT only)
Text Orientation (A) button	Specifies the orientation of the text for the annotation: horizontal, vertical up, or vertical down. (LabChip XT only)

Option	Function
Set Font button	Opens the Font window to choose the font, style, and size of the text for all annotations. (LabChip XT only)
Annotation 2	Labels each peak in the graph with a peak property selected from the drop down list. Default is None. (LabChip XT only)
Peak Annotation Legend	If selected, the types of the annotations display in the upper left corner of the graph. (LabChip XT only)
Channel Annotation	Displays the selected channel property outside the graph. (LabChip XT only)
Channel Annotation Location Button (arrow)	The location of the channel annotation. Click the button to change to location: upper right, upper left, lower left, or lower right. (LabChip XT only)
Show Data Points	If selected, displays a dot on the graph at the location of each data point.
Show Peak Baselines	If selected, displays the baseline for each peak on the graph.
Show Smears	If selected, displays smears as a colored line on the trace and displays the smear baseline. This option only displays if smears are defined in the Method Window.
Only Annotate Expected Peaks	If selected, only the peaks that are labeled as Expected Fragments display the annotations. If not selected, all peaks display the annotations. (LabChip XT only)
Graph Selected Gels Only	If selected, only the channels selected in the Gel View or Channel Table View are displayed in the Electropherograms tab. If not selected, all channels in the collection are displayed. (Only displayed when the Electropherograms tab is selected.)
Sample Name/Color Table	Displays the names of the samples (channel names) on the graph and the color associated with each sample (channel). Click on the color to choose a different color for a sample. (LabChip XT only)
X Axis Scale	Specifies the units displayed on the X Axis, either Time, Size, or Log Size. Log Size displays the size on a logaritmic scale.
Grid Style	Displays grid lines on the graph: vertical, horizontal, both, or none. Click the button to cycle through the grid options.
Data Legend Location	If multiple channels are displayed, specifies the location where the legend displays on the graph. The legend shows the color used for each channel. (LabChip XT only)
Pin icon	In the top right corner, locks in place or unlocks the Properties tab. If locked, the Graph resizes to fit the tab.

#### Filter View

The Filter view in the Collection Pane is used to define criteria to automatically select the channels to display in the Collection tab. The filter types available depend on the method type. Each filter can be assigned a different color to determine which filter applies to each channel. See Example: Expected Peaks Filter for an example of a filter.

The Filter tab is only available in the LabChip XT software.

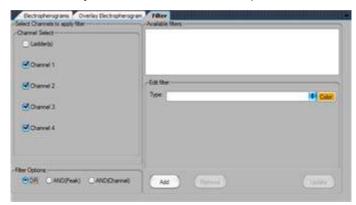


Figure 30. Filter View

One or more filters can be defined independently by selecting the appropriate filter type, range mode, and range values, and then clicking the **Add** button. The **Available Filters** list box displays all of the filters that are part of the current collection. The check box next to each filter in the list is used to include or exclude that filter from the analysis.

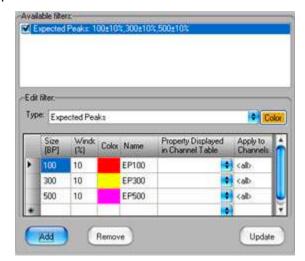
The **Filter Options** selection determines how multiple filters are logically combined. The options available are OR, AND(Peak), and AND(Channel).

- OR Selects any channel that contains a peak that matches any
  of the filters selected in the Available Filters list.
- AND(Peak) Selects any channel that contains a single peak that matches all of the filters selected in the Available Filters list.
- AND(Channel) Selects any channel that contains peaks that match all of the filters selected in the Available Filters list.
   Different peaks in the same channel can match different filters, as long as all filter conditions are met in the same channel.

## Filter View (Continued)

#### **Example: Expected Peaks Filter**

In the example below, the sizes 100 +/- 10%, 300 +/- 10%, and 500 +/- 10% are selected, with each expected peak size identified by a different color. This filter will select any channels that contain **all three** expected peaks: 100, 300, AND 500. Note that the filter is selected (checked) under Available Filters, indicating that the filter is being applied to the data.



To select channels that contain **any of the three** peaks, create a separate filter for each peak and select OR as shown below.



### Filter View (Continued)

When using multiple filters that include peak properties, if AND(Peak) is selected, a single peak in the channel must meet all selected filter properties. See the examples below, which each use two filters:

- Height > 100 AND(Peak) Conc > 50 selects any channel that contains a single peak that meets both criteria.
- Height >100 OR Conc > 50 selects any channel that contains a peak that meets either (or both) criteria.
- Height >100 AND(Peak) Height <50 does not select any channels because a single peak cannot have a height that is both less than 50 and greater than 100. Use OR to select channels that have peaks that match either criteria. Use AND(Channel) to select channels that contain peaks that match both criteria.

Expected Peak Filters can contain multiple size peaks in the same filter as shown above. Expected Peak filters with multiple peak sizes in the <u>same filter</u> always select only channels that contain all the peaks listed.

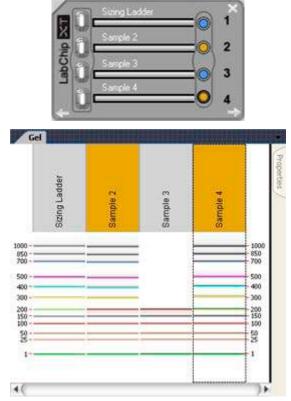


Figure 31. Filter Applied Example

## Filter View (Continued)

In the chip diagram in Figure 31 on page 126, the orange channels are the channels that meet the filter criteria. To see the graph for each channel, click on the channel in the chip diagram and view the graph in the Graph view.

The gel in Figure 31 on page 126 shows the expected peaks marked with colored lines on the Gel view. The channel header is orange if the channel meets the filter criteria. If a channel meets the criteria of multiple filters, the header color is a combination of the filter colors.

#### **Gel View**

The Gel view in the Collection Pane is a visual representation of the data formatted to look like the Gel slabs that were originally used to provide DNA data. The data is shown in Time vs. Fluorescence (or digital form).

Click on a gel lane (channel) to select the channel. Ctrl + click to select multiple channels. Selected channels are outlined with a dotted gray line. Channels selected in the Gel view are also selected in the Channel Table View and are displayed in the Overlay Electropherograms Tab.

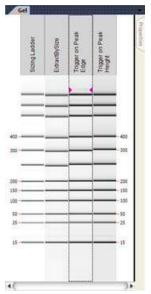


Figure 32. Gel View

Moving the cursor over a band in the Gel view displays a tool tip that includes the same information about the peak as the Peak Table View. (Changing the columns displayed in the Peak Table will change the contents of the tool tip in the Gel view.)

**Expected Peaks** are indicated on the gel by colored horizontal lines.

**Smears** (representing the portion of the sample that was routed to the collection well) are indicated on the gel by colored regions in the gel.

For DNA assays, the lower markers of all channels are aligned to the lower marker of the first channel in the gel view.

### **Gel View (Continued)**

A colored column header indicates that the channel is selected by a filter. Click the Filter View to view the color of each filter. A red exclamation point under the header indicates an analysis error occurred in the channel. A yellow exclamation point under the header indicates an analysis warning occurred in the channel. A gray header indicates a normal channel. To change the size of the gel header, click on the border between the header and the channel and drag the header to the desired size.

The graphs displayed in the Graph View are synchronized with the lanes selected in the Gel tab.

You can drag-and-drop the gel lanes to change the order of the channels for comparing two or more gel channels. To drag-and-drop a gel lane, click in the header of the lane to be moved and drag the gel lane to the desired location.

Double-click in the Gel view to zoom out to the previous zoom level.

Gel data in the LabChip XT software can be exported to a graphic file by choosing **Export** on the File Menu (see "Exporting Data" on page 74 for details). If the workspace contains multiple collections, data is exported from the active/selected collection.

To change the Lane Width or Gel Contrast Range, see Gel View Properties.

#### Right-Click Menu

Right-click anywhere in a gel to display a shortcut menu containing the following commands:

**Unzoom** - Zooms out to the previous zoom level.

**Unzoom All** - Zooms out completely and returns to the standard view.

**Scale Gel Contrast to this Lane** - If selected for a lane, the minimum and maximum RFU values for all lanes in the collection are set to the minimum and maximum RFU values in the selected lane.

**Remove** - Removes the sample from the collection.

**Copy Gel** - Copies all of the open lanes (channels) to the clipboard in a .bmp format.

**Copy Lane** - Copies the selected lane (channel) to the clipboard in a .bmp format.

## **Gel View (Continued)**

Analysis Settings - Opens the Method Window to change the analysis settings. (LabChip XT only.)

Edit Sample Name - Opens the Edit Sample Name window to change the channel name or add a comment to the channel. The comment displays in the Channel Table View and in printed reports.

Rename Chip - Opens the Rename Chip window to specify a new name for the chip. Also enables you to rename the data file to match the name of the chip by selecting the Rename File to Match check box. The data file cannot be renamed if the 21 CFR Security option is installed.

# **Gel View Properties**

To view the Gel View Properties, click the Properties tab on the right side of the Gel View.

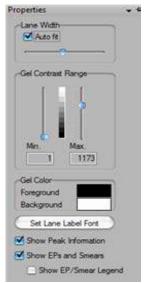


Figure 33. Gel View Properties

The following properties can be set for the Gel view:

Option/Button	Function
Lane Width	Sets the width of the Gel column. Select <b>Auto Fit</b> to have the software automatically fit all the data, or use the slider to manually set the width.
Gel Contrast Range	Sets the minimum and maximum Gel Band Contrast for the bands in each channel. Use the sliders to change the Min and Max values.
Gel Color	Click on the Foreground color or the Background color to open the Color window to choose the desired colors for the gel.
Set Lane Label Font button	Opens the Font window to change the font or font size of the labels in the gel headers.
Show Peak Information	If selected, displays peak information in a tool tip when the cursor moves over a peak. If not selected, the tool tip does not display when the cursor is over a peak.
Show EPs and Smears	If selected, EPs are indicated by a solid color triangle above the peak and smears are indicated by bands of translucent color in the Gel view. (Expected Peaks are only supported in LabChip XT.)

Show EP/Smear Legend	Displays a legend of the colors of the Expected Peaks and Smears in the Gel view. Click and drag to move the legend. (Expected Peaks are only supported in LabChip XT.)
Pin icon	In the top right corner, this is used to lock in place or unlock the Properties tab. If locked in place, the Gel display panel is resized to accommodate the tab.

#### **Channel Table View**

The Channel Table view in the Collection Pane contains a summary of analysis results for the channels selected from the chips in the collection.



Figure 34. Channel Table View

In the LabChip XT software, the **Total Conc**. (ng/uL) reports the concentration of all DNA as was present in the sample well. The **Conc. of Collections (ng/uL)** column reports the total extracted concentration over all fractionation steps diverted to the Collection well as was present in the sample well, not the concentration that will be extracted from the collection well. To compute the mass of the collected DNA, multiply by the sample volume in uL. For example, for a typical sample volume of 10 uL, the collected mass will be 10 times the reported concentration. To estimate the concentration in the collection well, divide the mass by the buffer volume in the collection well (20 uL). (The Conc. of Collections column is not shown by default, but can be viewed by right-clicking on the column headers in the Channel table and move the column to the Selected columns list.)

As the run progresses in the LabChip XT software, the concentration for each extraction is calculated and displays in columns named Concentration of Collection Region<#> (ng/uL). These concentrations are reported as was present in the sample well.

The LabChip XTe software does not display the quantitation values, Chip ID, Barcode, or Molarity in the Channel Table.

The following values are calculated for each extraction step as the run progresses: Molarity of Collection Region<#> (nMol/l) (LabChip XT only), Fractionation Start<#> [min], and Fractionation End<#> [min].

To view or hide columns in the Channel Table view, right-click on any column header in the table. The Select Channel Table Columns window displays all available columns and the currently selected columns. Show columns in the Channel Table by moving the column name to the Selected Columns list. Hide columns by moving the column name to the Available Columns list.

### **Channel Table View (Continued)**

Change the order of columns in the table by clicking on a column header and dragging the column to the desired position in the table. Click a column header to sort the table in ascending/ descending/ original order.

Right-click in the **Chip Name** column to open the **Rename Chip** window to rename the chip. The Data file can also be renamed by selecting the Rename File to Match check box if the 21 CFR Security option is not installed.

Right click in the **Sample Name** column to edit the channel name or copy the row to the clipboard.

Right click in the **User Comment** column to add or edit the User Comment or copy the row to the clipboard.

Analysis error messages display in the Channel Table View. Most are the result of peaks not being located by the analysis algorithms. This can be due to a sample or ladder peak not appearing as expected. In the LabChip XT software, the settings in the Peak Find Tab can also cause peaks to be undetected. Manually excluding a peak (see page 55) from analysis in the Peak Table View or changing the start or end times for a run can also cause errors with the peak find algorithm in the LabChip XT software.

The Channel table in the LabChip XT software can be exported to a .csv file by choosing **Export** on the File Menu (see "Exporting Data" on page 74 for details). The .csv file includes the columns in the order displayed in the Channel Table at export time. The .csv file can be opened in Microsoft Excel. If the workspace contains multiple collections, the data is exported from the active/selected collection. (Exporting the Channel table and opening multiple collections are not supported in the LabChip XTe software.)

#### **Peak Table View**

The Peak Table view in the Collection Pane is a text-based representation of all the information about each peak.

To view or hide columns in the Peak Table view, right-click on the column headers in the table. The Select Peak Table Columns window displays all available columns and the currently selected channels. Show columns in the Peak Table by moving the column name to the Selected Columns list. Hide columns by moving the column name to the Available Columns list.

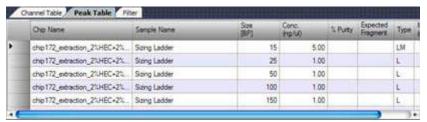


Figure 35. Peak Table View

To change the order of columns in the table, click on a column header and drag the column to the desired position in the table. Click a column header to sort the table in ascending/ descending/ original order.

The analysis normally labels the lower marker (LM) in each sample and in the ladder. The labels display in the Type column of the table. If the analysis has misidentified the markers, the correct marker can be selected manually by right-clicking on the peak row to open a shortcut menu of possible peak types for the peak. This can also be used to label a peak as Excluded (X). The concentration of an excluded peak is forced to zero so that it does not affect the total channel concentration and the Percent Purity calculation.

Expected Peaks are indicated by the Expected peak name in the Type column.

The peak table in the LabChip XT software can be exported to a .csv file by choosing **Export** on the File Menu (see "Exporting Data" on page 74 for details). The .csv file includes the columns in the order displayed in the Peak Table at export time. the .csv file can be opened in Microsoft Excel. If the workspace contains multiple collections, the data is exported from the active/selected collection. (Multiple collections are not supported in the LabChip XTe software.)

### Peak Table View (Continued)

To show only filtered peaks, sort within each channel, or hide excluded peaks, see Peak Table Properties.

The Peak Table displays the following columns by default:

Chip Name - The name of the chip defined in the workspace.

**Sample Name** - The sample name defined in the Setup Tab on the Start Fractionation Window. The Sample name can also be changed in the Channel Table View or the Gel View.

**Type** - Displays the type of peak for markers or expected peaks.

**Migration Time (min) - Center -** The time, in minutes, at which the center of the peak reaches the detector.

**Size (BP)** - The size of the peak based on the ladder sizes specified in the assay.

**Height** - The height of the peak.

**Aligned Area -** The area of the peak after the data has been aligned with the ladder. Used to calculate the concentration.

**Conc.** (ng/uL) - The concentration calculated relative to the ladder and marker peak concentrations. The ladder concentration is displayed in the Analysis Tab of the Method Window. This value represents the concentration of each fragment as was present in the sample well. To compute the fragment mass, multiply by the sample volume in uL.

**% Purity -** The ratio of peak concentration to total concentration (above the lower marker) in the sample.

Molarity (nmol/l) - Displays the molarity of the peak.

#### **Peak Table View Shortcut Menus**

Right-click on a peak in the peak table to display a shortcut menu containing the following commands:

- Exclude Peak
- Force Lower Marker
- Force Expected Peak

#### NOTE



Excluding a peak or manually setting a peak to be a lower marker can cause errors with analysis.

# **Peak Table Properties**

To view the Peak Table Properties, click the **Properties** tab on the right side of the Peak Table View.



Figure 36. Peak Table Properties

This window contains the following options:

Option	Function
Sort within each Channel	If selected (default), sorting occurs only within each channel rather than across the entire table. Click a column header to sort the table rows by the column value. If cleared, uses conventional sorting, which mixes together peaks from all channels. Clicking the column header sorts in ascending/descending/original order.
Hide excluded peaks	If selected, excluded peaks and unknown peaks are hidden in the Peak Table view.
Expected Peaks only	If selected, only peaks identified as Expected peaks display in the Peak Table.
Filtered peaks only	If selected, the Peak Table displays only peaks that match the filter criteria. Useful when generating a collection based on a filter whose selection criteria are peak specific, such as Area, Concentration, %Purity, Expected Peaks, and Size.
Show all Peaks	If selected, all peaks display in the Peak Table.
Selected in Gel	If selected, only the gel lanes selected in the Gel View display. To select multiple channels, Ctrl + click on the lanes in the Gel view.
Entire Collection	If selected, all channels in all chips that are included in the collection are displayed.
Pin icon	In the top right corner, used to lock in place or unlock the Properties tab. If locked in place, the Peak Table display panel is resized to accommodate the tab.

# **About LabChip XT/XTe Window**

The About LabChip XT/XTe window displays the software and firmware versions. Selecting About LabChip XT or About LabChip **XTe** on the Help Menu opens this window.



Figure 37. About LabChip XT Window

# **Add New Expected Peak Window**

Use the Add New Expected Peak Window to add an expected peak to specific channels. To open this window, right-click near a peak in the Graph View and select Add Expected Peak. (Expected Peaks are only supported in the LabChip XT software.)

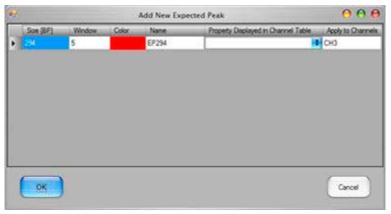


Figure 38. Add New Expected Peak Window

Size (BP)	Specifies the expected size of the peak in BP. The default size is the size of the peak that was selected.
Window (%)	Specifies the tolerance window as a percent of the expected size for the fragment to allow for small variations in expected peak size.
Color	Displays the color to use to mark the peak in the Graph View or the Gel View.
Name	Specifies a name to display in the Type description for the peak.
Property Displayed in Channel Table	Specifies the content of a column added to the channel table for each expected peak.
Apply to Channels	Specifies the channels that the expected peak is applied to. <all> specifies that the expected peak applies to all channels. Clicking on the column opens the Select Channels window to choose the specific channels to apply the expected peak to.</all>

# **Audit Trail Window**

The Audit Trail Window enables you to search the Audit Trail Log for specific events, to export the events, or to print events. (Only available if the 21 CFR Security option is installed with the LabChip XT software.)

To open the Audit Trail window, select **Security** → **Audit Trail Log** on the LabChip XT/XTe Main Window.



Figure 39. Audit Trail Window

The Audit Trail Window contains the following options:

Search most recent entries	If selected, the specified most recent number of entries is searched for entries matching the selected criteria.
Number of entries	Specifies the number of most recent entries to search.
Search by dates	If selected, entries between the specified dates are searched for entries matching the selected criteria.
From and To text boxes	Select the dates that contain the events that you want to view.
Search entire database	If selected, all entries in the database are searched.
Username text box	Select a specific user name to view only events performed under the specified user name. Select All Users to view events performed by any user.
Filename text box	Clicking the Browse () button opens the Audit Trail CDR Browser window to open the audit trail for a different data file.

Event Category	Specifies the Event Category of events to search for. Default selects all event categories.
Green Arrow button	Displays the Audit Trail Manage Columns Window to select the columns to view in the Audit Trail window.
Search button	Searches for events matching the search criteria specified.
Export button	Opens the Audit Trail Export Window to export a copy of the selected events out of the audit trail log.
Print View button	Displays a preview for printing the Audit Trail Report.
Close button	Closes the Audit Trail Window.

# **Audit Trail Export Window**

Use the Audit Trail Export Window to export the contents of the Audit Trail Window to either an ASCII text file, and XML file, or a Microsoft Excel file. Only the events displayed in the Audit Trail Window are exported. Events filtered out of the view are not exported. (Only available if the 21 CFR Security option is installed with the LabChip XT software.)

To open the Audit Trail Export Window, click the **Export** button in the Audit Trail Window.



Figure 40. Audit Trail Export Window

The Audit Trail Export Window contains the following options:

File Formats - Select the desired format for the exported file:

- ASCII Text File If selected, the file is saved as a .txt file.
- XML File If selected, the file is saved as an .xml file.
- MS Excel If selected, the file is saved as an .xls file.

**Number of Events Included** - Displays the number of events that will be exported.

# **Audit Trail Manage Columns Window**

Use the Audit Trail Manage Columns Window to select the columns to view at the bottom of the Audit Trail Window. (Only available if the 21 CFR Security option is installed with the LabChip XT software.)

To open the Audit Trail Manage Columns Window, click the Green Arrow button next to the Event Category text box in the Audit Trail Window.



Figure 41. Audit Trail Manage Columns Window

The Audit Trail Manage Columns window contains the following parts:

Show All check box	Selecting the check box selects all of the listed columns to display at the bottom of the Audit Trail window. Clearing the check box clears all of the column check boxes.
Column list	Only the selected columns display at the bottom of the Audit Trail window. Cleared (unselected) columns are hidden.
Green Up and Down Arrows	Moves the selected column up or down in the list. The columns display in the Audit Trail window in order from the top column on the left to the bottom column on the right.
Save button	Saves the selections and applies the current column view to the Audit Trails window.
Close button	Closes the window without saving changes to the selections.

# **CDR Manager Window**

Use the CDR Manager Window to select a data file to open, to create, rename, or delete CDR data folders, and to show or hide data files from view in the CDR Manager Window.

To open the CDR Manager Window, select **File** → **Import Data File** on the LabChip XT/XTe Main Window. The CDR Manager window only opens if the 21 CFR Part 11 Security option is installed with the LabChip XT software. If the 21 CFR Part 11 Security option is not installed, see "Select a Data File Window" on page 184.

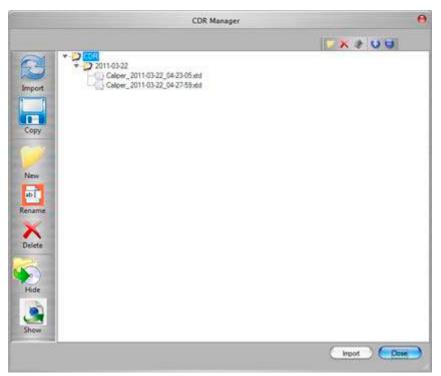


Figure 42. CDR Manager Window

The CDR Manager Window contains the following options

Left Side Buttons	
Import Button	Imports a CDR data file into the open workspace.
Copy Button	Copies the selected data file to another location. The copy of the data file will not be part of the CDR and will not be change-controlled.
New Button	Creates a new folder in the CDR.
Rename Button	Renames the selected folder in the CDR. (Data files in the CDR cannot be renamed.

Delete	Deletes an empty folder in the CDR. If the folder is
Button	not empty, you cannot delete the folder.
Hide Button	Hides the selected folder or data files from view in the CDR Manager window. If a folder is selected, all files and subfolders in the selected folder are hidden.
Show Button	Displays all hidden data files and folders in the selected folder.
Top Right Buttons	
New Button	Creates a new folder in the CDR.
Delete Button	Deletes an empty folder in the CDR. If the folder is not empty, you cannot delete the folder.
Show/Hide Hidden Files Button	Shows or hides the filenames of all files that have been hidden in the CDR Manager window.
Expand All Button	Expands all folders in the CDR to show all data files and folders.
Collapse All Button	Closes all folders in the CDR folder.

# **CDR Server Utility Window**

Use the CDR Server Utility Window to create a repository (the Remote CDR Server Folder) on a remote computer to back up the CDR. The repository stores secure backup copies of data files. The CDR Server Utility Window is only available if the CDR Server Utility is installed on the remote computer. (Only used if the 21 CFR Security option is installed with the LabChip XT software.)

To open the CDR Server Utility Window, double-click the CDR Server Utility icon on the remote computer desktop.

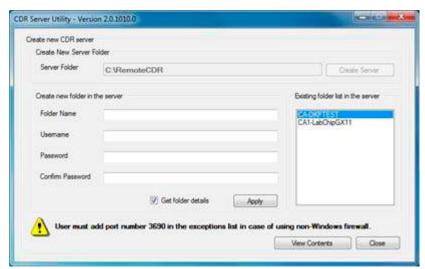


Figure 43. CDR Server Utility Window

The CDR Server Utility Window contains the following options:

Server Folder	The name of the repository that will contain the data folders.
Create Server	Creates the repository for backup data in C:\RemoteCDR.
Folder Name	Specifies the name of the data folder to create in the repository.
Username	Specifies the user name to use when accessing the data folder.
Password	Specifies the password to use when accessing the data folder.
Confirm Password	The same password as typed in the Password text box.
Get Folder Details	If selected, creates a text file containing the URL, Folder Name, Username, and Password for the new data folder.
View Contents	Opens the CDR Server Viewer window to view the data files and folders in the remote CDR server. Click a folder and enter the user name and password that was used to create the folder to view the contents of the CDR server folders.
Apply button	Creates the specified data folder.

# **CDR Utility Window**

Use the CDR Utility Window to view the location of the local CDR folder, specify whether the CDR folder is accessible by Windows Administrators, and to enable Remote CDR Backup. Before enabling remote CDR Backup, the remote CDR server and folder must be set up (see page 93).

To open the CDR Utility Window, select **Tools** → **CDR Utility** on the LabChip XT/XTe Main Window. The CDR Utility command is only available if the 21 CFR Part 11 Security option is installed with the LabChip XT software.

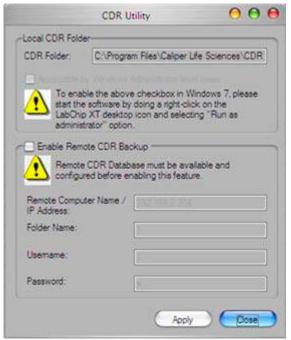


Figure 44. CDR Utility Window

The CDR Window contains the following options:

CDR Folder	Displays the location of the CDR folder where the LabChip XT data files will be saved. This location cannot be changed.
Accessible by Windows Administrator	To access the check box, right-click on the LabChip XT icon on the Windows desktop and select <b>Run as Administrator</b> . If selected, Windows Administrators who are logged into the computer can access the CDR folder. If not selected, Windows Administrators are prompted to set full permission when opening the folder.

Enable Remote CDR Backup	If selected, all new or edited data files are automatically copied to the specified remote database.
Remote CDR Database	Specifies the path to the remote database.
Folder Name	Specifies the name of the folder in the database in which to save copies of the data files.
User Name	Specifies the user name assigned to the folder when the folder was created.
Password	Specifies the password assigned to the folder when the folder was created.
Apply button	Applies the changes and closes the window.
Cancel button	Closes the window without saving any changes.

# **Change Password Window**

Use the Change Password Window to change the password for the current user. (To change passwords for other users, see User Administration Window.) This window is only available if the **21 CFR Security** option is installed with the LabChip XT software.

To open the Change Password Window, select **Security** → **Change Password** on the LabChip XT/XTe Main Window.



Figure 45. Change Password Window

The Change Password Window contains the following options:

Username	Displays the user name for the current user.
Current Password	Type the current password for the current user.
New Password	Type the new password for the current user.
Confirm Password	Retype the new password for the current user.
OK button	Saves the new password and closes the window.
Cancel button	Closes the window without saving changes to the password.

## **Data File Version Window**

Use the Data File Version Window to view the saved versions of the data file in the LabChip XT software. Also displays when the data file was signed, whether the file was locked, and the current approval state if the 21 CFR Part 11 Security option is installed.

To open the Data File Version Window, select  $View \rightarrow Version$  Change Details on the main menu.

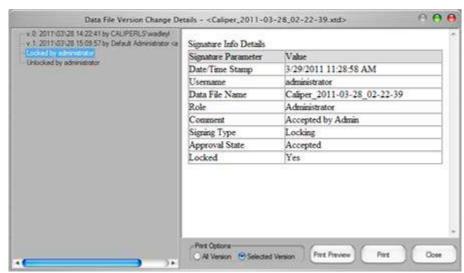


Figure 46. Data File Version Window

The Data File Version Window contains the following options:

List of Versions	Displays the list of all saved data file versions and electronic signatures. (To open a different version of the data file, click the <b>Restore Chip</b> button in the Method Window.)
Details	Displays the details of the changes or signature. Signature details include approving and locking/unlocking the data file.
Print Options	All Versions: If selected, version information and details for all data versions is printed. Selected Version: If selected, version information and details for only the selected version is printed.
Print Preview button	Opens the Print Preview window to preview the printed version information.
Print button	Opens the Print window to print the data file version information.
Close button	Closes the Data File Version window.

## **Event Viewer Window**

Use the Event Viewer window to view events and errors that occur during the current run or during a previous run.

To open the Event Viewer window, select **View** → **Event Viewer** on the LabChip XT/XTe Main Window.

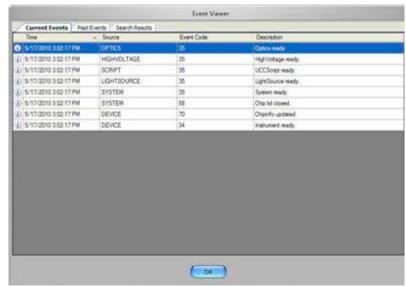


Figure 47. Event Viewer Window

The Event Viewer window contains the following tabs:

**Current Events tab** - Displays the events that occurred during the current session.

Past Events tab - Displays all events from previous sessions.

**Search Results tab** - Enables you to search for specified text in past events, current events, or all events.

The tabs on the Event Viewer window contain the following columns:

Column Title	Description
Time	The data and time the event or error occurred.
Source	The system component that generated the event or error.
Event Code	The event/error ID number used by Caliper to troubleshoot errors.
Description	Text describing the event or error.

Click the **OK** button to close the Event Viewer window.

## **Export Window**

Use the Export window to export data manually. To open the Export window, select **File** → **Export** on the main Menu Bar.

The Auto Export window contains the same options and is used to automatically export data at the end of each run. To automatically export data, click the **Settings** button next to Automatic Export in the Output Tab on the Start Fractionation Window.

Manual and Auto Export are only available in the LabChip XT software.

Peak Tables and Channel Tables are exported to .CSV files, which can be imported into a spreadsheet program such as Microsoft Excel. Raw Data can be exported to either a .CSV file or to a Chromatography Data Interchange Format file (formerly AIA), which is used by some graphical analysis software tools.

Electropherogram and Gel data are exported to the selected image format. See "Exporting Data" on page 74 for instructions.

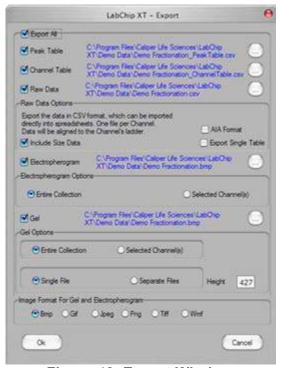


Figure 48. Export Window

#### **Peak Table**

If selected, the data in the Peak Table View is exported to a .CSV file. Click the Browse (...) button to specify the desired path and file name for the .CSV file.

## **Export Window (Continued)**

#### **Channel Table**

If selected, the data in the Channel Table View is exported to a .CSV file. Click the Browse (...) button to specify the desired path and file name for the .CSV file.

#### **Raw Data**

If selected, the raw (unanalyzed) data from the run is exported.

- If the AIA Format check box is selected, the raw data is exported to a file in the Chromatography Data Interchange Format (formerly AIA). (Include Size Data and Export Single Table are not available.)
- If the AIA Format check box is NOT selected, the raw data is exported to a .CSV file. Click the Browse (...) button to specify the desired path and file name for the .CSV file. The following options are available:
  - **Include Size Data**: If selected, the data is aligned to the channel's ladder (for one file per channel) or to the first channel (for a single data file) and the size data is included in the exported data. If not selected, the data is not aligned to a ladder.
  - Export Single Table: If selected, the data for all channels in the chip is exported to one .CSV file. If not selected, the data from each channel is exported to a separate .CSV file.

#### **Electropherogram**

If selected, the graph displayed in the Graph View is exported to the specified folder in the selected image format. Click the Browse (...) button to specify the desired path for the image file. The file name format is <sample name> <chip name> Egram <channel number>. The following options are available on the Export window. (These options are not available on the Auto Export window.)

- **Entire Collection**: If selected, a separate graph is exported for each channel in the collection.
- **Selected Channels**: If selected, a separate graph is exported for each of the channels selected in the Gel View or Chip View or List View.

## **Export Window (Continued)**

#### Gel

If selected, the gels selected in the Gel View are exported to the specified folder in the selected image format. Click the Browse (...) button to specify the desired path for the image file. The file name format is <sample name>\_<chip name>\_Gel\_<channel number>. The following options are available on the Export window.

- Entire Collection: If selected, a gel is exported for each channel in the collection. (This option is not available on the Auto Export window.)
- Selected Channels: If selected, a gel is exported for each of the channels selected in the Gel View or Chip View or List View. (This option is not available on the Auto Export window.)
- **Single File**: If selected, the selected gels are all included in the same image file.
- Separate Files: If selected, the selected gels are each exported to a separate image file.
- **Height**: Specifies the desired height, in pixels, of the gel graphic.

### Image Format for Gel and Electropherogram

Select the desired format for the exported image files.

## Flush Chip Window

Use the Flush Chip window to flush used channels on a chip for the specified times. Individual times can be specified for each channel on a chip.

To open the Flush Chip Window, insert the chip in the instrument and then select **Instrument** → **Flush Chip**.



Figure 49. Flush Chip Window

**Channel Flush Time** - Specifies the desired time (in minutes) to flush each channel. Unused channels should not normally be flushed, but can be flushed if necessary.

**All Used Channels Time** - Sets the Flush time for all used channels to the specified time. If the time for any channel is changed, the time specified in the Channel Flush Time text box is used.

**Flush button** - Starts flushing the channels using the times specified.

**Stop button** - Stops a flush that is in progress. Only displays when a Flush operation is in progress.

**Done button** - Closes the window without starting the Flush operation.

## **Layout Options Window**

Use the Layout Options window to change the location of the views in a collection. To open the Layout Options window, select Collection → Layout on the LabChip XT/XTe Main Window.



Figure 50. Layout Options Window

**Viewer** - Lists the viewers available to display in the Collection Pane.

**Left** - If selected, the view displays on the right side of the Collection pane. (The view displays at the top if any view is selected to display at the bottom of the pane.)

**Right** - If selected, the view displays on the left side of the Collection pane. (The view displays at the top if any view is selected to display at the bottom of the pane.)

**Bottom** - If selected, the view displays at the bottom of the Collection pane. (The view displays at the top if there are no views displayed at the top left or right in the pane.)

**Apply button** - Applies the selections to the active collection and closes the Layout Options window.

**Reset to Factory Defaults button** - Restores the active collection to the default Layout options.

**Cancel button** - Closes the Layout Properties window without changing the collection layout.

# **Layout Options Window (Continued)**

### **NOTES**



- A view can only be displayed in one location. Selecting a location automatically clears any other selected location.
- To hide a view, click on the selected location to clear the selection.
- A location is hidden if it contains no views.
- The Gel View is always displayed and cannot be hidden.

# **Login Window**

Use the Login Window to log into the LabChip XT software when the 21 CFR Part 11 option is installed. The LabChip XT software will not start until a valid user name and password are entered.

The Login Window opens when you start the LabChip XT software with the 21 CFR Part 11 option is installed.



Figure 51. Login Window

The Login Window contains the following options:

Username text box	Type the username to log into the LabChip XT software. Each user should have a unique user name.
Password text box	Type the password assigned to the Username. All passwords must be at least 5 characters long and must contain at least one uppercase letter and at least one number. The User Account Policies specify additional password requirements.

## **Method Window**

The Method window specifies the analysis parameters for the channels in the collection. Use the analysis settings to analyze the data after the fractionation is complete. To view the method for the selected data file, select Analysis → Analysis Settings. Methods cannot be edited in the LabChip XTe software.

The Method Editor window contains the same options as the Method window. To open the Method Editor window to view or edit a saved method file, select **Tools** → **Method Editor** on the main menu. The Method window contains the following tabs:

- Method Info Tab
- **Analysis Tab**
- Peak Find Tab
- **Expected Fragments Tab**
- **Excluded Fragments Tab**
- **Smear Analysis Tab**
- **Advanced Tab**

The following buttons at the bottom of the Method window are used to save, apply, or cancel changes:

Buttons	Function
Apply	Applies setting changes and re-analyzes the chip, but keeps the Method window open.
Apply Global	Applies the selected analysis settings to all chips in the open workspace.
Restore Chip	Restores the analysis settings for the chip to the version of the data file selected in the Restore Chip Settings to Version window. If the 21 CFR Security option is installed, opens the Restore Chip Settings To Version window to choose which version of a data file to restore.
OK	Applies the changes in the Method window and re-analyzes the chip with the new settings.
Print Preview	Opens the Print Preview window to view the analysis settings before printing.
Print	Opens the Print window to print the default ladder, Analysis and Chip Peak Find Settings, Analysis Parameters, Expected Fragments, Excluded Fragments, and Smear Analysis.
Cancel	Restores the settings that were selected when the window was opened or when the last Apply was performed. No re-analysis is performed because the settings were used for the last analysis performed.

# **Method Window (Continued)**

The following buttons at the bottom of the Method Editor window are used to save or cancel changes:

Buttons	Function
Save Method	Opens the Save Method to File window to specify a name for the modified method. If the specified name is the same as an existing method, you are prompted to overwrite the existing method.
Restore Method	Restores the analysis settings to the last saved settings. All changes are discarded.
Close	Closes the Method Editor window. If the method contains unsaved analysis changes, you are prompted to discard the changes.

#### **Method Info Tab**

The Method Info tab on the Method Window displays the header information for the current method.



Figure 52. Method Window - Method Info Tab

The following information is displayed:

Method Class - All methods on the LabChip XT/XTe are XT DNA 750, XT DNA 750 Ver2, or XT DNA 300, method class DNA1.

Name - The name of the method.

Title - The title of the method. (This field can be changed in the Method Editor window.)

Comments - An optional comment that can be used to identify the method.

**Version** - The current version of the method that was run.

Format - The format of the data file.

## **Analysis Tab**

Use the Analysis tab on the Method Window to view the Lower Marker peak designation, Ladder Sizes, Ladder Concentration, Standard Curve, Data Range, and Marker Concentration.

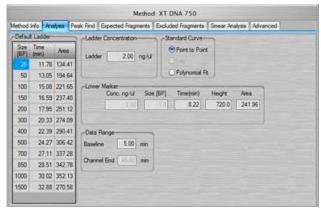


Figure 53. Method Window - Analysis Tab

**Default Ladder -** A table showing the sizes (in base-pairs) of the ladder peaks.

**Ladder Concentration -** The concentration (in ng/uL) for the ladder peaks.

**Standard Curve** - Determines whether the fit for the standard curve used to calibrate migration time to size will be done on a point-to-point, or Polynomial fit of the ladder. DNA methods are set to point-to-point curve fits but can be changed to Polynomial.

#### **Lower Marker**

- Conc. ng/uL The concentration of the lower marker in ng/uL.
- Size [BP] The size of the lower marker.
- **Time (min)** The expected time when the lower marker will be detected in the sample.
- Height The expected height of the lower marker.
- Area The expected area of the lower marker in a sample.

#### **Data Range**

- Baseline Specifies the time in minutes after the start of the run when the first peak can appear (any peaks appearing before this time are ignored).
- **Channel End** Specifies the time when peak detection stops. The graph ends at this time.

#### Peak Find Tab

Use the Peak Find tab on the Method Window to adjust parameters to detect peaks for individual channels, or the entire chip specified in the Chip field.



Figure 54. Method Window - Peak Find Tab

To change the options for all channels on the chip, change the options in the Chip Peak Find Settings at the top of the window (see Table 1 on page 162).

To select a single channel, right-click on a channel in the Gel View or a graph in the Graph View and select the Analysis Settings option. The settings for the single channel are displayed in the Channel Peak Find Settings fields at the bottom of the window (see Table 2 on page 163). Select other individual channels in the chip by selecting the channel name in the Channel drop-down list. The channel list includes all the channels on the currently selected chip. The Channel Name field is read only, and cannot be changed from the Peak Find Tab.

# Peak Find Tab (Continued)

This window contains the following options:

Table 1. Chip Peak Find Settings

Chip Settings	Function
Minimum Peak Height	Specifies the height limit below which a peak is not detected. For each peak, the difference between the peak start time and the peak apex must be greater than the Min Peak Height value.
Minimum Peak Width	Specifies the limit (in minutes) for the peak width. Peaks narrower in time than this value are <b>not</b> detected.
Slope Threshold	Represents the amount of change in absorbance units over time required to indicate that a peak has occurred. This setting is used to detect the leading and trailing edges of a peak. Increasing this setting may cause broad rolling bumps to be ignored or merge multiple bumps into a single peak. Decreasing this setting will broaden the peaks' width and potentially pick up broad bumps as peaks. See "Peak Identification" on page 250 for more information.
Inflection Threshold	Represents the value that the slope minimum must be below to trigger a splitting of the peak. As the threshold is increased, more peak splitting occurs. See "Inflection Threshold Example" on page 244 for more information.
Start Time	Specifies the time after the start of a run when the first peak will be detected (any peaks appearing before this time are ignored). The Gel and Graph views will not plot data earlier than this time.
End Time	Specifies the time after which peak detection stops. The Gel and Graph views will not plot data beyond this time.
Filter Width	Specifies the width, in minutes, of the low pass filter to be convolved with the data. The width of this filter should be about 6 samples wide. If this setting is too large, peaks will develop spurious side lodes (ringing) due to over-filtering.
Baseline Plateau	Specifies a baseline selection parameter for peak finding. The signal is at baseline whenever the slope of the data is less than the slope threshold setting (positive or negative) for longer than the Baseline Plateau. This rejects brief, low slope areas such as in between non-baseline-resolved peaks.
Polynomial Order	A filter algorithm is used to filter the data, increasing the signal-to- noise ratio. The data is convolved with a polynomial of this order to produce filter data and a filter slope and decrease the background or baseline noise and/or spikes in the signal. This value is read only.

**Table 1. Chip Peak Find Settings** 

Chip Settings	Function
Baseline	None - No correction.
Algorithm	<ul> <li>Zero Baseline - Offsets all graphs to zero baseline but does not affect analysis.</li> </ul>
	Baseline Subtraction - A dynamic subtraction of the baseline that corrects for drifting Baseline.
	Spline - This algorithm creates a smooth line fit to the baseline data points and subtracts this smooth fit from the data. The threshold specifies how much the baseline fit tries to follow changes in the data. Lowering the Threshold below the default value of 20 allows the baseline fit to ignore regions that are slow changes of real signal peaks and not baseline drift.
	Rolling Ball - This algorithm simulates rolling a ball under the valleys of the signal. The ball size determines how closely the baseline follows the signal. A larger ball size creates a smoother baseline. Time Diameter specifies the size of the ball in the X direction. Signal Diameter specifies the size of the ball in the Y direction.
High Size Filtering	If selected, a second, larger filter is applied to the data after the specified time. This is useful for assays where the peaks are narrow at the start of the assay and become broad and noisy for larger sizes of DNA. If not selected, the same size filter is used for all data.
	Filter Width (min) - The width of the second filter to be applied after the specified transition time. Filter Width must be greater than the Sample Channel Filter width and less than or equal to 3.0 minutes.
	Transition Time (min) - The time at which to transition to the larger filter size. Transition time must be greater than the Baseline Time on the Analysis tab and less than the Channel End time.

**Table 2. Channel Peak Find Settings** 

Channel Settings	Function
Channel	Displays the channel being edited. Select any channel or ladder on the chip.
Ladder	Read only. Displays the ladder used for aligning this channel.
Minimum Peak Height	Specifies an override to the Peak Find Settings for Minimum Peak Height for the entire chip. Specify a valid numeric value to override, or clear the field to reset to the Global setting.

**Table 2. Channel Peak Find Settings** 

Channel Settings	Function
Minimum Peak Width	Specifies an override to the Peak Find Setting for Minimum Peak Width for the entire chip. Specify a valid numeric value to override, or clear the field to reset to the Global setting.
Slope Threshold	Specifies an override to the Peak Find Setting for Slope threshold for the entire chip. Specify a valid numeric value to override, or clear the field to reset to the Global setting.
Use Chip Value button	Sets Min Peak Height, Min Peak Width, and Slope Threshold text boxes to <uses chip="" value=""> settings.</uses>
Apply Channel/ Ladder button	Apply channel-specific peak find settings only to the channel or ladder showing in the Channel field.
Apply Chip button	Apply channel-specific peak find settings to all channels on the same chip.

### **Expected Fragments Tab**

Use the Expected Fragments tab on the Method Window to enter Expected Fragments for DNA assays. (See "Using Expected Fragments" on page 48 for more information.) After the data is analyzed, any peaks matching the expected fragments are shown in the Peak Table View, Channel Table View, Gel View, and Graph View (if Type is selected as an Annotation in the Graph View Properties).

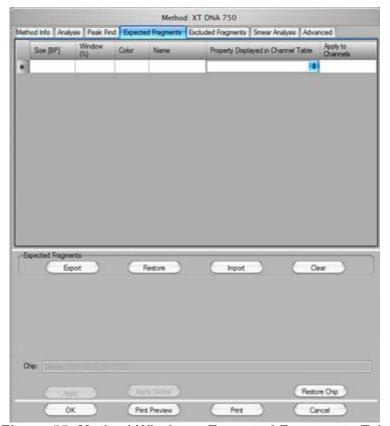


Figure 55. Method Window - Expected Fragments Tab

The Expected Fragments tab contains the following options and buttons:

**Expected Fragments Table** - Lists the expected fragments for the method.

- Size Specifies the expected size of the fragment in BP.
- Window (%) Specifies the tolerance window as a percent of the expected size for the fragment to allow for small variations in expected fragment size.
- Color Displays the color to use to mark the fragment in the Graph View or the Gel View.

### **Expected Fragments Tab (Continued)**

- Name Specifies a name to display in the Type description for the fragment.
- Property Displayed in Channel Table Specifies the content of a column added to the channel table for each expected fragment.
- Apply to Channels Specifies the channels that the expected fragment is applied to. <All> specifies that the expected fragment applies to all channels. Clicking on the column opens the Select Channels window to choose the specific Channels to apply the expected fragment to.

**Export button** - Opens the Export Expected Fragments window to create an Expected Fragments File (.gep) from the current settings in the tab. Import the .gep file into another method to use the same expected fragments in another method.

**Restore button** - Restores the settings to the last saved settings for expected peaks.

**Import button** - Opens the Import Expected Fragments Table window to select an Expected Fragments File (.gep) to import. The .gep file is created by exporting expected fragments from another method.

Clear button - Deletes all Expected Fragments from the table.

### **Excluded Fragments Tab**

Use the Excluded Fragments tab on the Method Window to enter Excluded Fragments for DNA assays. After the data is analyzed, any peaks matching the excluded fragments are excluded from the analysis.

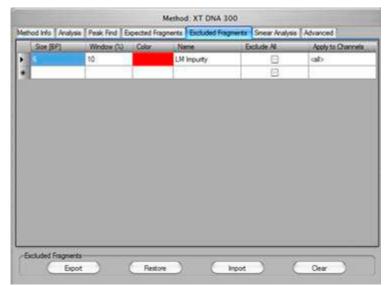


Figure 56. Method Window - Excluded Peaks Tab

The Excluded Fragments tab contains the following options and buttons:

**Excluded Fragments Table** - Lists the excluded fragments for the method.

- Size Specifies the size of the excluded fragments in BP.
- Window (%) Specifies the tolerance window as a percent of the size of the fragment to allow for small variations in fragment size.
- Color Displays the color to use to mark the fragment in the Graph View or the Gel View.
- Name Specifies a name to display in the Type description for the fragment.
- **Exclude All** If selected, all fragments in the specified range are excluded from analysis.
- Apply to Channels- Specifies the channels that the excluded fragment is applied to. <All> specifies that the excluded fragment applies to all channels. Clicking on the column opens the Select Channels window to choose the specific channels to apply the excluded fragment to.

## **Excluded Fragments Tab (Continued)**

**Export button** - Opens the Export Excluded Fragments window to create an Expected Fragments File (.gep) from the current settings in the tab. Import the .gep file into another method to use the same excluded fragments in another method.

**Restore button** - Restores the settings to the last saved settings for excluded fragments.

Import button - Opens the Import Excluded Peaks window to select an Expected Fragments File (.gep) to import. The .gep file is created by exporting excluded fragments from another method.

Clear button - Deletes all Excluded Fragments from the table.

### **Smear Analysis Tab**

Use the Smear Analysis tab on the Method Window to view the portion of the sample that was routed to the collection well on the chip as a Smear. Use the Smear Analysis tab on the Method Editor window to define smears before the method runs. (Defining a smear does not cause the region to be extracted, it is only marked on the display.) After the run, the area matching the smear is shown in the Channel Table View, Gel View (if Show EPs and Smears is selected in the Gel View Properties), and Graph View (if Show Smears is selected in the Graph View Properties). To view the smears for the open chip data file, select Analysis → Analysis Settings on the main menu.

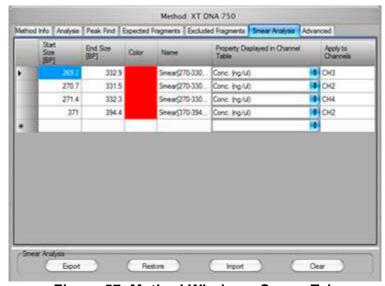


Figure 57. Method Window - Smear Tab

The Smear Analysis tab contains the following options and buttons:

**Smear Table** - Lists the smears for the chip.

- **Start Size** Specifies the starting size of the area to be included in the smear.
- **End Size** Specifies the ending size of the area to be included in the smear.
- Color Displays the color to use to mark the smear in the Graph View or the Gel View.
- Name Specifies a name to display in the Channel Table View.
   The smear name corresponds to the smear range and channel number.
- **Property Displayed in Channel Table** Specifies the content of a column added to the Channel Table for each smear.

## **Smear Analysis Tab (Continued)**

Apply to Channels - In the Method window, specifies the channel in which the extraction took place. In the Method Editor window, specifies the channels that the smear is applied to.
 <All> specifies that the smear applies to all channels. Clicking on the column opens the Select Channels window to choose the specific channels to apply the smear to.

**Export button** - Opens the Export Smear Analysis Table window to create a Smear Analysis Export File (.sma) from the current settings in the tab. Import the .sma file into another assay to use the same smear in another assay.

**Restore button** - Restores the settings to the last saved settings for smears.

**Import button** - Opens the Import Smear Analysis Table window to select an Smear Analysis Import File (.sma) to import. The .sma file is created by exporting smears from another assay.

Clear button - Deletes all smears from the table.

#### **Advanced Tab**

Use the Advanced tab on the Method Window to view the quantification marker settings or change the Peak Size Calibration point.

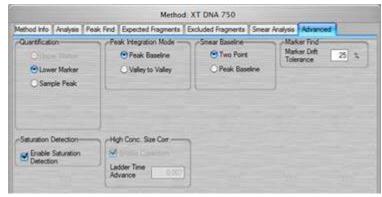


Figure 58. Method Window - Advanced Tab

#### Quantification

Determines whether the lower marker or a sample peak is used for quantitation. Selecting Sample Peak uses the peak size and concentration of the User Standard instead of the default ladder settings.

#### **Peak Integration Mode**

Specifies the mode for determining the baseline.

- Peak Baseline A global peak baseline is used as the baseline for all peaks. This baseline is determined by stitching together regions of low variance across the data signal.
- Valley to Valley Each peak is assigned a baseline by drawing a line that joins the start and end of the peak at the data signal values.

#### **Smear Baseline Mode**

Specifies the Smear Baseline option to use for all smears. See "Smear Baseline" on page 255 for more details on each option. This option only displays if smears are defined in the Smear Analysis Tab.

- **Two Point** If selected, a Two Point baseline from the start of the trace to the end of the trace is used as the baseline.
- Peak Baseline If selected, the local peak baseline is used as the start and end of the smear baseline.

## **Advanced Tab (Continued)**

#### **Marker Find**

Marker Drift Tolerance - Specifies the time within which to find the marker peak, specified as a percent of the marker migration time. Range is 1 to 100%. Peaks within the range are weighted based on the difference from the ladder time. The weight of peaks farther from the marker migration time decreases faster as the marker drift tolerance is made smaller.

**Enable Saturation Detection** - If selected (default), the software detects if the optics are saturated with a signal that is too high and approximates the signal with a flat straight line connecting the start of the saturated region to the end the saturated region.

#### **High Concentration Size Correction**

A correction factor that can be applied if the sample concentration is higher than the ladder concentration. This correction adjusts for higher mobility of sample fragments when the sample concentration is higher than the ladder concentration. If selected, the correction value is used when computing the collection start and end times.

## **Modify Run Settings Window**

Use the Modify Run Settings window to change settings for the method while the run is paused. To open the Run Settings, click the Pause/Stop button on the instrument icon while a method is running (see "Run Status and Chip Info" on page 109).

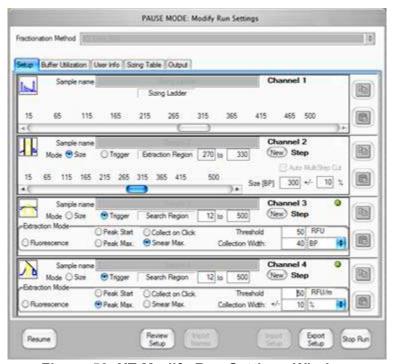


Figure 59. XT Modify Run Settings Window

Only the settings on the Setup Tab and User Info Tab can be edited while the run is paused. Some settings cannot be changed while the run is paused:

- The Operation for a channel cannot be changed.
- Multistep Cut settings cannot be changed.
- Steps can be deleted if they have not been executed yet.
- Editing a completed step has no effect and is ignored.
- Editing the running step is blocked with a message indicating that the change was ignored.
- Inserting a new Collect on Click step before a running Collect on Click step does not change running step, but the old step becomes the next step and executes after the running step.
- Deleting the last running step is ignored.

The options available on each tab are the same options available in the Start Fractionation Window. See page 186 for details.

## **New Collection Window**

The New Collection window is used to create a new collection using either a Template, a Blank Collection (default), or the Current Collection. This option is only available in the LabChip XT software.

To open the New Collection window, select Collection → New Collection on the LabChip XT/XTe Main Window.



Figure 60. New Collection Window

The following options are available:

**Template** - Opens a blank collection and then applies the selected collection template.

**Blank Collection** - Opens a blank collection that does not contain any data. The new collection will use the same settings as the last saved collection of the same assay type.

The current collection settings are automatically saved in a blank collection template in the current user's "Documents and Settings" folder on the local computer. These preferences are applied when a blank collection is created.

**Current Collection** - Opens a blank collection and applies the settings from the currently open collection as a template.

Assay Type - The LabChip XT/XTe only supports DNA assays.

Name - Specifies the name of the new collection.

# **Perform Signature Window**

Use the Perform Signature Window to add an electronic signature to a data file. Signatures can be added as required by the company's standard operating procedures. (Data files cannot be signed while the assay is running.) If multiple data files are open in the workspace, only one data file can be signed at a time. (Only available if the 21 CFR Part 11 Security option is installed.)

To open the Perform Signature Window, select Security → Perform Signature on the LabChip XT/XTe Main Window.



Figure 61. Perform Signature Window

The Perform Signature Window contains the following options:

Data File Name	Displays the name of the data file being signed.
Username	Select the username of the user that is signing the data file.
Role	Displays the Access Level of the selected LabChip XT user.
Enter Comment	Details on why the signature is being performed and what actions have taken place. It is the signer's responsibility to ensure all details required by the company's procedures are included in this comment.
Approval State	Displays the approval state of the data file. Unreviewed data files cannot be locked.
Lock	Select the check box to prevent any future changes to the data file. Locked data files cannot be saved. To unlock the data file, a user with the correct permissions can choose <b>Security → Unlock Data File</b> .
User Password	The password for the user.
Sign button	Signs the data file and closes the window.
Cancel button	Closes the window without signing the data file.

### **Print Window**

Use the Print window to print information from the currently open workspace. If the workspace contains multiple collections, information from the active (selected) collection is printed. To open the Print window, select **File** → **Print** on the LabChip XT/XTe Main Window.

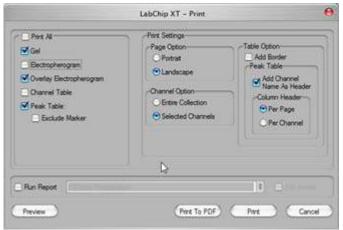


Figure 62. Print Window

The Print window provides the following options for printing:

- · Print All Selects all of the options.
- **Gel** Prints a graphic of the gel for either all channels in the collection or all selected channels.
- **Electropherogram** Prints a graph of either all channels in the collection or all selected channels.
- Overlay Electropherogram Prints a graphic of all electropherograms (either all selected or all in the collection) over-laid onto the same graph.
- Channel Table Prints the channel table for either all channels in the collection or all selected channels. The columns selected for view in the Channel Table are printed. Changing the columns selected to view in the Channel Table View changes the columns that are printed.
- Peak Table Prints the peak table for all channels in the collection or all selected channels. The columns selected for view in the peak table are printed. Changing the columns selected to view in the Peak Table View changes the columns that are printed.
  - Exclude Marker If selected, markers are not printed.

## **Print Window (Continued)**

Page Option - Select the page orientation, either Portrait or Landscape.

Channel Option - Select the channels to be included in the printout, either Entire Collection or Selected Channels.

Add Border Option - If selected, the Channel Table and Peak Table will print with a border between each column and a border below the column header.

Add Channel Name as Header - If selected, a channel header, containing the chip name, channel name, and sample name is printed before each set of peaks in a channel. (This option is only available if Peak Table is selected.)

**Column Header** - Specifies where to print the column headers, which identify each column in the Peak Table. (This option is only available if Peak Table is selected and Channel Table and Electropherogram are not selected.)

- **Per Page** the column header is printed only at the top of each
- **Per Channel** the column header is printed at the top of each page and at the start of each new channel.

**Run Report** - Generates a one page report of the selected data file. The report includes gel and graph views of the data, Method Info. and the contents of the Channel Table. This option is only available in the LabChip XT software.

Add Border- If selected, borders are printed for the tables in the Method Info and Channel Table sections.

**Preview button** - Displays a preview of the selected options.

Print to PDF button - Prints the selected information from the active collection to a pdf file.

**Print button** - Prints the selected information from the active collection to the default Windows printer.

**Cancel button** - Closes the Print window without printing.

# **Print Validation Reports Window**

Use the Print Validation Reports Window to print the results after performing Installation Qualification (IQ) or Operational Qualification (OQ). OQ is performed in the System Diagnostics Window.

To open the Print Validation Reports Window, select Validation → Reports on the LabChip XT/XTe Main Window.

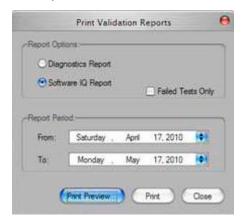


Figure 63. Print Validation Reports Window

The Print Validation Reports Window contains:

Option/Button	Function
Diagnostics Report	If selected, the results of Hardware OQ tests are printed.
Software IQ Report	If selected, the results of Software IQ tests are printed.
Failed Tests Only	If selected, only tests that have failed are printed. If not selected, both passed and failed tests are printed.
Report Period	Specifies the dates when the tests were run. Tests performed between the From and To dates (inclusive) are printed.
Print Preview button	Displays a preview of the report and enables you to print or export the results.
Print button	Opens the Print window to print the report.
Close button	Closes the window.

## **Rename Collection Window**

Use the Rename Collection window in the LabChip XT software to rename the currently selected collection. The collection name displays on the Collection tab at the top of the LabChip XT/XTe Main Window. To open the Rename Collection window, select Collection → Rename Collection on the LabChip XT/XTe Main Window.



Figure 64. Rename Collection Window

Name - Type the desired name for the selected collection.

## **Run File Editor Window**

Use the Run File Editor window to create run files (\*.xml) to import run settings into the Start Fractionation Window. The run file contains all of the run settings that would be specified in the Start Fractionation Window. Using a run file enables you to quickly specify the settings for the run after the chip has been prepared. To open the Run File Editor window, choose Tools → Run File Editor on the LabChip XT/XTe Main Window.

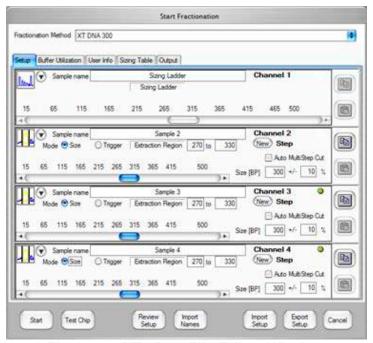


Figure 65. XTe Run File Editor Window

The tabs on the Run File Editor contain the same options as the tabs on the Start Fractionation window. See Start Fractionation Window for definitions of specific options or settings. The following buttons are located at the bottom of the Run File Editor window:

Button	Description
Save	Saves the selected settings in a run file with the specified name (*.xml).
Review Setup	Opens the Fractionation Setup Review window to view the settings for the current run.
Import Names	Opens the Import Sample Names window to select the desired Sample Name File (.csv). (LabChip XT only.)
Import Setup	Imports the settings from an existing run file (*.xml) into the Run File Editor window.
Close	Closes the Run File Editor window without saving the settings.

## **Run Info Window**

Use the Run Info window to view information about the run options for the selected chip data file.

To open the Run Info window, select **View** → **Run Info** on the LabChip XT/XTe Main Window, or right-click on the name of the data file above the chip diagram and select **Run Info**.

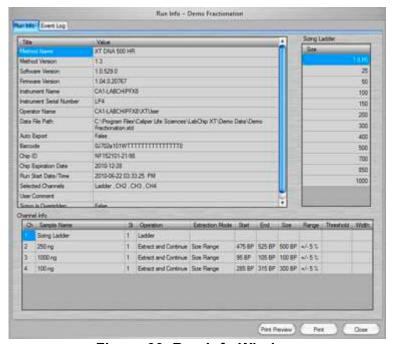


Figure 66. Run Info Window

The information in this window is view-only and cannot be changed.

The Run Info Tab displays method and run information.

The **Event Log tab** displays the events that occurred during the run.

The Run Info window contains the following buttons:

Print Preview	Opens the Print Preview window to view the run information before printing.
Print	Opens the Print window to print the run information.
Close	Closes the Run Info window.

### **Run Info Tab**

The Run Info tab on the Run Info Window displays information about the method and the run.

The Channel Info table at the bottom of the window contains the following information:

Column	Description
Ch	The number of the channel.
Sample Name	The name of the channel/sample.
St	The step number of the channel. Each step creates one row in the table.
Operation	The Operation mode selected for the step.
Extraction Mode	The Extraction mode selected for the step.
Start	The start of the Size Range or Search Region set in the method.
End	The end of the Size Range or Search Region set in the method.
Size	The actual center size of the extracted or excluded region. Displays 0 until the step is complete.
Range	The actual range of the extracted or excluded region. Displays 0 until the step is complete.
Threshold	The Threshold set in the method (for Fluorescence, Peak Start, Peak Max, and Smear Max).
Width	The collection width set in the method (for Fluorescence, Peak Start, Peak Max, Collect on Click, and Smear Max).

# Save Workspace File As Window

The Save Workspace File As window saves the currently open workspace with the specified name in the specified location. This window is only available in the LabChip XT software. The LabChip XTe software does not support saving workspace files.

To open this window, choose **File** → **Save Workspace As**. This window also opens the first time you save a new workspace.

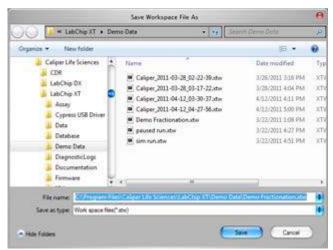


Figure 67. Save Workspace As Window

Tip: You may want to save the workspace file in the same location as the chip data files to prevent missing chip data files when moving workspace files.

## Select a Data File Window

When you choose **Import Data File** from the File Menu, the Select a Data File window opens as shown in Figure 68. (If the 21 CFR Part 11 option is installed, the CDR Manager Window opens.) Data files generated by the LabChip XT software have an .xtd file extension. Data files generated by the LabChip XTe software have an .xte file extension. The LabChip XT software can only open XT data files, and LabChip XTe software can only open XTe data files.

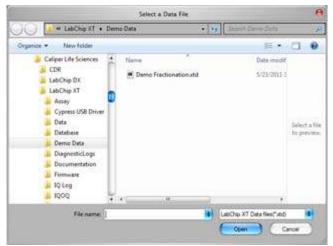


Figure 68. Select A Data File Window

Select a data file name in the list box and click the **Open** button or double-click a file name to open the data file.

To select multiple files, press and hold CTRL then click each file name. To select a continuous block of files, click the first file, press and hold SHIFT, and then click the last file. To select all files, press CTRL+A.

## **Software Installation Qualification Window**

Use the Software Installation Qualification Window to perform the IQ test. The IQ test verifies proper installation of the LabChip XT/XTe software and verifies no unauthorized changes have been made to the software. To open the Installation Qualification Window, select Validation → Software IQ on the LabChip XT/XTe Main Window.



Figure 69. Software Installation Qualification Window

The Software Installation Qualification Window contains the following information:

Application Information	Verifies that the LabChip XT/XTe Registry Entries exist. If all expected registry entries are found, displays Passed. If any problems are found, displays Failed.
Directory Structure	Verifies that all folders exist. If all expected folders exist, displays Passed. If any folders are not found, displays Failed.
Files	Verifies that all files that were installed by the LabChip XT/XTe software still exist. If all files exist, displays Passed. If any files are not found, displays Failed.
Summary	Displays Passed if all tests passed. Displays Failed if any of the IQ tests failed.
Progress	Displays a progress bar while the IQ test is running.
Previous Result button	Displays the results of the last IQ that was completed. (Only available before another IQ test is run.)
Save As button	Saves the results of the IQ in an .xml file.
Start IQ button	Begins running the IQ.
Close button	Closes the Installation Qualification Window.

## **Start Fractionation Window**

The Start Fractionation window specifies the method to run, the collection settings for each channel, the user name, auto export settings, and import options for sample names and expected peaks.

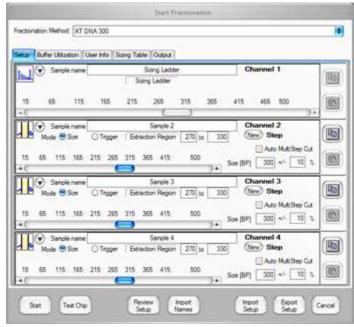


Figure 70. XTe Start Fractionation Window

The Start Fractionation window opens when you click the **Run** button on the LabChip XT instrument graphic. (If a workspace is open in the LabChip XT software, you are prompted to save the workspace before the Start Fractionation window opens.) To begin the run, select the desired settings on each tab and then click the **Start** button.

The Start Fractionation Window contains the following tabs:

- Setup Tab
- Buffer Utilization Tab
- User Info Tab
- Sizing Table Tab
- Output Tab

# **Start Fractionation Window (Continued)**

The following buttons are located at the bottom of the Start Fractionation window:

Button	Description
Start	Starts the run using the options specified in the tabs on the Start Fractionation window.
Test Chip	Performs the same chip test that automatically runs at the beginning of every run. The chip must be properly filled with buffer, but do not load any sample DNA prior to running the test. Only run the chip test separately if directed by Caliper Technical Support.
Review Setup	Opens the Fractionation Setup Review window to view the settings for the current run.
Import Names	Opens the Import Sample Names window to select the desired Sample Name File (.csv). (LabChip XT only.)
Import Setup	Imports the settings from a run file (*.xml) into the Start Fractionation window. (Use the Run File Editor Window or export the desired settings to create a run file.)
Export Setup	Exports the settings from the Start Fractionation window into a Run file (*.xml).
Cancel	Closes the Start Fractionation window without saving any changes and without starting the run.

### Setup Tab

The Setup Tab in the Start Fractionation Window specifies the operation, the extraction mode, the extraction or search region, the threshold, and/or the collection width for each channel. Some Operations allow additional extraction steps to be added to the same channel to support extracting multiple ranges of material from the same channel.

For Extraction Modes that are centered on the trigger point (% for any mode except Size Range, or Manual Width for Peak Max and Smear Max), the distance on the chip between the detection point and the switch point provides time to divert the sample to the collection well, as long as the collection width is not too large.

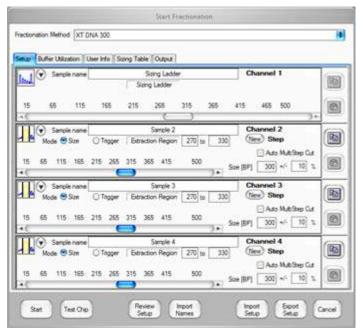


Figure 71. Setup Tab

The Setup tab contains the following options and settings for each of the four channels on the chip:

**Sample name -** Displays the name of the sample in the channel. To change the name, type the desired name in the text box.

**Channel Number -** Displays the number of the channel on the chip.

**New Step button** - Adds another step to the channel to create a multistep extraction. Use the up and down arrow buttons to display each step. If you want the run to pause after an extraction to enable you to remove the extracted sample from the collection well, select the **eXtract and Pause** operation. Click the small gray X button above the step number to delete that step from the channel.

**Step** - Displays the selected step in a multi-step extraction. Click the up or down arrows to display the settings for the desired step. Use the New Step button to add steps.

**Buffer Utilization** - Displays an icon that represents the buffer use for the currently selected channel options.

**Operation -** Specifies the action for each channel as described below. Click on the channel icon to choose the desired operation for each channel.

- Disabled The channel is not used in the run. Any channel that has already been used is automatically set to Disabled and cannot be reused.
- Ladder The channel contains a sizing ladder that is used to calculate the sizes in the samples in the remaining three channels during the run. Only one channel in the chip can be designated as a ladder channel.
- **eXtract and Stop** The sample in the channel runs until the extraction is complete and then the voltage to the channel turns off. After the extraction, the run ends if no other channels are busy. If channels are busy, the run ends as soon as all channels are complete. The extracted material is located in the Collection well. (Only the Flush Sample step can follow this step.)
- eXtract and Continue The sample in the channel runs until
  the end of the chip range. The sample specified by the
  Extraction Mode is collected in the Collection well. In a multistep
  extraction, the next step begins after the extracted region is
  removed from the collection well (the instrument lid must be
  opened).
- eXcLuDe Region The sample in the channel is collected in the
  Waste well except for the sample specified by the Extraction
  Mode, which moves into the Collection well. The sample minus
  the excluded region is located in the Waste well. The sample in
  the channel runs until the end of the chip range. In a multistep
  extraction, the next step begins immediately after the excluded
  region is complete. Only available in the LabChip XT software.

- **Separation** The entire sample in the channel moves into the Waste well. The channel runs until the end of the chip range. Only available in the LabChip XT software.
- eXtract and Pause The sample in the channel runs until the
  extraction is complete. When the extraction is complete, the run
  immediately pauses so the desired extracted sample can be
  removed from the Collection well. The method can also be
  edited while the run is paused. In a multistep extraction, the next
  step begins when the run is resumed.
- Skip Extraction Skips over a known region in the sample without extracting any sample to the Collection well.
   Automatically moves to the next step in a multistep extraction immediately after the skipped region is complete. Only available in the LabChip XT software.
- Flush Sample The remaining sample in the channel moves into the waste well. If preceded by an extraction step, execution of this step only begins after the run has been paused and the instrument lid has been opened to remove the extracted material from the Collection well. Using a Collect and Stop step ensures that the collected material is not drawn out of the collection well while other channels are completing their extractions. The Flush Sample step after a Collect and Stop step moves the remaining sample to the waste well. Flush Sample must be the last step in the channel and can be preceded by any of the Extraction operations except the Ladder, Separation, or Exclude Region steps.

**Extraction Mode -** Specifies how the range of material to be collected is selected. The range of material extracted depends on both the Extraction Mode and the Collection Width.

- Size: The size range specified in the Extraction Region text boxes is diverted to the Collection well. Size range can be specified as a Size +/- a percent of the size, or as a specific start and end size in the Extraction Region text boxes.
- **Trigger** The software searches for the specified trigger point within the specified Search Region.

Auto MultiStep Cut - If selected, an extraction range larger than the assay Maximum Extraction Width can be entered for an extraction. The extraction is automatically split into multiple eXtract and Pause steps. To view the MultiStep Cut steps, click the Review Setup button on the bottom of the Start Fractionation window. Only available if Extraction Mode is Size and Operation is eXtract and Stop, eXtract and Continue, or eXtract and Pause.

#### **Trigger Extraction Modes:**

- Peak Start: Specifies a slope Threshold, in RFU/minute, to use
  to detect the start of a peak within the specified Search Region.
  The trigger point for collection is the point where the slope is
  greater than the specified threshold. Collection ends when the
  sample specified by the Collection Width has been collected.
- Collect on Click: Collects the region displayed in green on the Graph View when you click the Start Now button. To start the extraction, click on the word CLICK next to the channel number in the LabChip XT/XTe Main Window. The Fractionation Pending Window opens. Click the Start Now button when the desired region is displayed in green. (Clicking the Cancel button closes the window and allows you to choose a region later in the run.) The collection region displays in red as the collection is occurring. Note that for some width settings, the target region may extend beyond the last visible data point on the graph. In this case, the highlighted region ends at the last visible data point and the dialog box indicates the time when the target region ends. When manual mode is selected in the width setting, click on the word STOP in the Run Setup section to end the collection or exclusion.
- Fluorescence: Specifies an RFU Threshold which must be exceeded within the specified Search Region. The trigger point for collection is the point where the RFU value exceeds the specified threshold. Collection ends when the sample specified by the Collection Width has been collected. This option is only available in the LabChip XT software.
- Peak Max: Specifies that the trigger point for the extraction is the first point found within the specified Search Region where the signal slope is at or above the specified threshold (RFU/min) and the signal has switched to a negative slope that is above the specified threshold. If no local maximum is found by the end of the specified search region and the signal is increasing, the extraction trigger point is at the end of the search region. If the signal has a large negative slope at the beginning of the search region, the extraction will not trigger until after the slope has again turned positive and exceeded the slope threshold. When the software detects the peak maximum in the search region, the collection start size is calculated based on the collection width. The actual collection range achieved is reported in the Channel Table. This option is only available in the LabChip XT software.

• Smear Max: Specifies that the trigger point for the extraction is the first point found in the specified Search Region where the signal is at or above the specified Threshold (RFU) and the signal decreases after averaging over three consecutive data points. Collection will trigger at the end of the search region if the signal threshold value has been exceeded but the signal has yet to start decreasing. Collection ends when the sample specified by the Collection Width has been collected. This option is only available in the LabChip XT software.

**Collection Width -** Specifies the range that will be collected based on the trigger point specified by the Extraction Mode.

- % Specifies the Collection Width as a percent of the size at which the extraction is triggered. The extracted range is centered at the trigger point, and the collection width is from (size %) to (size + %). Half of the collection range occurs before the trigger point, so depending upon the migration time of the fragment, it is possible that the specified start of the collection range may have already passed the point at which the sample is diverted into the collection well. If this occurs, the extraction is started immediately and the extraction range shifts forward to meet the specified collection width.
- BP Specifies the number of base pairs (BP) to collect. For Fluorescence, Peak Start, and Collect on Click, the collection starts at the specified trigger point in the Extraction Mode and collects the specified number of base pairs from the trigger point forward. For Peak Max and Smear Max, the collection range collects the specified number of base pairs centered on the trigger point.
- Manual For Peak Start, Collect on Click, and Fluorescence, the collection begins at the trigger point and ends when the user clicks STOP in the Run Setup. For Peak Max and Smear Max, collection begins at the specified percent before the trigger point (size %) and immediately ends when the user clicks STOP in the Run Setup. (The collection stops at the end of the red smear region on the Graph View, not where the graph ends.) If the user has not stopped the extraction when the end of the search region has been reached, the extraction will end automatically there.

The size collected is displayed in the Run Setup area, Channel Table View, and the red smear region on the Graph View.

**Slider -** If the Extraction Mode is Size, the **blue marker** indicates the size of DNA to collect in the collection well of the chip. Move the slider left or right to select the desired size to collect. The setting in the Size text box changes to reflect the position of the slider.

**Copy button -** Copies the current settings of a channel so the settings can be pasted into another channel.

Paste button - Pastes the last copied channel settings to a channel.

#### **Buffer Utilization Tab**

Use the Buffer Utilization tab on the Start Fractionation Window to view estimates of the buffer use for each channel during the run. The buffer use is estimated based on the current selections in the Start Fractionation window. The run can be started even if the run is over the buffer limit, but be aware that if the buffer capacity runs out, the current will drop and the DNA will not continue to migrate into the collection well.



Figure 72. Start Fractionation Window - Buffer Utilization Tab

The Buffer Utilization tab displays the following information:

**Channel -** Displays channel numbers 1 through 4.

**Estimated Extraction Time -** Displays an estimated range of time required to perform the extraction in each channel.

**Status -** Displays an icon indicating whether the buffer is estimated to be exhausted during the run:

Icon	Туре	Description
Ø	OK	Buffer is estimated to be sufficient for the channel.
1	Warning	Buffer may be exhausted if the extraction occurs at the end of the run.
3	Error	Extraction may occur after the buffer has been exhausted.
•	Unknown	An estimate cannot be made whether the buffer is sufficient. Usually occurs with a Collect on Click extraction or a manual endpoint.

#### **User Info Tab**

The User Info Tab in the Start Fractionation Window specifies the operator name and any comments added to the run.

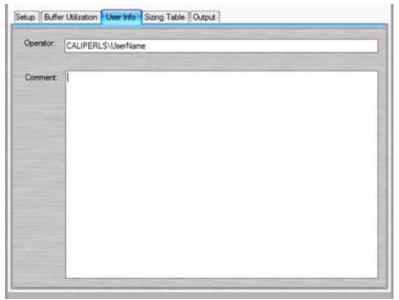


Figure 73. User Info Tab

The User Info tab contains the following settings:

Operator - Type the name of the operator performing the run. If the 21 CFR Security option is installed, the user name of the logged in user is automatically entered and cannot be edited.

**Comment -** Type comments that are saved in the data file for the run.

### Sizing Table Tab

The Sizing Table Tab in the Start Fractionation Window, specifies the ladder to use when aligning all the sample channels on the chip. This tab is not available in the LabChip XTe software.

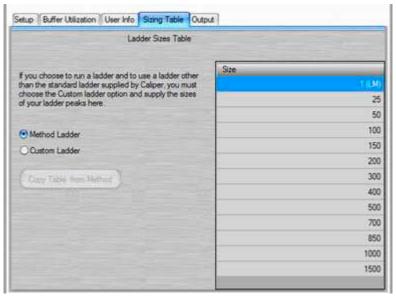


Figure 74. Sizing Table Tab

The Sizing Table Tab contains the following settings:

**Method Ladder -** If selected, the default Caliper-supplied ladder is used to align the samples during the run.

Custom Ladder - If selected, the custom ladder sizes in the Size Table are used to align the samples with a custom ladder during the run instead of the ladder supplied by Caliper. This option can be used to improve sizing in the fragment size range of interest. Select the Custom Ladder option and specify the fragment sizes for the custom ladder in the Size Table. Since the custom ladder fragments will also be used to establish the relationship between area and concentration, each fragment should be supplied at the same concentration, nominally 2 ng/µl, to match the Caliper ladder. If an alternate concentration is used, enter the concentration in the Ladder Concentration parameter in the Analysis properties of the method. Using custom ladder fragments of unequal concentration is not currently supported. A ladder with unequal concentrations can be used but the displayed sample concentrations will be inaccurate.

**Copy Table from Method -** Imports the ladder from the selected method in the currently open workspace.

### **Output Tab**

The Output tab on the Start Fractionation Window specifies the location, name, and export settings for chip data files created during the run. LabChip XT software data files are \*.xtd. LabChip XTe data files are \*.xte. LabChip XTe software does not support exporting analyzed data.

The data file name can include a specific prefix, the computer name, a project name, the Chip ID (LabChip XT only), the date, and the time. For example, including the prefix LabChip\_XT, the date, and the time would create file names such as LabChip\_XT\_2011-04-24\_10-23-48.

If you choose not to use the time of the run as part of the data file name, the LabChip XT and XTe software automatically appends \_1, \_2, etc., for each subsequent run on the same day.

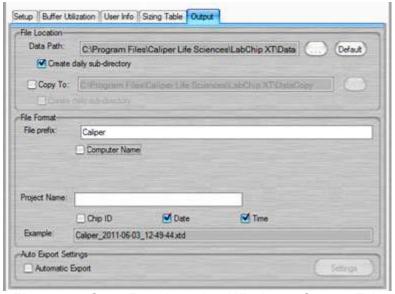


Figure 75. Start Fractionation Window - Output Tab

**Data Path** - Specifies the location where the data files will be saved. Click the **Default** button to reset the text box to the default directory.

**21 CFR Part 11 option not installed:** The default location is C:\Program Files\Caliper Life Sciences\LabChip XT\Data\. Click the Browse button to choose a different location.

**21 CFR Part 11 option installed:** The default location is C:\Program Files\Caliper Life Sciences\CDR\. Click the Browse button to choose a folder in the CDR.

### **Output Tab (Continued)**

#### NOTE



Data files should be saved to a local folder on the computer's hard drive. Saving data files to a network drive may cause loss of data if the network connection is slow or interrupted.

Create Daily Sub-Directory check box - If selected, a new directory is created each day in the specified Data Path, and all of the data files from that day are saved in the directory. The directory name is the current date, and the format is YYYY-MM-DD, where YYYY is the year, MM is the month, and DD is the day.

**Copy To -** If selected, the data file is copied to the specified folder after the run is complete.

**File Prefix -** Specifies the text for the first characters of the data file name.

**Computer Name -** If selected, adds the name of the LabChip XT computer to the data file names.

**Project Name -** The text is added to the data file names.

**Chip ID** - If selected, adds the Chip ID to the data file names. The Chip ID is read from the barcode on the chip. (*LabChip XT only*.)

**Date check box -** If selected, the current date is included in the data file name. The date format is YYYY-MM-DD, where YYYY is the year, MM is the month, and DD is the day. The date is automatically added to the data file name when the 21 CFR Part 11 option is installed.

**Time check box -** If selected, the time that the run was started is included in the data file name. The time format is HH-MM-SS, where HH is the hour (0 to 24), MM is the minutes, and SS is the seconds. The time is automatically added to the data file name when the 21 CFR Part 11 option is installed.

**File Name Example text box -** Read-Only text box that displays the selected format for the data file name.

**Automatic Export -** If selected, data is automatically exported at the end of each run. Select the type of data to export by clicking the **Settings** button and choosing the desired settings in the Export Window. For more information, see Exporting Data. (*This option is not available in the LabChip XTe software.*)

# **System Diagnostics Window**

Use the System Diagnostics window to run the diagnostics tests on the LabChip XT/XTe instrument. All tests should be run periodically to verify proper operation of the instrument. To verify proper operation of a particular function, you can select specific tests to run. To open the System Diagnostics window, select **Validation** → **Diagnostics**.

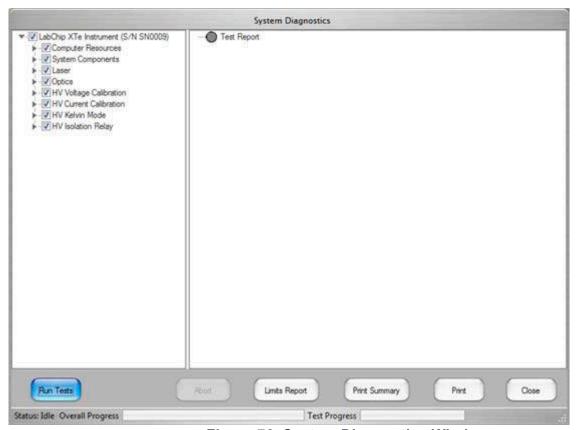


Figure 76. System Diagnostics Window

(The Barcode Reader test is not shown in Figure 76.)

The left side of the window displays the tests to run on the instrument. Expand each section to view all of the tests in each section. Tests selected with a check mark will run. To skip a test, click on the check box to clear the selection. Click on a section check box to select or clear all of the tests in the section. See "Description of Diagnostic Tests" on page 230 for a description of each test.

# **System Diagnostics Window (Continued)**

The right side of the window displays the results of the tests. The icon color indicates the status of each test:

- Blue The test is in progress.
- Yellow The test was skipped.
- Green The test passed.
- · Red The test failed or was aborted.

The bottom of the window displays a progress bar for the entire set of selected tests and a separate progress bar for the test that is currently running.

After all tests are complete, the **Test Report Generation** section at the bottom of the right side of the window displays the date and time when the test report was created, the name of the test report (\*.log), and the location where the test report was saved. Test report files can be opened with a text editor such as Windows Notepad.

Option/Button	Function
Run Tests button	Runs the selected tests. The Test Report Generation section displays.
Abort button	Stops running the diagnostic tests.
Limits Report button	Generates a report that contains the limits (upper and lower) for each selected test. Displays date/time, File name (*.lmt) and location of report file.
Print Summary button	Prints the summary of the report to the default Windows printer. This button is disabled after running the Limits Report.
Print button	Prints the details of the tests to the default Windows printer.
Close button	Closes the System Diagnostics window.

# **Unlock Application Window**

For LabChip XT software with the 21 CFR Part 11 Security option installed, use the Unlock Application Window to access the LabChip XT software after it automatically locks. This window displays on top of the LabChip XT software when the software is locked. The automatic lock option is set in the Set Policies tab on the User Administration Window. This window only displays if the 21 CFR Part 11 option is installed.

The 21 CFR Part 11 Security option is not available for the LabChip XTe software.

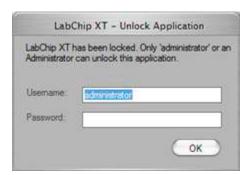


Figure 77. Unlock Application Window

The Unlock Application Window contains:

Option/Button	Function
Username	Type the user name of the current user or a LabChip XT administrator's user name.
Password	Type the password for the specified user name.
OK button	Verifies the username and password and opens the LabChip XT software if the username and password are correct.

## **Unlock Data File Window**

For LabChip XT software with the 21 CFR Part 11 Security option installed, use the Unlock Data File window to unlock a data file. The user name must have the appropriate permissions.

The 21 CFR Part 11 Security option is not available for the LabChip XTe software.



Figure 78. Unlock Application Window

The Unlock Data File Window contains:

Option/Button	Function
Username	Select the username of the user that is unlocking the data file.
Reason	Type the reason that the data file is being unlocked. Follow laboratory procedures for required information.
Password	Type the password for the selected user name.
Unlock button	Verifies the username and password and unlocks the data file. Locked data files cannot be saved.
Cancel button	Closes the Unlock Data File window without unlocking the data file.

## **User Administration Window**

For LabChip XT software with the 21 CFR Part 11 Security option installed, use the User Administration window to create new LabChip XT users, to edit existing users, to view user information, to activate or deactivate users, to set rights for each access level, and to set LabChip XT software policies.

The 21 CFR Part 11 Security option is not available for the LabChip XTe software.

To open the User Administration window, choose **Security** → **User** and **System Administration**.

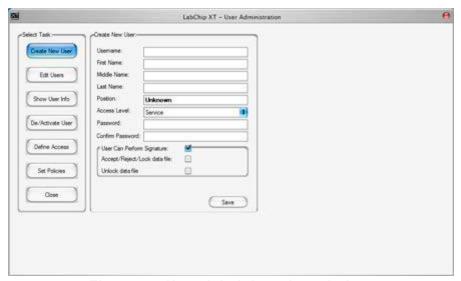


Figure 79. User Administration window

The User Administration window contains the following tabs:

- "Create New User" on page 204
- "Edit Users" on page 205
- "Show User Info" on page 206
- "De/Activate User" on page 207
- "Define Access" on page 208
- "Set Policies" on page 209

**Close button** - Closes the User Administration window without saving changes. Save the changes on each tab before closing the window.

#### **Create New User**

Use the Create New User tab on the User Administration Window to add a new user name to the LabChip XT software. This window creates the LabChip XT user account, it does not create a Windows user account to log into the computer.



Figure 80. User Administration Window - Create New User

The Create New User tab contains:

Option/Button	Function
Username	Type the user name that the new user will use to log into the LabChip XT software.
First Name	Type the first name of the user.
Middle Name	Type the middle name or initial of the user.
Last Name	Type the last name of the user.
Position	If desired, type the job title of the user.
Access Level	Choose the access level for the user. The access level controls the user's rights in the LabChip XT software (see "Define Access" on page 208 to view the rights for each access level). The following access levels are available:  Restricted User  Operator  Supervisor  Administrator  Service
Password	Type the desired password for the user. The password must meet the password policies selected on the Set Policies tab.
Confirm Password	Repeat the desired password for the user.

User Can Perform Signature	If selected, the user can sign data files using the Perform Signature Window.
Accept/Reject/Lock Data File	If selected, the user can accept, reject, and lock data files using the Perform Signature Window.
Unlock Data File	If selected, the user can unlock data files.

### **Edit Users**

Use the Edit Users tab on the User Administration Window to edit an existing LabChip XT user account.



Figure 81. User Administration Window - Edit Users

The Edit Users tab contains:

Option/Button	Function
Select User to Edit	Select the Username for the account to edit.
First Name	The first name of the user.
Middle Name	The middle name or initial of the user.
Last Name	The last name of the user.
Position	If desired, the job title of the user.
Access Level	The Access Level of the user.
User Can Perform Signature	If selected, the user can sign data files using the Perform Signature Window.
Accept/Reject/Lock Data File	If selected, the user can accept, reject, and lock data files using the Perform Signature Window.

Unlock Data File	If selected, the user can unlock data files.
Edit User Password	If selected, the user's password can be changed.
Password	Type the desired password for the user. The password must meet the password policies selected on the Set Policies tab.
Confirm Password	Repeat the desired password for the user.

#### **Show User Info**

Use the Show User Information tab on the User Administration Window to view the account information for an existing username.

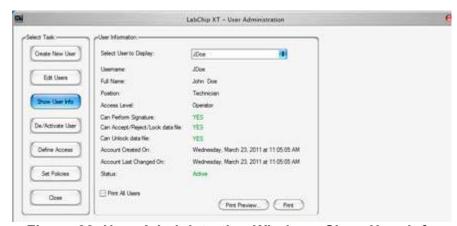


Figure 82. User Administration Window - Show User Info

The Show User Info tab contains:

Option/Button	Function
Username	Select the Username for the account to view.
Full Name	The first, middle, and last name of the user.
Position	The job title of the user.
Access Level	Displays the Access Level of the user.
Can Perform Signature	Displays Yes if the user has rights to perform signatures using the Perform Signature Window. Displays No if the user does not have rights.
Can Accept/Reject/Lock Data File	Displays Yes if the user has rights to accept, reject, and lock data files in the Perform Signature Window. Displays No if the user does not have rights.
Can Unlock Data File	Displays Yes if the user has rights to unlock data files. Displays No if the user does not have rights.
Account Created On	Displays the date and time when the account was created.

Account Last Changed On	Displays the date and time when the account was last changed.
Status	Displays Active if the user account is activated. Displays Deactivated if the account has been deactivated.
Print All Users check box	If selected, information for all user accounts will be printed.
Print Preview button	Displays a preview of the printed report. The report can be exported to a .rpt file from the Print Preview window.
Print button	Opens the Print window to print the report.

#### **De/Activate User**

Use the De/Activate User tab on the User Administration Window to Deactivate an active user or to Activate a deactivated user. Users cannot be deleted from the database. User names that will not be used should be deactivated to prevent unauthorized access to the LabChip XT software.

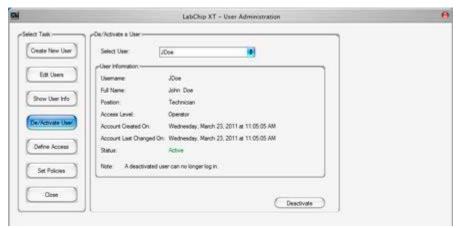


Figure 83. User Administration Window - De/Activate User

The De/Activate User Info tab contains:

Option/Button	Function
Select User	Select the username to be activated or deactivated.
User Info	Displays the information associated with the selected username.
Activate button	Click to activate a deactivated username.
Deactivate button	Click to deactivate an active username.

#### **Define Access**

Use the Define Access Tab on the User Administration Window to assign the desired rights to each access level. These rights control the actions each user is permitted to perform in the LabChip XT software. The Define Access tab is not available while an assay is running.

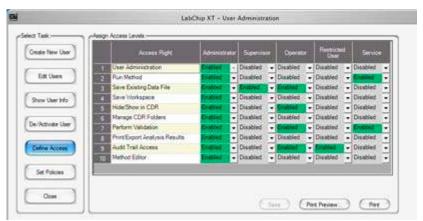


Figure 84. User Administration Window - Define Access

The Define Access tab displays a column for each access level (Administrator, Supervisor, Operator, Restricted User, and Service). Select Enabled for each right to be allowed for an access level, or select Disabled for each right not allowed for an access level.

The table below describes the function of each Access Right.

Access Right	Function
User Administration	If enabled, allows access to the User Administration Window to add and edit users, set access rights, and set policies.
Run Method	If enabled, allows users to run methods and save the new data files that are created by the run. Users are not permitted to save changes to existing data files.
Save Existing Data File	If enabled, allows users to save changes to existing data files.
Save Workspace	If enabled, allows users to save new and existing workspaces. If Save Existing Data Files is not selected, users can only save workspaces where the data files have not changed.
Hide/Show in CDR	If enabled, allows users to hide and show data files in the CDR Manager Window.

Manage CDR Folders	If enabled, allows users to create, rename, and delete folders in the CDR Manager window. This permission is not required for automatically creating daily subdirectories or to move data files in the CDR.
Perform Validation	If enabled, allows users to perform IQ (Installation Qualifications) and OQ (Operation Qualifications).
Print/Export Analysis Results	If enabled, allows users to print or export analysis results.
Audit Trail Access	If enabled, allows users to view the Audit Trail in the Audit Trail Window.
Method Editor	If enabled, allows users to edit and save methods.
Save button	Saves the current settings.
Print Preview button	Displays a preview for printing the access levels.
Print button	Prints a report of the access rights for each access level.

### **Set Policies**

Use the Set Policies tab on the User Administration Window to specify password, login, automatic lock, and signature policies for the LabChip XT software.



Figure 85. User Administration Window - Set Policies

The Set Policies tab contains:

Access Right	Function
Password Expires After	Specifies the number of days until each password expires. Range is 1 to 1000 days.
Number of Retired Passwords to Remember	User cannot reuse the specified number of old passwords.

Minimum Password Length	Specifies the minimum length of each password.
Maximum Login Attempts	Specifies the maximum number of times the user can attempt to log in before being locked out of the LabChip XT software. Range is from 3 to 20. This option can be disabled to allow unlimited retries without locking the user out.  This setting does not apply to Administrator level users.
Minutes to Automatic Lock	Specifies the number of minutes that the software is inactive until the LabChip XT software locks automatically. Range is from 5 to 4320 minutes (3 days). To disable this option, clear the check box.
Require Signature on File Update	If selected, an electronic signature is required to save modified data files. Signatures can be performed by any user who has the Perform Signature option selected in the Create New User or Edit Users tab.
Save button	Saves the settings on the Set Policies tab.
Print Preview button	Displays a preview for printing the policies.
Print button	Prints a report of the policies.

# LabChip XT/XTe Instrument **Description**

This section identifies and describes the hardware components of the LabChip XT and XTe instruments.

This section includes the following topics:

- "Front View" on page 212
- "Rear Connectors" on page 213
- "Lid" on page 214
- "Optics" on page 215
- "Barcode Reader" on page 215
- "XT Chips" on page 216
- "USB Key for 21 CFR Part 11 Option" on page 217
- "Specifications" on page 218

# **Front View**

Figure 86 shows the front view of the LabChip XT/XTe and identifies the parts on the front of the instrument.



Figure 86. Front View

Status Light	Indicates the state of the instrument:  Dark (not lit) - Power is off.  Solid green - Power is on and instrument is idle.  Flashing green - Running a chip.  Yellow - Power is on, cannot communicate with software.
Lid	Provides access to the chip and electrodes.
Lid Latch	Lift latch to open the lid.

## **Rear Connectors**

The rear connectors are used to connect the LabChip XT/XTe instrument to the computer and power supply.



Figure 87. Rear Connectors

The following connectors are located on the back of the instrument:

Power Connector	Plug the power supply into this connector and a power outlet.  WARNING  Appliance inlet is disconnecting device. Place device or equipment in a manner so that disconnecting device is accessible at all times.
USB Connector	Connects the LabChip XT/XTe instrument to the computer.
Power Switch	Turns the LabChip XT/XTe instrument On (Run) or Off (Standby). Turning the instrument on reads the barcode on the chip if there is a chip in the instrument.

## Lid

The lid holds the chip in the instrument and provides the voltage to the chip channels to separate the sample and move the sample in the channels.

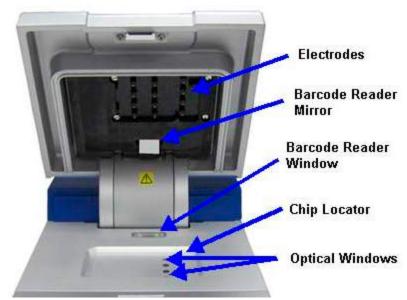


Figure 88. Lid

Electrodes	Apply voltage to the chip to move fluid through the chip and drive electrophoretic separations in the chip channels.
Barcode Reader Mirror	Reflects the barcode label on the chip so it can be read by the barcode reader inside the instrument.
Barcode Reader Window	Window for barcode reader to read the 2D matrix barcode on the chip.
Chip Locator	Recessed area to hold the chip in the correct position for the electrodes to contact the electrode pads on the chip and to align the chip with the optical windows.
Optical Windows	Windows for laser to illuminate channels and detector to read fluorescence.

## **High Voltage Interface**

Supplies DC voltage to the separation channels in the chip via pins on the lid that contact electrode pads on the chip. HV channels run in constant voltage mode.

## **Optics**

The LabChip XT and XTe optics provide fluorescence detection (532nm green excitation and 547-750nm green to red emission) for DNA chips and methods.

#### **Green Laser**

The LabChip XT and XTe instruments include high intensity 532nm green lasers to excite fluorescence in microfluidic chips.

#### Focusing, Alignment, and Calibration

The LabChip XT and XTe instruments are optically focused, aligned, and calibrated at the factory. The optics does not require alignment or focusing. An optical test chip is available for instrument performance verification by the customer.

#### **Photodiode Detector**

The LabChip XT and XTe use a silicon photodiode detector for fluorescence detection. Fluorescence signal from each channel is acquired at a rate of 80Hz.

#### **Optical Train**

The fluorescence excitation and detection optical trains contain lenses, fiber optics, and a high efficiency interference filter.

## **Barcode Reader**

The LabChip XT and XTe instruments are equipped with an internal Barcode Reader. The Barcode Reader reads the Caliper-applied barcode on the edge of the chip.

The barcode reader is internal to the system and cannot be viewed from the outside.

# XT Chips

The figure below show the parts of the microfluidic chips used in the LabChip XT and XTe instruments to perform DNA collection, sizing, and quantitation.

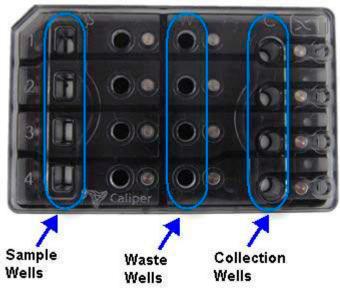


Figure 89. Top of Chip

Sample Well - Add the sample to this well using the instructions in the LabChip XT Assay User Guide. The Assay User Guide is included with the assay kit.

Waste Well - After the run, contains the part of the sample that was not extracted during the run. For Separation channels, contains the entire sample up to the assay kit range.

**Collection Well** - After the run, contains the portion of the sample that was extracted.

**Detection Point** - The location on the chip where the fluorescence excitation and detection optics align with the channels on the chip.

Switch Point - The location on the chip where the sample is diverted to either the waste or collection well.

Barcode Label - The 2D Matrix barcode used to identify the chip in the LabChip XT or XTe instrument.

# **USB Key for 21 CFR Part 11 Option**

If the 21 CFR Part 11 option is installed in the LabChip XT software, the USB Key must be plugged into a USB port on the LabChip XT computer. If the USB key is not plugged in, the LabChip XT software displays an error message when starting and then shuts down.

The 21 CFR Part 11 Security option is not available for the LabChip XTe software.



Figure 90. USB Key for 21 CFR Part 11 Option

# **Specifications**

This section lists the technical specifications for the LabChip XT and XTe instruments. Technical specifications are subject to change without notice.

#### General

Size	7.09"H (180mm) H-lid closed x 7.09" (180mm)W x 12.99" (330mm)D, additional 7" (178mm) required above instrument to open lid.		
Weight	10 lbs. (4.6 kg)		
Chip Capacity	one 4-channel chip		
Ventilation/ Cooling	3" (77 mm) minimum space required around instrument for proper air flow.		

### **Environmental**

Operating Temperature	65° to 82°F (18° to 28°C)
Operating Humidity	10% to 70% relative humidity, noncondensing
Storage Temperature	50° to 104°F (10° to 40°C)
Storage Humidity	20% to 70% relative humidity, noncondensing
Transient Overvoltages	Installation Category II Overvoltage
Pollution	Pollution Degree 2
Altitude	Up to 2000m
Indoor Use Only	

### **Electrical**

Power Input	1.0Arms max at 90Vac, 47-63Hz 0.6Arms max at 264Vac, 47-63Hz	
Input Voltage	100-127/200-240V~ nominal 90-264V~ maximum operating range	
Power Consumption	24VDC, 1.2A max	
Fuses	No customer-replaceable fuses in system. Contact Caliper Technical Support (see page 2) if blown fuses are suspected	
Grounding	Through the power cord	
Computer Interface	USB 2.0	

### **Assay Voltage**

Minimum Voltage/Current	50V (limited by current)
Maximum Voltage/Current	600V (limited by current)

### **Fluorescence Detection**

Detection Wavelength	Bandpass 547-750nm
Data rates	80Hz

### Light Source (Green laser diode)

Warmup Time	30 seconds
Excitation/Emission Wavelengths	532 nm
Power output	5 mW maximum continuous (CW)

### **Barcode Reader**

Barcode Engine	Motorola
Supported Barcode Types	2D Matrix

## Maintenance and Service

Cleaning the electrodes and chip interface prevents current leaks. The electrodes should be cleaned daily, or more often if dyes or reagents contact the electrodes or the chip locator. See Cleaning the LabChip XT/XTe.

The test chip should be cleaned as needed before testing the instrument. See Cleaning the Test Chip.

If the instrument will not be used for an extended period of time, see Long Term Shutdown.

The LabChip XT Assay User Guides contain LabChip Kit Essential Practices and instructions for preparing samples and chips. Make sure to follow the instructions to ensure the optimum performance of your instrument.

The current version of the Assay User Guides can be accessed on the Caliper web site at:

http://www.caliperls.com/support/reference-library/datasheets/labchip systems data sheets.htm.

If you have any questions concerning maintenance or require additional assistance, please contact Caliper Technical Support (see page 2).

#### WARNING



Laser maintenance and service should be performed only by a qualified Caliper representative.

#### WARNING









Some chemicals or samples used with the LabChip XT/XTe are potentially hazardous and can cause illness. Follow the precautions in "Chemical Safety" on page 8.

# Cleaning the LabChip XT/XTe

Make sure the chip locator and inside of the lid are clean before beginning a run. Leave the instrument lid closed when not using the instrument to prevent dust or fibers from settling in the chip locator. Any potentially fluorescent material, such as lint, paper dust, dyes, or reagents, or materials that may block the light in the optical windows must be removed before starting a run.

- Inspect the chip locator, especially the optical windows, and the inside of the lid for debris or fibers that may scatter light or fluoresce during the run.
- 2 Dust can be removed with pressurized and filtered air.
- 3 To remove liquid spills from the lid and chip locator, soak up the spilled liquids with a lint free wipe. Remove any liquid on the optical windows only with the swabs provided. Lightly press the swab on the optical window to or remove the liquid.

#### NOTE

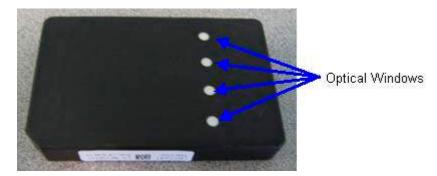


Do not apply pressure to the optical windows when using the swabs. Lightly press the swab on the windows to prevent scratching or damaging the optical fiber tips.

- **4** After the spilled liquid is removed, use a lint free wipe dampened with DI water to rinse the lid and chip locator.
- **5** After the spilled liquid is removed, clean the optical windows with DI water, using ONLY the swabs provided. Lightly press the swab on the optical window to apply or remove the DI water.
- **6** Use a lint free swab dampened with 70%-isopropanol solution in DI water to clean the electrodes.
- 7 Use a lint free swab dampened with DI water to rinse the electrodes.
- **8** Let all parts air dry.

Do not use detergents or other cleaners, as they may contain fluorescent dyes that interfere with the run.

# **Cleaning the Test Chip**



- 1 Inspect the chip for debris or fibers that may scatter light, fluoresce, or block light during the run.
- 2 Dust can be removed with pressurized and filtered air.
- 3 To clean dyes or reagents from the chip, use a lint free wipe dampened with 70%-isopropanol solution in DI water.
- 4 To clean dyes or reagents from the optical windows, use only the provided swabs dampened with 70% isopropanol solution in DI water. Rinse with swab dampened with DI water.

#### NOTE



- Do not apply pressure to the optical windows when using the swabs. Lightly press the swab on the windows to prevent scratching or damaging the optical fiber tips.
- Do not touch the optical windows when handling the test chip.
- 5 If necessary, the PCB on the Test Chip can be cleaned with a swab dampened with 70% isopropanol solution in DI water. Rinse with swab dampened with DI water.
- **6** Let all parts air dry.
- 7 Run the High Voltage Diagnostics after cleaning the system to verify cleaning is successful. If the High Voltage Diagnostic fails, repeat the cleaning procedure. If a second cleaning does not resolve the error, contact Caliper (see page 2).

# **Long Term Shutdown**

If the LabChip XT/XTe will not be used for an extended time (more than 10 days) the instrument should be shut down as follows:

- Remove the chip from the instrument.
- 2 Turn off the power switch on the back of the instrument and unplug the power cord from the wall outlet.
- **3** Clean the inside of the lid and the chip locator if any reagents or dyes are present. Follow the instructions in "Cleaning the LabChip XT/XTe" on page 221.
- **4** Allow to air dry.
- **5** Close the lid and cover the instrument with a light cloth or dust cover.
- **6** Store the instrument in a location that meets the storage requirements in "Specifications" on page 218.

# **Troubleshooting and Diagnostics**

This section contains the following topics to help troubleshoot problems with the LabChip XT/XTe software:

- "Searching for Events in the Events Tab" on page 224
- "Viewing Current Events in the Events Tab" on page 225
- "Error Messages" on page 226
- "Diagnostics" on page 229
- "Troubleshooting Assay Problems" on page 232
- "Software Problems" on page 233
  - "Cannot Save a File" on page 233
  - "Computer Software Lock-Ups" on page 233
- "Zipping the Log Files" on page 235

# Searching for Events in the Events Tab

Events and errors that occurred during the screening of previous jobs are displayed in the Past Events tab in the Event Viewer Window.

To search for a specific event:

- 1 On the Event Viewer window, click the **Search Result** tab.
- 2 In the Events list, select Current, Past, or All.
- 3 In the **Search Text** box, type a search guery and click the **Search** button. The Source, Event Code, and Description fields are searched. The search results appear in the Search Result fields.

The Search Result tab contains the following fields:

**Time** - The time the event or error occurred.

**Source** - The source of the event or error.

**Event Code** - The event/error ID number used by Caliper to troubleshoot problems.

**Description** - A detailed description of the event or error that occurred.

## Viewing Current Events in the Events Tab

While a job or batch is running, the events and errors that occur during the screening display in the **Current Events** tab in the **Event** Viewer Window.

 On the Event Viewer window, click the Current Events tab. The **Current Events** fields display. (These fields are read only.)

The Current Events tab contains the following fields:

**Time** - the time the event or error occurred.

**Source** - The source of the event or error.

**Event Code** - The event/error ID number used by Caliper to troubleshoot problems.

**Description** - A detailed description of the event or error that occurred.

# Viewing Past Events in the Events Tab

All events and errors that have occurred during the screening of previous jobs or batches display in fields on the Past Events tab in the Event Viewer Window.

On the Event Viewer window, click the **Past Events** tab. The Past Events fields display. (These fields are read only.)

The Past Events tab contains the following fields:

**Time** - The time the event or error occurred.

**Source** - The source of the event or error.

**Event Code** - The event/error ID number used by Caliper to troubleshoot problems.

**Description** - A detailed description of the event or error that occurred.

# **Error Messages**

Before a run is started and while an assay is running, the instrument firmware and software checks for errors (e.g., disconnected devices, bad parameters, bad data, etc.). If an error is detected, an error or warning message displays on the LabChip XT/XTe Main Window. Depending on the error, the run may continue or be aborted. The error or warning message describes the problem and either contains information on how to resolve the problem or directs you to call Caliper Technical Support (see page 2).

For specific information about an error or warning message, click one of the links below.

#### **General Errors**

Device <Name> is Disconnected

### LabChip XT/XTe Warnings

- Pin Test Failed
- Current Leakage Check Failed

### **Device <Name>** is Disconnected

This error message indicates that there is no communication between the software and the specified device.

Possible Causes	Recommended Actions	
1. Cable between computer	Verify that the USB communication cable is secure.	
and instrument unplugged.	Verify the power cord is plugged in.	
2. Instrument power loss.	Outlieb the Device switch are the Leb Obje VT/VT- to the	
3. Computer went into hibernation.	Switch the Power switch on the LabChip XT/XTe to the ON position. See page 213.	
	Restart the LabChip XT/XTe software.	
	If the problem is not resolved, contact Caliper Technical Support (see page 2).	

## **Pin Test Failed**

Warning Message: "Pin test failed."

Possible Causes	Recommended Actions
1. Not enough liquid in the chip wells.	1. Prepare the chip as described in the LabChip XT Assay User Guide.
	2. If the problem is not resolved, contact Caliper Technical Support (see page 2).

# **Current Leakage Check Failed**

Warning Message: "Current leakage check failed."

Possible Causes	Recommended Actions	
Dirty electrode block.	Clean the electrodes (see page 221).	
	Run the Current Leak Diagnostic Test (see page 229).	
	If the problem is not resolved, contact Caliper Technical Support (see page 2).	

# Running Installation Qualification (IQ)

The Installation Qualification (IQ) verifies proper installation of the LabChip XT/XTe software and verifies no unauthorized changes have been made to the software. The IQ can be run whenever required by your laboratory procedures.

The Installation Qualification can be used to check software installation qualification after routine computer maintenance, such as disk cleanup, after installing antivirus software, or after installing Microsoft service packs. The Installation Qualification checks LabChip XT/XTe software registry settings, the directory structure, and the integrity of each file specified for the software application.

#### To run the IQ:

- 1 On the LabChip XT/XTe Main Window, select Validation → Software IQ. The Software Installation Qualification Window opens.
- 2 To view the results of the previous IQ before running a new IQ, click the **Previous Result** button. The View Installation Qualification Results Window displays the results of the last IQ that was run.
- 3 To start the IQ, click the **Start IQ** button. The Installation Qualification window displays the tests that are run for the IQ, the progress of each test, and the Pass/Fail status of each test as it is completed.
- 4 To save the results of the IQ, click the **Save As** button, specify the desired location and name of the file, and click the **Save** button. IQ results are saved as .xml files.

# **Running Operational Qualification (OQ)**

The System Diagnostics window performs an automated Operational Qualification whenever required by your laboratory procedures.

The System Diagnostics Window displays the tests that are performed on the left side of the window. The test results are displayed on the right side of the window. After all tests are complete, the test report is generated and saved to a file for review, printing, and documentation purposes.

See "Diagnostics" on page 229 for details on running the Diagnostics.

# **Diagnostics**

The LabChip XT/XTe software contains a set of diagnostic tests to verify proper operation of the LabChip XT/XTe instrument. These tests are not dependant on assay chemistry. All tests must pass to ensure the instrument is functioning properly. To open the System Diagnostics Window, select Validation → Diagnostics.

The following procedures are included in this section:

- Running the Diagnostics Tests
- "Description of Diagnostic Tests" on page 230

### Running the Diagnostics Tests

Before running the Diagnostics tests, turn on the instrument and allow the instrument to run for at least 30 minutes before starting the Diagnostics tests.

To begin running the Diagnostics tests, click the **Run Tests** button on the System Diagnostics Window. The tests run from top to bottom, displaying prompts for any actions necessary during the tests. Follow the prompts. As each test is completed, the results display on the right side of the window.

Supplies required to run diagnostics tests:

XT Test Chip (Caliper P/N 127872)

To order the XT Test Chip, contact Caliper Technical Support (see page 2).

## **Description of Diagnostic Tests**

The table below lists the test names, descriptions, potential failures, and the chip required to run the test.

	Chip		
Test Name	required	Description	Potential Failures
Computer Resources	Any	Check for CFR database connection	SQL server not started. Start SQL Server Express.
			Database has not been installed properly. Contact Caliper Technical Support (see page 2).
		Check for CDR Service	Service exited unexpectedly or not started.
		Check for Remote CDR Connection (Run only if Remote CDR is set up.)	Remote server is down. Network is down.
		Memory Check	Available memory below 500 MB. System may function with lower memory but there is risk of failure if analyzing many chips.
		Disk Space Check	Available disk space below 4 GB. Risk of losing data as disk space is used. Free space on local hard drive.
System Components	XT Test Chip	Verify Fan operation	Damaged fan. Contact Caliper Technical Support (see page 2).
		Board Temperature	Board temperature is not between 18 and 39°C. Verify room temperature is between 65° to 78°F (18° to 26°C). Contact Caliper Technical Support (see page 2).
		Low Voltage Supply	Low voltage supplies are not delivering 3.3±0.15V, 5.0±0.25V. and 3.4±0.15V. Contact Caliper Technical Support (see page 2).

Test Name	Chip required	Description	Potential Failures
System	XT Test	Check Instrument Lid	Lid is open. Close lid.
Components, continued	Chip	Interlock	Interlock Switch is defective. Contact Caliper Technical Support (see page 2).
Barcode	XT Test Chip	Verify barcode reader	Barcode reader hardware or software not functioning. Contact Caliper Technical Support (see page 2).
Laser	XT Test Chip	Channel (1 - 4) Laser Power Readback	Laser power read back is not within 0.2mW of tested power levels: 3.0, 4.0, and 5.0 mW. Contact Caliper Technical Support (see page 2).
Optics	XT Test Chip	Channel (1 - 4) Detector Response	A channel's gain is not adequate or background is too high. Contact Caliper Technical Support (see page 2).
HV Voltage Calibration	XT Test Chip	HV Supply at (-450V)/(-250V)	Voltage out of calibration. Contact Caliper Technical Support (see page 2).
		Channel (1 - 4) Hi/Lo Voltage	Pin not connected to power supply. Contact Caliper Technical Support (see page 2).
HV Current Calibration	XT Test Chip	Channel (1 - 4) Hi/Lo/Zero Currents	Current out of calibration. Pin not connected to power supply. Contact Caliper Technical Support (see page 2).
HV Kelvin Mode	XT Test Chip	Channel (1 - 4) Kelvin Mode Hi/Lo Voltages	Contact Caliper Technical Support (see page 2).
HV Isolation Relay	XT Test Chip	Channel (1 - 4) Isolation Relay	Faulty isolation relay. Contact Caliper Technical Support (see page 2).

# **Troubleshooting Assay Problems**

For problems with assays, see the Assay User Guide for the specific assay you are running. The Assay User Guides contain common problems that may occur for each type of assay, and suggested solutions to resolve the problems.

The current version of the Assay User Guides can be accessed on the Caliper web site at:

http://www.caliperls.com/support/reference-library/datasheets/labchip\_systems\_data\_sheets.htm.

If the problem is not resolved by following the suggestions in the Assay User Guide, contact Caliper Technical Support (see page 2).

### **Software Problems**

If any of the following software problems occur, follow the suggestions to correct the problem:

- Cannot Save a File
- Computer Software Lock-Ups
- Software Display Flashes

### Cannot Save a File

#### File has been saved as a Read Only file.

If you editing an existing file, verify the file is not Read Only. If it is, the title bar shows Read Only after the file name. Read-only files can be edited and saved with a new name or in a new location with the same name, but cannot be saved over the original file.

#### Hard drive is full.

Verify there is sufficient free space on the drive to save the file. If not, clear some space on the hard drive. On non-21 CFR Part 11 systems, you can archive files that you are not using to another location.

If you do have sufficient space, try closing all open applications and then turning off the power to the computer. After a few seconds, restart the computer, open another file, and try resaving it to verify the Save function is working properly.

#### LabChip XT/XTe software is corrupted.

Reinstall the software. If the problem persists, contact Caliper Technical Support (see page 2).

## **Computer Software Lock-Ups**

If a computer or software lock-up occurs:

- Try to exit and then re-launch the LabChip XT/XTe software.
- 2 If this is not successful, exit the application using the **Task** Manager:
  - a Right-click in the desktop menu bar and select Task Manager.
  - **b** Click on the **Applications** tab.
  - **c** While holding down the **Shift** key, select all running applications.

## **Computer Software Lock-Ups (Continued)**

- d Hold the Ctrl key and click End Task.
- 3 If the Task Manager cannot be accessed, try one or all of the following:
  - Press the Ctrl, Alt, and Delete keys on the keyboard simultaneously.
  - Perform a hard reboot by turning off the computer and then restarting it.
  - Power cycle the LabChip XT/XTe instrument.
- 4 If problems persist, contact Caliper Technical Support (see page 2).

### **Software Display Flashes**

During a run, the views in the LabChip XT/XTe software may flash occasionally as the new data is displayed.

Do not run any other software applications while running the LabChip XT/XTe software, especially while a run is in progress. The LabChip XT/XTe Controller should only be used to run the instrument and should not be used for general computing tasks.

# **Zipping the Log Files**

The Caliper Log Zipper is a small software utility that zips the LabChip XT log files and system info files and places the resulting DiagnosticsLog.zip file on the computer desktop. This utility can be used to package all of the log and diagnostic files together if the files need to be emailed to Caliper Technical Support.

To zip the LabChip XT diagnostics logs:

On the Windows desktop, select Start → All Programs → Caliper Life Sciences → LabChip XT → Caliper Log Zipper. The Caliper Log Zipper window opens.

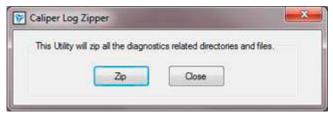


Figure 91. Caliper Log Zipper Window

- 2 Click the Zip button. The DiagnosticsLog.zip file is saved to the computer desktop. Any existing older file with the same name is over-written.
- 3 To save a copy of the file, either rename the file or move the file to a different location.

# **Tips and Shortcuts**

This section describes the shortcuts and actions that can be performed in the LabChip XT/XTe software by clicking, rightclicking, etc.

### Single Click

- In Chip View Selects a channel.
- **In Gel View** Selects a channel and displays the graph in the Graph view.
- In Channel Table View Selects a channel, displays the graph in the Graph view, and selects the channel in the Gel view.
- **In Peak Table View** Selects a peak, displays the graph in the Graph view, and selects the channel in the Gel view.

#### Ctrl + Click

- In Gel View Overlays second and subsequent channel data over original channel data in the Graph view (for each Ctrl + click on a channel in the gel). Each channel in the graph is shown in a different color.
- In Channel Table view Overlays second and subsequent channel data over original channel data in the Graph view (for each Ctrl + click on a row in the Channel Table). Each channel in the graph is shown in a different color.

#### Ctrl + Shift + Click

In Gel View - Highlights corresponding channel data trace in Overlay Electropherogram view (adds trace to overlay if not already included). This trace becomes the foreground trace for peak selection. Repeat click to undo highlighting.

### Right-Click

Right-click in any view to display a shortcut menu with available options. In the Graph View, different shortcut menus display depending on whether the cursor is near a peak or not near a peak.

# **Glossary of Terms**

**Apex** 

**Baseline** 

**Bubble** 

Clipboard

Collection

**Collection Template** 

**Collection Well** 

**Data Files** 

**Data Points** 

**Data Filtering** 

**DNA Assay Analysis** 

**Electrode Cleaner** 

**Electrokinetic Forces** 

Electroosmotic Flow

Electrophoresis

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**Start Point** 

Start Time

Tool Tip

Workspace

**XTD Files** 

Zero Baseline

## **Apex**

After locating a start point, the peak find algorithm looks for the first negative slope value and saves the previous point as the apex. If the value of the apex is less than the minimum peak height limit, the algorithm starts looking for a new peak.

### **Baseline**

A baseline is established just after the start time setting. (The Baseline Start time can be changed on the Analysis Tab in the LabChip XT software.) After the overall baseline is established, a local Peak Baseline is calculated for each peak to compensate for baseline drift.

For isolated peaks, the local peak baseline is a straight line connecting the start point of the peak with the end point. For peaks that are very close together, an average baseline is used when the value between the peaks does not drop to the actual baseline.

In the LabChip XT software, you can select the desired baseline algorithm for all of the samples in the chip. Choose the desired option on the Peak Find Tab: No baseline, Zero Baseline, or Baseline Subtraction.

- For the "Zero Baseline" option, a single value of baseline shift is determined by averaging over a 1 second region just before the Data Range Baseline time. This shift is subtracted from all of the data.
- The "Baseline Subtraction" option uses a spline fit or rolling ball fit to the data to determine a smooth baseline that is subtracted from the data. The percentage of data points used in the spline fit is specified by the Threshold value in the Method window. The collection of points with the lowest variance up to this percentage is used for the spline fit. The Rolling Ball algorithm uses the Time Diameter to specify the size of the ball in the X direction and the Signal Diameter to specify the size of the ball in the Y direction.

Figure 92 shows baselines established for DNA assay peaks (based on the settings in the Peak Find Tab). DNA peak baselines are determined on a peak-by-peak basis.

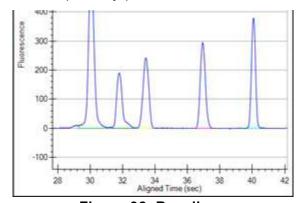


Figure 92. Baselines

## **Bubble**

If the tip of a pipette is not positioned below the liquid level in the chip well, bubbles can result. If a large bubble forms at the bottom of a chip well, remove the sample from the well, pipette the sample back into the chip well, and continue with the loading procedure.

# Clipboard

A temporary storage area that contains information you have cut or copied. You can paste the contents of the clipboard into other programs (provided that program supports that type of information). Information remains on the clipboard until you replace it with the information from another cut or copy command.

## Collection

Use a collection to view the chip data. In the LabChip XT software, a workspace can contain multiple collections to supply different views of the same data.

Each collection specifies:

- the channels selected for view in each chip data file,
- the layout of each Collection tab, and
- the display properties for each view in each collection.

# **Collection Template**

In the LabChip XT software, a collection template saves the display options for a collection and any defined filters in the collection. Collection templates are used to create new collections using the saved display settings and filters. Collection templates do not save the list of chips or the channels selected in the chips.

To save a collection template based on the settings in the open collection, select Collection → Save Template on the main Menu Bar.

To apply a collection template to a new collection, select the **Template** option in the New Collection Window.

To apply a collection template to an existing collection, select the tab for the desired collection and then select Collection → Apply **Template** on the main Menu Bar.

Collection Templates are not supported in the LabChip XTe software.

### **Collection Well**

The wells on the chip that will contain the fractionated samples at the end of the run. There is one waste well and one collection well per channel. There are four channels on each LabChip XT chip.

### **Data Files**

While running an assay, the raw data received from the instrument is automatically saved to the chip data file (\*.xtd or .xte). As the data is received, it is saved to the data file. The name of the data file is specified in the Start Fractionation Window.

After a run is complete, the data is analyzed using the analysis settings in the method. The analysis settings are saved in the data file (.xtd or .xte).

After the run in the LabChip XT software, you can change the analysis settings using the Method Window. When the new settings are applied, the data is reanalyzed and the updated results are displayed. Changes to the analysis settings are not saved until the workspace is saved. To save analysis settings without saving the workspace, select **Workspace** → **Save Chip** or right-click on the chip name above the chip diagram on the left side of the window and choose Save Chip.

In the LabChip XT software, changes to the analysis settings are saved at the end of the chip data file without overwriting previous settings in the file. The Restore Chip button can be used to return to previous analysis settings.

## **Data Points**

Data points are determined by the data collection rate set in the method properties.

Show Data Points is an option in the Graph View Properties that displays the data points used to generate the graph.

# Data Filtering

Before identification of peaks in the fluorescence data can proceed, the raw data must be smoothed to prevent the detection of signal noise as peaks.

To smooth the data, the LabChip XT/XTe software:

- 1 Eliminates any narrow spikes from the data and replaces the spike with a local average of surrounding points.
- 2 Applies Baseline correction (if selected in the Method Window) to the data.
- 3 Smooths the data using a Savitzky-Golay filter using the Filter Width and Transition Time specified in the Peak Find Tab of the Method Window.

# **DNA Assay Analysis**

DNA samples contain a lower marker peak below the limit of the DNA fragment sizes the method is designed to detect. The ladder contains the same lower marker peak. The sample data is aligned to the ladder data by matching the peak time of the marker in the sample data with the same marker in the ladder data. The size of each sample peak is calculated by linear interpolation between the known ladder peak migration time and size using the peak aligned migration time. In the LabChip XT software, the analysis settings can be changed to perform the interpolation using a local third order polynomial fit to the time instead of the size relationship provided by the ladder.

The concentration of the sample peaks is calculated using the known area and concentration of the ladder peaks. The molarity of each sample peak is calculated using the sample concentration, the DNA fragment size (in base pairs) attributed to the peak, and the known molecular weight of the DNA base pair.

## **Electrode Cleaner**

The electrode cleaner looks like a chip except that it is clear. Use the electrode cleaner in place of a chip when cleaning electrodes.

### **Electrokinetic Forces**

Electrokinetic forces are used to move, switch, mix, and separate the nucleic acid samples. Active control over voltage gradients directs the movement of materials using the phenomenon of electroosmotic flow or electromigration.

## **Electroosmotic Flow**

A phenomenon that results from an electrical double layer formed by ions in the fluid and surface electrical charges immobilized on the capillary walls. When an electric field is applied, the bulk solution moves towards one of the electrodes. This phenomenon can be used to move fluids through microfabricated channels

# **Electrophoresis**

A technique of separating molecules on the basis of their mobility. An electrical potential is applied across a capillary containing a sample in a fluid medium. Positive molecules migrate towards the cathode and negative molecules migrate towards the anode at different speeds depending on their electrophoretic mobility.

### **End Point**

The peak find algorithm looks for a leveling off when the value of the slope is less than the value set for the slope threshold. This is marked as the end point of the peak.

## **End Time**

This setting determines the time after the start of a run before which the last peak or fragment will be located (any peaks appearing after this time are ignored).

## **Filter Width**

This setting on the Peak Find Tab determines the width of the polynomial (in minutes) to be applied to the data for filtering (noise reduction). The default depends on the method selected.

# **Hardware Diagnostics**

Whenever a run begins, the instrument checks for errors (e.g., defective high-voltage supplies, missing conductivity between channels, etc.). If an error is detected, a message box displays and the run stops. The message box describes the problem and either contains information on how to resolve the problem or directs you to call Caliper Technical Support (see page 2).

# Inflection Threshold Example

Peaks that are very close together will be identified as a single peak if the peaks do not have a clear valley between them. The Inflection threshold property in the LabChip XT software allows splitting of peaks evidenced by a region of lower slope. The figures below illustrate the operation of the Inflection threshold.

The green line in the figures below shows the signal slope. The shoulder peaks have a slope minuma (inflection point) but the slope doesn't change sign so they are not split into multiple peaks via the slope threshold.

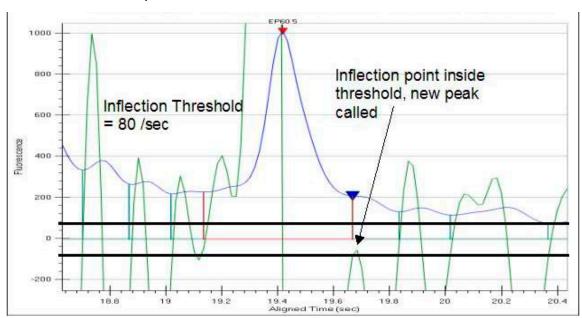


Figure 93. Slope Threshold 0

The inflection threshold defines the value that the slope minimum must be below to trigger a splitting of the peak. As the threshold is increased, more peak splitting occurs. The figures below show the same data with the slope threshold set to 80 and 200.

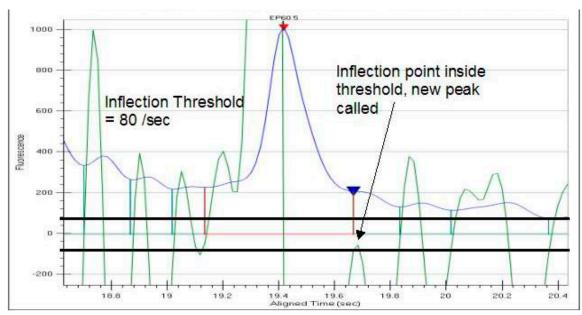


Figure 94. Slope Threshold 80

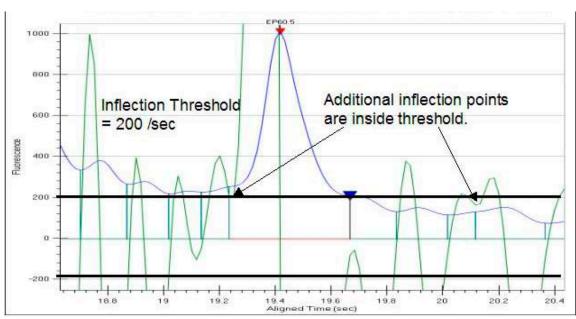


Figure 95. Slope Threshold 200

# Lab-on-a-Chip

The generic term for a microfluidic product, signifying a chemical process or material movement taking place on a microchip. In contrast to analysis in a standard laboratory that relies on human intervention at several stages to manipulate or observe samples and record results, the self-contained lab-on-a-chip represents an almost hands-free technology.

## Ladder

A channel on the chip can be designated as a Ladder channel if it is running a Real Time Ladder at the same time the samples are running. A default Caliper Ladder is provided if all four channels of the chip are used to run samples. The ladder is used to calculate sample sizes and migration times of the sample to accurately determine the collection start time and collection end time for each sample.

In the LabChip XT software, the Peak Table View for the ladder channel shows the peak size and concentration set in the Method Window.

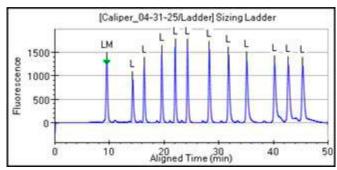


Figure 96. Ladder Graph

# **Ladder Analysis**

A ladder is a mix of compounds of known sizes that is used to create a size ruler for the samples. Ladder data is used to convert the migration time of each sample peak into a size for the compound responsible for that peak. The known sizes of the ladder compounds are supplied in the method file. In the LabChip XT software, the ladder sizes can be viewed in the Analysis Tab on the Method Window.

The ladder analysis identifies the most prominent peaks in the ladder channel and associates each peak with the known ladder sizes. The ladders provide a table of values relating size to migration time. Typically the migration time uses the center of the peak in the ladder and the sample.

### Lower Marker

An internal standard that is added to a sample in a channel to assist in determining size and concentration of the sample. The marker is the same as the first peak in the ladder.

# Log Files

The LabChip XT/XTe software log file displays in the Event Viewer Window. The log file maintains a running record of all events that occur with the instrument while it is online with the software and records all events that occur in the software. Each event specifies the date and time of the event, source of the event, the event code, and a description of the event.

## **Method File**

File created in the LabChip XT software to specify assay and analysis settings, such as Ladder and marker sizes and concentrations, peak find settings, expected peaks, and smears.

Editing method files and changing analysis settings are only supported in LabChip XT software.

## **Microfluidics**

The miniaturization of chemical processes generally pertaining to systems involved in the control of fluid flow. This includes pumps, valves, jets, and microchannels.

# Minimum Peak Height

The Minimum Peak Height value determines the height limit below which a peak will not be detected. For each peak, the difference between the peak start time and the peak apex must be greater than the Minimum Peak Height value.

The Minimum Peak Height is specified on the Peak Find Tab on the Method Window in the LabChip XT software. The Minimum Peak Height cannot be changed in the LabChip XTe software.

### Minimum Peak Width

The Min Peak Width value determines the width (in minutes) under which a peak will not be detected. For each peak, the difference between the peak start time and the peak end time must be greater than the Minimum Peak Width value.

The Minimum Peak Width is specified on the Peak Find Tab on the Method Window in the LabChip XT software. The Minimum Peak Height cannot be changed in the LabChip XTe software.

# **Molarity**

Molarity = (Concentration \* 10<sup>6</sup>)/(660 \* Size)[nmol/I]

where molarity is measured in nanomoles per liter (nmol/l).

Concentration is measured in nanograms per microliter (ng/µL).

Size is measured in base pairs (bp).

660 \* [g/(mol \* bp)] is the molecular weight of a single base pair.

# **Molecular Separation Techniques**

Processes such as gel electrophoresis, liquid chromatography, and capillary electrophoresis, which can separate biomolecular organic substances from other compounds.

## **Peak Baseline**

A local peak baseline is calculated for each peak. For isolated peaks, the local peak baseline is a straight line connecting the start point with the end point. For peaks that are very close together, an average baseline is used when the value between the peaks does not drop to the actual baseline. The peak baseline for each peak in Figure 97 is shown in a different color.

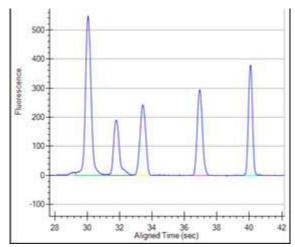


Figure 97. Peak Baselines

The baseline algorithm starts at the earliest peak and checks whether the end point is within a certain distance from the start of the next peak. When a cluster of peaks is detected, the baseline is the line joining the first peak's start to the last peak's end. The start and end points of adjacent peaks in the cluster are averaged to the same point so that no gaps exist between peaks.

The peak baseline Start Point and End Point can be moved in the Overlay Electropherograms Tab if **Show Peak Baselines** is selected in the Graph View Properties.

# **Peak Height**

The value at the apex of the peak minus the local baseline start value.

### **Peak Identification**

From the smoothed data, peaks are identified using a hill-climbing algorithm running along the smoothed data and its first derivative.

The slope threshold determines peak start point and end point:

- The first point with local derivative above the slope threshold indicates the peak start point.
- The first point where the negative slope on the falling edge of the peak drops below the slope threshold indicates the peak end point.

The peak baseline is stitched across the peak bottom by taking local averages just outside the peak start and end points. The peak height, measured from the apex down to the peak baseline, must exceed the minimum peak height specified in the Method Window to have a bump tagged as a peak.

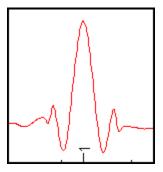
The peak start, end, and baseline can be viewed in the Graph View by selecting the Show Peak Baselines option in the Graph View Properties. The area of each peak is determined by trapezoidal integration of the peak signal between peak boundaries and above the peak baseline.

## Point-to-Point Fit

This curve fit is composed of line segments between each pair of data points that are used to interpolate data between the points.

# **Polynomial Filter**

The first step the software takes in analyzing the raw data is to apply Data Filtering. Data filtering is performed by means of a polynomial "filter" that is applied to the raw data. The figure below approximates the shape of the filter and shows what peaks may resemble if the filter application is too strong.



# **Polynomial Order**

This setting on the Peak Find Tab in the LabChip XT software determines the order of the polynomial filter used to convolve with the data. A polynomial filter is used to filter the data to increase the signal-to-noise ratio and calculate filter slope information for peak detection. The default setting is 6 (for 6th order).

### **Run Button**

To begin running an assay, click the **Run** button located on the graphic of the LabChip XT/XTe instrument at the top left of the LabChip XT/XTe Main Window:



The Start Fractionation Window opens to select the method, channels, data file name, etc.

After the run has begun, this button changes to Pause/Stop. See "Stop a Run" on page 38.

### NOTE



The Run button does not display if the software was installed in Reviewer mode.

# Sample Name File

Use a Sample Name file to import the desired sample names into the Run File Editor Window or the Start Fractionation Window. (LabChip XT only.)

The entries in the Sample Name file must be formatted as shown below, with one pair on each line.

<Channel, Sample name >

### **Example:**

CH2, 1ug of 2.5k gDNA Smear 1k extraction CH3, 2ul library CH4, "HL60 500 ng, starting 4microl"

Sample names containing commas must be enclosed in double quotes.

The Sample Name file can be created in Microsoft Excel or a similar spreadsheet program, and must be saved as a .csv file.

## **Saturation Detection**

The LabChip XT software can be set to compensate for optics detector saturation on the Advanced Tab on the Method Window.

The instrument electronics saturate at approximately 3200 RFU (optics detector voltage of approximately 3.2 volts). When the analog amplifier saturates, it switches rapidly to 0 volts output. The detection is based on the very high negative slope of the signal as it transits into saturation and very high positive slope when it comes out of saturation.

The corrected signal is flat over the saturated region with a value equal to the maximum of the largest RFU value detected just before entering saturation and just leaving saturation. The well is annotated in the Analysis Error column with the message: Signal Saturation Detected.

Figure 98 shows a signal that saturated the electronics. The left graph with the Saturation Detection option disabled shows the true signal with a saturation artifact which would seriously compromise the quantization accuracy. The right graph shows the same signal with the Saturation Detection option enabled. The saturation is corrected so the signal appears as expected and will quantized fairly closely to a value that would have been attained if no saturation had occurred.

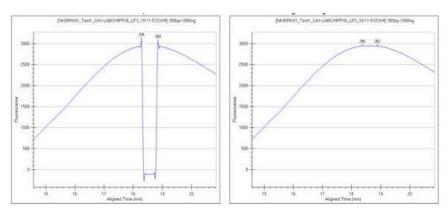


Figure 98. Correction by Saturation Detection

# Slope Threshold

The **Slope Threshold** setting represents the amount of change in response over time required to differentiate between an eluting peak and baseline noise. Changing this setting may cause certain peaks that were previously detected to be ignored or to interpret noise as peaks.

The **Slope Threshold** setting is one of the user-definable parameters in the Peak Find Tab. in the LabChip XT software.

## Smear

Specifies a size range in which to detect the region of the fluorescence signal instead of specifying a specific size for a peak. Use a smear to detect a broad mix of molecules of similar but distinct sizes in a sample. The concentration or fractional presence within a specified range of molecule sizes is measured. Specify the Start Size and End Size of a smear in the Method Window on the Smear Analysis Tab.

Smears are also used to display the region of extraction. The extraction smears are created automatically during an extraction run.

The Smear Properties can be viewed in table form in the Channel Table View. To view the Smear Properties in the table, add the desired property to the Channel Table View. The properties extracted from the smear match those of a peak, having extends, area, concentration, etc. % Purity is the ratio of smear concentration to total sample peak concentration, exclusive of markers, system peaks, and excluded peaks. Excluded peaks are not excluded from analysis calculations such as concentration or area within the smear region, so the limits must avoid excluded peaks. An additional Peak Count property is available for smears. Peak Count is the number of non-excluded sample peaks in the region, where the center of the peak is inside the smear limits.

In the Graph View, the smear regions display with the integration extends drawn at the base of the smear in the chosen color and the trace highlighted with the smear color. Override the smear base by dragging with the mouse in the Graph view. Only the vertical position of the base corners can be adjusted in the graph, since the size limits are specified and should not be altered.

In the Gel View, the smear region is shown on the gel as a colorized region. The color is a transparent version of the color selected for the region, so the fluorescence intensity still shows through.

## **Smear Baseline**

A Smear baseline is calculated for each smear. Choose the desired Smear Baseline option on the Advanced Tab on the Method Window in the LabChip XT software. The following options are available to calculate the smear baseline:

- Two Point The baseline is a single straight line between the flat baseline regions at the beginning and end of the trace. During extraction, when the end of the signal has not yet been reached, the baseline uses a single value averaged over the Baseline region at the beginning of the trace. Two Point is the default selection.
- Peak Baseline The local baseline computed for peaks is used as the smear baseline. The baseline is a straight line from the beginning of the smear region to the end of the smear region and follows the local peak baseline.

The Two Point baseline option is best for traces where both ends of the signal return cleanly to background levels. If there are local artifacts before the lower marker, after the upper marker (when used), or at the end of the trace, the Two Point baseline may shift above the smear trace, resulting in poor quantization of the smear. Figure 99 shows a trace with a large sample artifact after the upper marker which elevates the two point baseline.

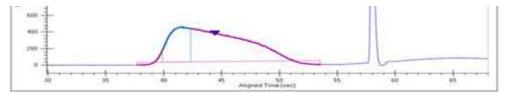


Figure 99. Smear with Poor Two Point Baseline

Figure 100 shows the same smear using the Peak Baseline option. Note that the smear baseline drops to the local baseline at the end of the smear.

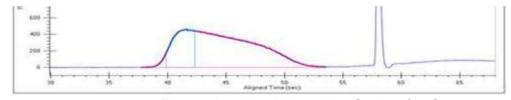


Figure 100. Peak Baseline Option for Smear

The Peak Baseline option is not a good choice for very shallow smears which do not rise above the Peak slope threshold. The peak baseline will follow up into the smear and the smear baseline will depend strongly on where the smear extends are set.

## Standard Curve Window

Only the LabChip XT software supports viewing or changing the Standard Curve.

The Standard Curve window shows the standard curve used for the selected chip data.

When you choose **Standard Curve** from the **Analysis** menu for a DNA assay, a window similar to Figure 101 opens. The standard curve is drawn from the values obtained for the DNA ladder. It is a plot of the size of the ladder peaks vs. time with a point-to-point fit. For each sample peak, the apex is interpolated from the Standard Curve to determine the peak size in base pairs (BP).

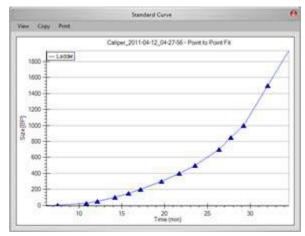


Figure 101. DNA Assay Standard Curve

For more information about the use of the standard curve during analysis, see "How the Software Analyzes DNA Data" on page 44.

# **Start Point**

The peak find algorithm analyzes the data from time zero looking for a slope greater than the **Slope Threshold**. The point where the slope is greater than the slope threshold specified in the Peak Find Tab is marked as the start point of a peak.

## **Start Time**

This setting determines the time after the start of a run when peaks will be detected. Any peaks appearing before this time are ignored.

# **Tool Tip**

A small box containing text that describes the item indicated by the mouse pointer. To view a Tool Tip, position the cursor over an item on the window. Leave the cursor stationary for a moment and a **Tool Tip** (if one exists for that item) displays.

# Workspace

Use a workspace file to view the chip data from a run. In the LabChip XT software, workspace files can be saved and opened. In the LabChip XTe software, a new workspace opens automatically when importing a data file. Multiple chip data files can be opened in the same workspace to enable comparison between data from different chips or different runs.

In the LabChip XT software, each workspace can contain multiple Collections for viewing the same data in different layouts. The LabChip XTe software only supports one collection in each workspace.

A Workspace file includes:

- the links to the chip data files in each collection,
- the selected channels and arrangement of the channels in the views, and
- the layout selected for each collection.

## **XTD Files**

The file extension for data files created in the LabChip XT software. The data file contains the data from the read, method information, analysis settings, and Run Information for the run.

Data is saved to the file during the run. If a run is stopped before the run is complete, the collected data for all channels is saved in the data file.

The file name is specified in the Start Fractionation Window.

## **XTE Files**

The file extension for data files created in the LabChip XTe software. The data file contains the data from the read, method information, and Run Information for the run.

Data is saved to the file during the run. If a run is stopped before the run is complete, the collected data for all channels is saved in the data file.

The file name is specified in the Start Fractionation Window.

## Zero Baseline

Changes to Analysis Settings are only supported for LabChip XT.

Selecting this setting in the Peak Find Tab offsets the graphs shown for the individual channels but does not affect analysis. The mean of 100 points before the baseline time (derived when calculating channel noise) is used as the zero baseline value.

All electropherograms produced with the instrument show some amount of background fluorescence. By default, the LabChip XT software enables the Zero Baseline function. To change the Baseline Algorithm, select None, Zero Baseline, or Baseline Subtraction on the Peak Find Tab.

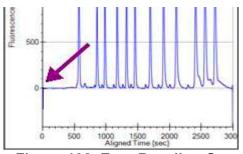


Figure 102. Zero Baseline On

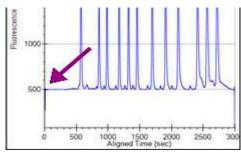


Figure 103. Zero Baseline Off

## Caliper Life Sciences, Inc. Product Warranty

#### I. INSTRUMENTS

Caliper® Life Sciences, Inc. ("Caliper") warrants your Caliper-manufactured instrument's hardware and firmware against defects in material and workmanship for a period of one (1) year from the date of installation, but not later than 14 months from shipment, subject to the exclusions set forth below and: (i) the warranty for Limited-Life Parts (as defined below) shall be thirty (30) days from the date of installation, and (ii) the warranty for cosmetic surfaces shall be thirty (30) days from the date of installation (each, a "Warranty Period"). Ongoing service support after the Warranty Period may be available at an additional expense.

### A. What is Included during the Warranty Period

- unlimited emergency on-site repair services<sup>1</sup>, parts and software updates that affect original functional design specifications, their associated labor and travel expenses.
- unlimited access to Caliper's Technical Support Center, which provides troubleshooting, repair instruction, service dispatching (other than for LabChip XT and Twister I), replacement part information and shipment.
- A completed Caliper Field Service Report provides thorough documentation of all maintenance and service work performed by the Caliper Field Service Engineer during an on-site visit. Documentation is not provided when Caliper provides service via telephone, fax or email.

Any failure of a product to conform to this Warranty shall be corrected by replacing or repairing the affected product or refunding the purchase price (as described below), in each case at Caliper's option. Parts replaced during the Warranty Period will be covered for the remaining term of the original Warranty Period, or for thirty (30) days from time of replacement, whichever is longer. Such replacement parts may, at Caliper's option, be new or remanufactured. All parts removed from warranted equipment become the property of Caliper. Caliper reserves the right to satisfy its warranty obligations in full by refunding the purchase price of any non-conforming product, minus any service, validation, or travel charges.

### **B.** Customer Responsibilities

In order for a product to be covered under this Warranty, Customer must comply with the following terms:

- · The equipment must be used under normal installation and application conditions as described in the product's User Manual.
- · The equipment must be maintained as described in the User Manual.
- Only water or DMSO at a maximum concentration of 65% may be used as a system fluid in the Sciclone inL10. Any other system fluid must be approved by Caliper before use in the inL10.
- When Caliper provides telephone, fax, or email support, Customer is responsible for completing any necessary documentation of the service.
- If Customer maintains a change control/validation logbook as a permanent record, then Customer is responsible for entering all service documentation into such logbook.
- Customer must perform the appropriate level of revalidation required as a result of the maintenance or service provided.

### C. Exclusions

- · Failure to comply with any of the Customer Responsibilities listed above will void this Warranty.
- Any alteration of hardware or software on products covered under this Warranty that are not performed by Caliper or an approved Caliper vendor will void this Warranty.
- A product that has been subject to misuse, accident, negligence or improper transportation, handling, installation, storage, use, or maintenance is not covered under this Warranty.
- Many Caliper products require the use of Caliper Automation Certified Disposables for proper operation. These may include, but are not limited to: pipet tips, seals, labels and filters. Use of a Caliper product with any disposables other than the specified Caliper Automation Certified Disposables will void this Warranty.
- · This Warranty covers equipment manufactured by Caliper. Equipment purchased from other vendors is not covered by this Warranty.
- Damage to Limited-Life Parts caused by insufficient maintenance or cleaning practices or unauthorized applications are not covered under this Warranty.
- This Warranty applies only to the original buyer and delivery location. It is not transferable to other buyers or locations without Caliper's prior written approval.
- The Sciclone 384-channel low-volume head is warranted for one (1) year or 750,000 aspirate or dispense movements, whichever comes
  first.
- The Sciclone 100nL head is warranted for one (1) year or 600,000 aspirate or dispense movements, whichever comes first.
- The laser component of the LabChip 3000 is warranted for the earlier of one (1) year from the date of installation or 8,000 hours of use.
- The use in a Sciclone inL10 of DMSO above 65% concentration, or any other system fluid not sanctioned for use by Caliper, will invalidate this warranty as it relates to the pipetting head assembly.

<sup>1.</sup> LabChip XT and Twister I are not eligible for on-site service, and must be returned to Caliper's Repair Depot for warranty service pursuant to the process set forth in Section E below.

If Caliper performs service on equipment and determines that any of the exclusions set forth in this Warranty apply, then Caliper shall charge Customer its then-current current list prices for parts, labor and travel.

#### D. Limited-Life Parts

Limited-Life Parts are any parts that are exposed to solvents, reagents, or samples. Such parts include, but are not limited to syringes, valves, seals and fittings. A pre-defined list of Limited-Life Parts are routinely replaced by Caliper Field Service Engineers during an Extended Warranty or Service Contract Preventative Maintenance visit or during Caliper Repair Depot servicing. Otherwise, these parts are available from Caliper at current list prices and are designed for replacement by Customer.

## E. Equipment Return Policy

In servicing situations requiring the return of equipment to Caliper, equipment must be returned to Hopkinton, MA, USA, or another facility designated by Caliper. Customer shall prepay shipping charges for equipment returned to Caliper, and Caliper will pay for return shipment to Customer.

A Returned Material Authorization (RMA) must be obtained for any equipment being returned to Caliper. Contact the Caliper Technical Support Center by telephone at (508)-435-9761, or via the Internet at techsupport@caliperls.com or by fax at (508)-435-0950 before returning any equipment to Caliper. Customer must complete a Caliper Chemical Questionnaire prior to the issuance of an RMA. All equipment returned to Caliper must first be decontaminated to meet Caliper and United States Department of Transportation procedures and standards for the safety of Caliper personnel.

### F. Hazardous Limitation Statement

At no time will Caliper personnel perform service on unsafe equipment, perform service in unsafe environments or decontaminate equipment to make it safe.

Prior to performing any service work, Caliper personnel will evaluate the condition of the equipment and the environment in which the equipment is located. If Caliper determines that the equipment and/or the environment could be hazardous to Caliper personnel, Caliper reserves the right to refuse to service the equipment.

#### II. MICROFLUIDIC CHIPS

Caliper warrants that microfluidic chips (each, a "Chip") purchased from Caliper by Customer will be free from defects in material and workmanship for a period of sixty (60) days from the date of shipment (the "Warranty Period"). A "defect" for purposes of this Warranty is defined as any failure that occurs during analysis of the first one hundred (100) samples being run on a Chip. During the Warranty Period, if the Chip fails to comply with this Warranty, Caliper will repair or replace the Chip at its option and expense. If a Chip becomes damaged or its performance otherwise deteriorates due to solvents and or reagents other than those supplied or expressly recommended by Caliper, Caliper will replace the Chip at Customer's request and expense. No such replacement will extend the original Warranty Period. This Warranty does not extend to any Chip which has been (a) the subject of an accident, misuse, or neglect, (b) modified by a party other than Caliper, (c) used in a manner not in accordance with the instructions contained in the product User's Manual, or (d) used for an assay or application which has not been approved by Caliper. All claims under this Warranty must be made within thirty (30) days of the discovery of the defect. Caliper's obligations under this Warranty are limited to replacement as Caliper deems necessary to correct those failures of the Chip to comply with this Warranty of which Caliper is notified prior to expiration of the Warranty Period.

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