bio-techne® / R&D SYSTEMS

Instructions For Use
W-DOC-0022 Rev C

Ella™

Immunoassay Platform for Protein Quantification



IVD For *In Vitro* Diagnostic Use

CE

REF 600-100-CE

UDI 86001420031000139001CEYD

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Instructions for Use for Ella

W-DOC-0022 Rev C
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Revision Summary

W-DOC-0022 Rev A	Initial Release
W-DOC-0022 Rev B	Added CE mark on front page
W-DOC-0022 Rev C	Corrected Electrical Rating frequency range

Patents and Trademarks

Bio-Techne's Simple Plex technology is covered by issued and pending patents in the U.S. and other countries. For more information please visit: **bio-techne.com/support/instrument-support/intellectual-property**

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Ella Disclaimer of Warranty

Except as expressly provided in any Bio-Techne software license agreement or quotation, the products sold and services provided by Bio-Techne are provided on an “as is” and “as available” basis without warranty of any kind. Bio-Techne and its suppliers do not warrant the security, privacy, or accuracy of any data provided via the products or services, and you agree that the use of any such data by you is at your sole risk. To the maximum extent allowed under applicable law, Bio-Techne and its suppliers disclaim any and all warranties, whether expressed, implied or statutory, including, without limitation, any warranty of merchantability, title, non-infringement, or fitness for a particular purpose.

Scope

For the proper operation of the system and/or all parts thereof, the instructions in this manual must be strictly and explicitly followed by experienced personnel. All of the contents of this guide must be fully read and understood prior to operating the system or any parts thereof. Failure to completely read and fully understand and follow all of the contents of this guide prior to operating the system or parts thereof may result in damage to the equipment or parts thereof and injury to any person operating the same.

Intended Purpose

The Intended Purpose for the Ella Instrument is as follows:

> The Ella Instrument is a non-automated instrument intended for in vitro diagnostic use with a supported Ella IVD Assay to perform immunoassay diagnostics. The Ella Instrument sequences the processing of samples, reagents and wash buffers, and measures and sorts fluorescence signals, using a supported Ella IVD Assay Kit. The Ella instrument is intended for use by trained laboratory personnel.

The Ella instrument is to be used in professional healthcare settings (e.g., clinical laboratories, hospitals, clinics). The Ella system is not intended for use in near-patient settings, or for self-testing. Reasonably foreseeable misuse of the product includes the following. 1. Use by untrained users 2. Use with unsupported cartridges.

Test Principle

The Ella Instrument utilizes a sandwich immunoassay test principle involving the following steps:

First, the target antigen is captured using a solid phase Glass Nano Reactor coated with a capture antibody specific to the antigen. Sample is run through the cartridge to bind the target antigen to the capture antibody. A detection antibody which binds to the antigen is conjugated to a fluorescent label and introduced thereby forming a "sandwich" complex. After washing away unbound substances, the cartridge is read by the instrument and relative fluorescent units are reported. The intensity of the signal is directly proportional to the amount of antigen present in the sample. By comparing the signal obtained from the sample with a standard curve generated from known concentrations of the antigen, the concentration of the antigen in the sample can be determined. This principle allows for highly specific and sensitive quantification of antigens in various samples.

Warning and Residual Risk

None identified.

TABLE // 01

Label and Symbol Descriptions

Symbol	Description
	CAUTION Refer to the accompanying documentation
	NRTL approval mark Electrical safety approval to UL61010-1:2012; EN61010-1:2010; CAN/CSA C22.2 61010-1:2012
	The manufacturer’s assurance that the product meets the essential requirements of all relevant EU directives.
	WEEE Symbol Separate collection for electrical and electronic equipment.
	Manufacturer Indicates the medical device manufacturer, as defined in IVDR (2017/746).
	In vitro diagnostic medical device Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
	Catalog(ue) Number Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Unique device identifier A unique numeric or alphanumeric code that facilitates tracking and identification of the device

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Chapter 1

Meet Ella

System Overview

Ella™ is a fully automated cartridge-based system that enables researchers to measure biomarkers in multiple sample types. Ella, together with microfluidic technology (Simple Plex™ cartridges), allow for single analyte measurements, the measurement of multiple analytes in parallel (multi-analyte), and also multiplexed measurements. Researchers can also configure Simple Plex cartridges to be unique to their own research.

Using Ella you can:

- Automatically execute an immunoassay protocol
- Automatically acquire and process data
- View and analyze fluorescence and concentration data on a per analyte, per sample basis
- Extract and save fluorescence and concentration information for application-specific analysis



CAUTION: The Ella system is not intended for use in near-patient settings or for self-testing

Specifications

This section describes Ella's specifications, including environmental conditions, electrical ratings, physical conditions, laser classification, and external fusing

TABLE // 02

Instrument Specifications	
Environmental Conditions	For Indoor Use Only Altitude up to 2000 m (6500 ft) Temperature: 18° to 30°C, inclusive Humidity: 15 to 80% RH, inclusive, non-condensing
Storage and Transport Conditions	Temperature: -18° to 50°C, inclusive Humidity: RH ≤ 85% non-condensing
Physical Conditions	Overall dimensions: 37 cm (w) x 54 cm (d) x 26 cm (h) 14.6 in (w) x 21.3 in (d) x 10.2 in (h) Weight: 18.2 kg (40.1 lb)
External Fusing	Main fuse (appliance inlet): 4 A, 250 V; IEC 60127 rated as T4AL 250 V
Electrical Ratings	100-240 V(AC), 300 VA, 50/60 Hz, Class I Installation Category (Over Voltage) II *NOTE: Electrical values listed are nominal*
Electrical Test Specifications	CB Scheme: IEC 61010-1:2010 TÜV SÜD "CUE" Scheme: CAN/CSA-C22.2 No. 61010-1:2012 UL 61010-1:2012/R:2019-07 EN 61010-1:2012/R:2019-07 EN 60825-1:2014 Class 1 Laser Product according to IEC 60825-1:2014 and EN 60825-1:2014 Complies with FDA performance standards for laser products 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

Cautions and Warnings

The following sections describe the safety precautions you should observe when using Ella.

These include precautions for:

- General safety
- Electrical safety
- Laser light safety

General Safety Precautions

CAUTION: Ella's operator should be trained by qualified personnel on the correct operation of the instrument and be aware of the safety issues

Electrical Safety Precautions

This section describes the electrical safety precautions for Ella's electrical connections and fuse, as well as high voltage hazards.

Electrical Connections

Plug Ella into a grounded circuit capable of delivering at least:

- 15 amps for 100-volt to 120-volt power source
- 12 amps for 200-volt to 240-volt power source. See the manufacturer's label on the back of Ella for more information.

Fuse

The primary input fuse holder is on the right side of the back of Ella and contains one 4A, 250V slow-blow fuse. The fuse holder is designed to accept a 5 mm x 20 mm fuse. Replacement fuse specification shall meet the IEC 60127 and be rated as T4AL 250V.

CAUTION: Before replacing the fuse, turn Ella off and disconnect the power cord. If a fuse often requires replacement, Ella could have an electrical problem. Do not use Ella. You could expose yourself to electrical shock. Contact Bio-Techne Technical support for assistance.

High-Voltage Hazard and Precautions

The computer and monitor contain high-voltage electronics. See the computer and monitor precautions before opening the computer or monitor.

CAUTION: Do not remove Ella's main cover; there are no user serviceable components inside and you may be exposed to high voltage.

Laser Light Safety Precautions

CAUTION: Using controls, adjusting, or performing procedures other than those specified herein may result in hazardous laser light exposure.

Ella is a Class 1 laser instrument that houses a Class 3B laser that operates at 640 nm wavelength. Under the specified operating procedures, Ella does not allow operator exposure to laser light. The Ella system's laser design conforms to IEC (EN) 60625-1-2014.

CAUTION: Do not attempt to gain access to Ella's interior through any opening. Exposure to laser light can cause injury. For example, viewing the laser light directly can cause blindness.

CAUTION: Use of controls or adjustments, or performance of procedures other than those specified herein, may result in hazardous radiation exposure.

Please observe the following precautions:

- Do not remove Ella's main cover. There are no user-serviceable components inside and you may be exposed to laser light.
- Do not continue to use Ella if the main cover or cartridge lid becomes damaged and is no longer light-tight. Contact Bio-Techne support immediately to arrange for repair.

Adverse Event Reporting

If you need to report a serious incident which occurred with this medical device, then you shall do so by contacting the manufacturing site (refer to Manufacturer Contact) as well as contacting your national competent authority in which the user and patient are established.

User Qualifications

Personnel who use, maintain, or clean the Ella should be trained in standard laboratory safety practices and should follow those practices when handling the instrument, be fully qualified and trained to operate the Ella system, have read and fully understood the instructions in this user manual, and be familiar with the applicable safety regulations and directives for the use environment.

Installing Ella

Ella requires proper installation and operation qualification from a trained Bio-Techne employee. Ella is not ready for use until after receipt of the signed form from a Bio-Techne employee documenting a successful IQ OQ procedure.

Moving Ella

Ella is a sensitive optical instrument and can be damaged if moved improperly. Dropping may result in damage to the instrument. Always power Ella down prior to moving her. **See "Preparing Ella for Shipment" instructions on page 22** for guidance on preparing Ella for a move.

CAUTION: This product requires a two-person lift. Heavy lifting can cause injury. Use proper lifting techniques.

CAUTION: Do not place Ella near any device that can emit signification vibrations (e.g., a vortexer) as it may interfere with the measurements.

Disposing Ella

Dispose of in accordance with local, regional, national, territorial, provincial and international regulations. Review the Safety Data Sheets (SDS) to determine the safe disposal of materials for your region.

Interconnections: Ella to Computer

NOTE: Only one Ella instrument can be connected and controlled per PC. Multiple instruments cannot be connected to the same PC.

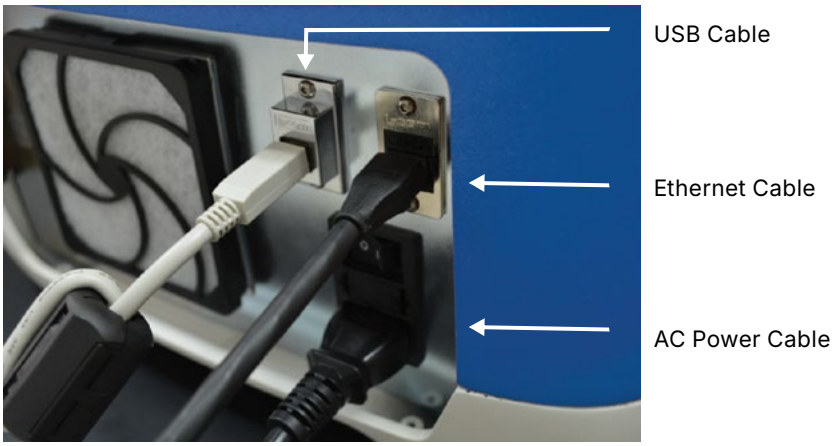
1. AC power cable
   This is used to supply AC power to Ella. The AC power cable shall have an IEC 320 female connector on one end (Ella connection) and a country specific male plug on the other end. Power cables are to be UL listed and CSA certified with amp rating that meets the electrical specification of Ella.

2. Ethernet cable (black)
   This is for communication with the high-speed camera inside the instrument.

3. USB cable
   This is for communication with all other capabilities of the instrument.

FIGURE // 01

Ella Connections

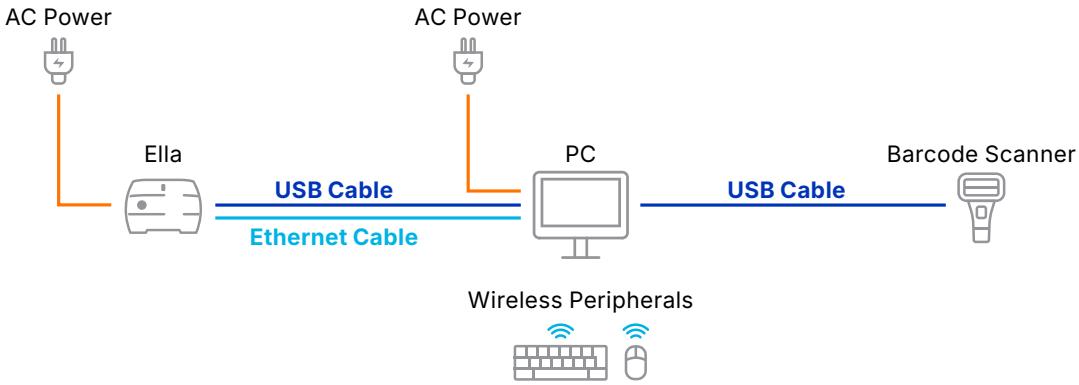


Ella System Interconnections

Figure 02 is a high-level overview of the interconnections between Ella, the PC, monitor, keyboard and barcode scanner. Refer to the specific setup instructions for your Ella and PC.

FIGURE // 02

Ella connection to PC as well as supporting peripherals.



Minimum IT and Hardware Requirements

There are no IT network requirements for Ella. It is not recommended to establish any network connections to Ella. Ella operates as a standalone system and is intended to function independently of a network connection. Any connections to a network, either intra- or inter- net are made at one's risk.

Ella requires no additional hardware to operate. Connecting additional hardware to Ella is not recommended and is done so at one's risk.

IT Security Measures



1. Control physical access to the instrument to prevent unauthorized access
2. Control access to the device's USB port to only trusted removable media

Contacting Customer Service

For customer support or ordering information, contact Customer Service.
For technical support contact Technical Support.

Customer Service	Telephone	1-408-510-5500 1-888-607-9692 (toll free, US and Canada only)
	Email	orders@proteinsimple.com
Technical Support	Telephone	1-408-510-5500 1-888-607-9692 (toll free, US and Canada only)
	Email	support@bio-techne.com
	Web	www.bio-techne.com

Chapter 2

Start Ella

Introduction

Ella is a fully automated cartridge-based system that allows you to perform multianalyte immunoassays with the specificity of a traditional single-plex ELISA (enzyme-linked immunosorbent assay).

Using Ella you can:

- Automatically execute an immunoassay protocol
- Automatically acquire and process intensity data
- View and analyze intensity and concentration data
- Extract and save intensity and concentration information for application-specific analysis

Ella System Components

Ella is comprised of five main components:

1. Ella instrument/reader
2. Barcode scanner
3. Personal computer
4. Runner CE software
5. Verification Cartridge (Simple Plex Cartridges are available separately)

Ella

A main component of the Ella system is a bench top analyzer with no on-board fluidics which significantly cuts down on waste and required preventive maintenance.

Designed with a “load and go” philosophy in mind, Ella controls the microfluidic assay cartridge by precisely manipulating volumes, flow rates, and flow patterns without human intervention. Following the assay portion of a run, Ella automatically performs fluorescence scanning, raw data processing, and calculates RFU (relative fluorescence units) and concentrations on a per analyte, per sample basis. To be used only with supported Ella IVD Assay Kits. A power cable is provided with the instrument.

Bar Code Scanner

The Ella system includes a general purpose, hand-held barcode scanner that is capable of scanning both 1D and 2D barcodes omni-directionally. Every cartridge kit shipped from Bio-Techne is labeled with a data-matrix 2D barcode that contains all relevant cartridge kit data including:

- Lot information
- Biomarker panel information
- Cartridge configuration information

Each cartridge run begins with scanning the cartridge kit barcode so as to provide the user with all the salient cartridge kit information, and the software with the necessary data to perform the cartridge run and raw data processing.

Personal Computer

A PC is included with Ella to allow you to control the system. A USB cable and a network cable are provided to connect with the Ella.

Assay Developer Software

Placeholder section for the assay developer to provide a description of their software.

Verification Cartridge

The Verification Cartridge is provided as a reusable reference necessary for performing an instrument Self Test. See **“Ella Self Test” on page 21** for details. (The Verification Cartridge is a system calibrator)

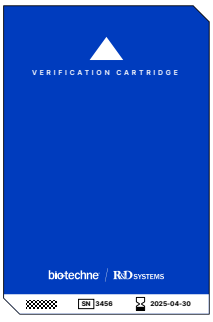
Simple Plex Cartridges and Assays

The ready-to-use, IVD cartridge is available in the 32 sample multi-analyte format (see Figure 03). The cartridge is developed with a panel unique to your research to allow you to scan the barcode, input your samples and buffer into the cartridge, place the cartridge in Ella’s cartridge holder, and run the cartridge. Simple Plex Cartridges and Assays are not included with the Ella system. Use only with cartridges and assay kits labeled for use with the Ella instrument.

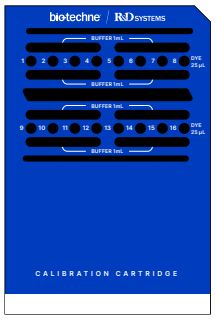
Each cartridge has many sample inlets. Each sample inlet has up to 4 dedicated channels. A single channel contains three Glass Nano-Reactors (GNR), that are functionalized with capture antibody, so you obtain three reportable results for each sample’s analyte. The GNR contains the immunoassay and is based on R&D Systems reagents to ensure high quality and reproducible sensitivity. The collection of GNRs in a given channel, in a given sample inlet, on a given cartridge are the basis of the set of measurements produced when running a Simple Plex Cartridge.

FIGURE // 03

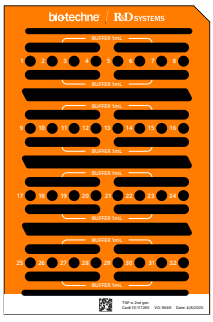
Cartridges that run in Ella.



Verification Cartridge



Test & Calibration Cartridge



32x4 Simple Plex Cartridge

32 Samples, 4 Analytes

CAUTION: Any configuration that does not employ the Runner CE software and supported **IVD** CE-marked cartridges does not conform to the configuration of the **IVD** CE marked system.

Starting and Shutting Down Ella

Follow the procedures in this section which describe how to position, start up and shut down Ella.

NOTE: When positioning Ella, care should be taken so that the back surface will have adequate clearance such that an operator's hand can access the power switch and power supply cable. With operator facing the front of Ella, the power switch and power supply cable are located at the back panel, lower left side.

Starting the System

To Start Ella:

1. Power up Ella.
2. Power up Ella's computer and monitor.
3. Login to PC and start
4. After power up of Ella the status light will illuminate (Figure 04). See Table 3 for a description of the status light.

Powering Up Ella

Press the power switch on Ella's back panel.

Shutting Down the System

To shut down Ella:

1. Shut down Ella's computer
2. Turn Ella off by pressing the power switch on the back panel.

FIGURE // 04

Ella status light.



TABLE // 03

Ella status light indications.

Light Color	Status
Green	Ella is powered and ready for use
Blue	Ella is running a cartridge
Red blinking	An error has occurred (Ella may optionally emit an audible alarm)

Chapter 3

Running Simple Plex Cartridges

Introduction

The following section is for information purpose only. Please refer to the Specification Sheet and product documentation for more information on how to run your cartridge.

Running a Cartridge

To run a cartridge, you'll need:

- Your samples
- Your barcode labeled Cartridge Kit (Figure 05) that contains:
    a. Wash Buffer A
    b. Sample Diluent component(s)
    c. Cartridge

The typical run sequence is:

1. Prepare reagents
2. Prepare cartridge
3. Configure and run with Ella

FIGURE // 05

Cartridge kit.



Boxed Kit



Wash Buffer and Sample Diluent



Cartridge in bag, including label with barcode (circled in red)

Barcode Labels

Kit Label

Found on the outside of the cartridge bag, circled in Figure 05.

Cartridge Label

The cartridge barcode label (see Figure 06) is located directly on the cartridge and is used to track the cartridge to the Kit. This cartridge barcode label is used as a confirmation that the cartridge being run matches the Kit.

Cartridge ID barcodes are found on the cartridge face near the bottom edge as shown in Figure 06.

FIGURE // 06

Cartridge ID Barcodes.



Cartridge ID Barcodes: Full 32×4 cartridge face (left). Detailed zoom view shows cartridge details and barcode (right).

Prepare Samples and Reagents

Plasma (EDTA or Heparin) and Serum Samples

Serum and plasma samples prepared with the protocol recommended on the assay specification sheet, and not containing visible particulate matter, do not require additional centrifugation before use in a Simple Plex assay.

For serum and plasma samples containing visible particulate matter it is recommended to remove particulates by centrifugation and dilute according to the instructions in the Assay Specification Sheets. The method below is designed to preserve sample but may by adjusted as needed based on sample availability and particulate content. The method below simulates the sample preparation for the 1:2 minimum required dilution (MRD) used in most Simple Plex assays. For higher dilution factors serial dilution may be necessary for accuracy.

Centrifugation for Serum and Plasma Samples

1. Aliquot 35 µL of serum or plasma into a microcentrifuge tube.

2. Centrifuge at 8,000-10,000 g for a minimum of 4 minutes.

3. Aliquot 30 µL of the appropriate sample diluent into another microcentrifuge tube.

4. Once centrifugation is complete, remove 30 µL sample taking care not to disturb the pellet at the bottom.

5. Add the 30 µL of centrifuged sample to the 30 µL of aliquoted diluent and mix thoroughly.

6. Pipette 50 µL of the 1:2 diluted sample into the specified cartridge inlet.

Other Specimen Types

Optimal dilutions should be determined by the end user.

Prepare Cartridge

NOTE: When handling cartridges, it is recommended that gloves be worn at all times and the plastic backer be removed only immediately to placing the cartridge into Ella.

Procedure

1. Scan the kit barcode on the outside of the cartridge vacuum bag.
2. Remove the cartridge from the vacuum bag.
3. Scan the cartridge barcode.
4. Pipette volumes into the cartridge in the following order:
    a. Wash buffer as described on your cartridge insert.
    b. Diluted sample matching your cartridge insert.
5. Peel off the protective lining from the bottom of the cartridge.
6. Place the cartridge into Ella's cartridge holder.

    NOTE: After removing the lining, use caution to not touch the bottom of the cartridge or place it on any surface.

7. Close the cartridge clamp and lid.

The sequence for preparing a cartridge is illustrated in Figure 07.

FIGURE // 07

Step-By-Step Visual Guide to Preparing a Cartridge to Run in Ella.

A. Prepare the Cartridge



1. Scanning the barcode.



4. Loading buffer.



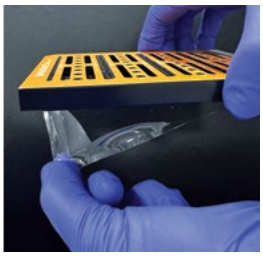
2. Removing cartridge protective casing.



5. Loading sample.



3. Scanning cartridge barcode for confirmation (optional).



6. Removing protective lining/backing.

FIGURE // 07

Step-By-Step Visual Guide to Preparing a Cartridge to Run in Ella (continued).

B. Load Cartridge into Ella



1. Ella open door.



2. Opening cartridge clamp.



3. Ella open door and clamp.



4. Loading cartridge in Ella.



5. Closing cartridge clamp.



6. Closing door.

CAUTION: Take care to not spill liquid into the Cartridge Nest

Simple Plex Runner CE

A headless, non-interfacing version of Runner CE is available in the hidden icons on your desktop taskbar (see Figure 08). This can be used to modify Runner settings, move the Ella stage, or export diagnostic or other data files.

FIGURE // 08

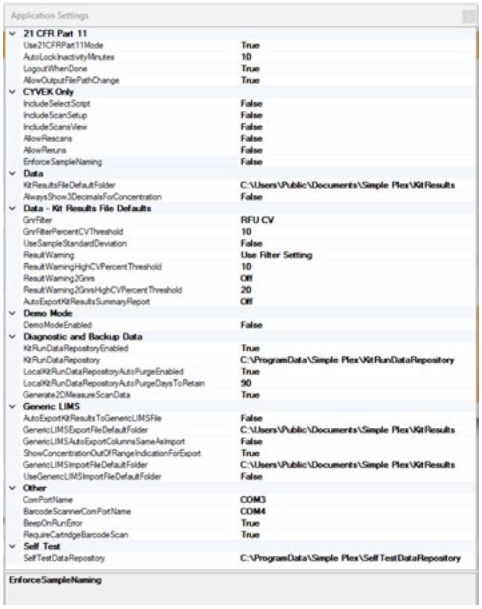
Simple Plex Runner CE icon.



Clicking Settings > Application from the menu will display the Settings Dialog as shown in Figure 09. Clicking on a row in the settings dialog will display a detailed description of the selected item at the bottom of the dialog. These descriptions are provided in Table 04 for reference. If changes are made the Save button will be enabled.

FIGURE // 09

Simple Plex Runner CE settings dialog.



Clicking Settings > Analyzer > Description from the menu will display a dialog box that can be used to rename the Ella instrument (Figure 10). The instrument name defined here is written to the instrument's on-board software and will persist even if the computer is changed. This name will be associated with all .cydat files produced by the instrument.

FIGURE // 10

Renaming Ella instrument in Simple Plex Runner CE settings.



TABLE // 04

Runner CE Settings.

Parameter	Description
Use21CFRPart11Mode	Determines whether or not to use 21 CFR Part 11 support (logins, audit trails, data encryption, etc.). 21 CFR Part 11 support must be activated for this setting to take effect.
AutoLockInactivityMinutes	Determines the length of a period of inactivity before the application screen automatically locks when in 21 CFR Part 11 mode. Set to 0 to disable this feature.
LogoutWhenDone	When true (default), the current user is logged out after Done is selected from the Kit Results panel. When false, the current user remains logged in and the application proceeds to the New Kit panel.
AllowOutputFilePathChange	When false, the kit results file name and location cannot be changed. This also applies to the generic LIMS export file (if enabled). This setting only applies when in 21 CFR Part 11 mode.
KitResultsFileDefaultFolder	The common directory in which to output the kit results file (*.cydat extension).
AlwaysShow3DecimalsFor Concentration	Always show 3 decimals for concentration. The default is for the number of decimals displayed to be based on how many significant digits there are in the measurement. This setting also changes how concentration values are exported.
GnrFilter	The filter used to select the resulting GNRs. None indicates select all GNRs found. RFU and Concentration CV performs a GNR outlier removal if the percent CV for all three GNRs is above the specified threshold.
GnrFilterPercentCVThreshold	The percent CV threshold used by GnrFilter.
UseSampleStandardDeviation	Preference used for calculating percent CV. If checked, sample standard deviation is used. Otherwise, population standard deviation is used (the default).
ResultWarning	This setting applies to all cartridge types except 32x8 and 72x2. Determines if an analyte result should be shaded light pink in the Results Summary View when the relevant CV percent is greater than or equal to the specified threshold. If Use Filter Setting is selected, the applicable CV and threshold are determined from the GnrFilter and GnrFilterPercentCVThreshold settings. The default value is UseFilterSetting.
ResultWarningHighCVPercent Threshold	The percent CV used by ResultWarning. The default value is 10.
ResultWarning2Gnrs	This setting only applies to cartridge type 32x8 and 72x2. Determined is an analyte result should be shaded light pink in the Results Summary View when the relevant CV percent is greater than or equal to the specified threshold. The default value if Off.
ResultWarning2GnrsHighCV PercentThreshold	The percent CV used by ResultWarning2Gnrs. The default value is 20.

TABLE // 04

Runner CE Settings.

Parameter	Description
AutoExportKitResults SummaryReport	Determines whether to automatically export a kit results summary report at the end of a run and whenever the kit results file is saved. The location and name of the file will be the same as the kit results file (.cydat or .ecydat) except that the file extension will be changed to .pdf
DemoModeEnable	Application will operate in demo mode and does not require a connected Ella system.
KitRunDataRepositoryEnabled	Determines if the Kit Run Data Repository (KRDR) is enabled. The KRDR includes all diagnostic run data for a kit as well as a backup of the kit results file. If disabled, kit result file recovery will not be possible.
KitRunDataRepository	The root directory in which to store all diagnostic run data for a kit as well as a backup of the kit results file. Folders are organized by date and then by kit ID with run time.
LocalKitRunDataRepository AutoPurgeEnabled	Determines if older data in a local Kit Run Data Repository (KRDR) is automatically purged. Auto-purge functionality is not applied to a KRDR on a network drive or share
LocalKitRunDataRepository AutoPurgeDaysToRetain	Determines the number of days of data to retain if LocalKitRunDataRepositoryAutoPurgeEnabled is set to true. The default number of days to retain local Kit Run data is 90 days.
Generate2DMeasureScanData	Generates additional diagnostic data for measure scans. Will increase space used by the Kit Run Data Repository by as much as 25%. The default is true.
AutoExportKitResultsTo GenericLIMSFile	Determines whether or not to automatically generate a generic LIMS export file at the end of the run.
GenericLIMSExportFileDefault Folder	Default directory location in which to output the auto-generated generic LIMS export file (*. csv).
GenericLIMSAutoExport AppendSampleAggregateData	When true, sample aggregate data is appended to the end of the automatically generated LIMS export file.
GenericLIMSAutoExport ColumnsSameAsImport	Determines whether or not the automatically generated generic LIMS export file uses the same columns as the import file (if available). Otherwise the default format is used.
ShowConcentrationOutOf RangeIndicationForExport	When true, out of range concentration values for generic LIMS exports are shown as the dilution factor scaled LLOQ or ULOQ with a prefix of '<' or '>' (such as '<2.00' or '>5000'). Otherwise if false, out of range concentration values are left blank
GenericLIMSImportFileDefault Folder	Default directory location for choosing the generic LIMS import file (*.csv).
UseGenericLIMSImportFile DefaultFolder	Determines whether or not to use the default directory specified in the GenericLIMSImportFileDefaultFolder. If the default directory is not used then the directory will default to the most recent used.
ComPortName	Communication port to instrument.
BarcodeScannerComPortName	Communication port to barcode scanner.
BeepOnRunError	Indicates if Ella should beep when an error condition is encountered during a run to attract the attention of the user.
RequireCartridgeBarcodeScan	Requires the cartridge barcode to be scanned on New Kit panel.
SelfTestDataRepository	The root directory in which to store all self test data. Folders are organized by Ella number and then by test date and time.

The Data Repositories

Simple Plex Runner CE software is configured to store the data associated with every kit and self test run. The data is placed into data repositories that are organized by date and run.

Kit Run Data Repository (KRDR)

- Provide for backup/recovery of CYDATs for every kit run.
- Provide diagnostics data in the unlikely event of system issues.

Self Test Data Repository (STDR)

- Provides a retrievable history of all Self Test runs.
- Provides diagnostics data in the unlikely event of system issues.

The location of the repositories may be configured using the Simple Plex Runner CE application settings.

Recovering a CYDAT

If you are using the KRDR and have misplaced or lost a CYDAT from a run, you may recover that Kit's CYDAT using the Recover Kit Results option located in Simple Plex Runner CE software under File > Recover Kit Results. Selecting this option will locate the specified Kit CYDAT in the repository and make a copy of it to the desired storage location.

Browsing/Retrieving the Self Tests

By selecting Self Test History located in Simple Plex Runner CE software under Tools > Self Test History, you can view a list of all Self Tests in the repository organized by Ella system and date. You also have the option to retrieve/save one or more Self Test Reports, and any Self Test's results details may be viewed.

Chapter 4

Maintaining Ella

Introduction

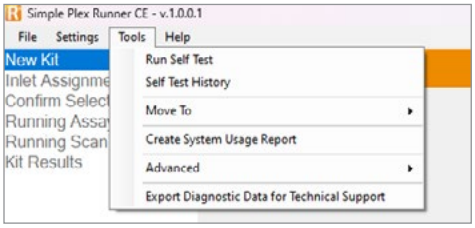
This chapter describes maintenance and service tasks for Ella. Refer to **Chapter 3** for accessing Simple Plex Runner CE.

Using the Simple Plex Runner CE Tools Menu

The Tools menu (Figure 11) is used to move the XY stage to predefined locations (must be done with the clamp and lid closed), and export diagnostics system logs to a compressed file for use by Technical Support.

FIGURE // 11

Simple Plex Runner CE Tools menu.



Ella Self Test

The Ella Verification Cartridge enables the system to perform a series of diagnostic tests that ensures the instrument is running properly. The Runner CE software supports the mechanisms to run a self-test, but the GUI must be designed by the Assay Developer to perform the test. For information or assistance on developing a GUI please contact Bio-Techne.

The results will be tabulated under the system log files. These results provide valuable troubleshooting information to Bio-Techne personnel in the event system maintenance is required. Accordingly, we advise that the Verification Cartridge is run weekly to create a running history of system performance.

Your Verification Cartridge was provided in a storage box as shown in Figure 12 A and B. Whenever handling your Verification Cartridge, wear gloves to avoid getting it dirty. The Verification Cartridge features a surface to seal Ella's pneumatic interface, and an auto-fluorescing surface as an RFU reference.

FIGURE // 12

Ella Verification Cartridge.



A.
Verification Cartridge box.



B.
Cartridge in box, barcode up.

CAUTION: Do not use a Verification Cartridge past its use-by date. This date is displayed either on the cartridge itself or on its Calibration Certification

Using the Move To Commands in the Simple Plex Runner CE Software Menu

Open Simple Plex Runner CE

Objective Window Position

The Tools > Move To > Objective Window Position command is provided to move to the correct position for removing or installing the objective window that is threaded into the heater plate.

Cartridge Load Position
The Tools > Move To > Cartridge Load Position command is provided to return to the load position if you have previously moved to the objective window position or ship position. It is also provided in the highly unlikely event that the instrument does not return the stage to the load position. If this occurs, please contact Bio-Techne Technical Support.

Ship Position
The Tools > Move To > Ship Position command is provided in the event that Ella is to be packed for shipment.

Preparing Ella for Shipment

To prepare Ella for shipment:

1. Close the clamp and the lid

2. Click Tools > Move To > Ship Position on the Simple Plex Runner CE menu.

3. Wait for the Moving to shipping position pop-up dialog to close.

4. Shut Ella down:

    a. Close Simple Plex Runner CE either by clicking File > Exit from the menu or Close (X) in the upper-right corner of the application window. Close software. Shut down Ella's computer.

    b. Turn Ella off by pressing the power switch on the back panel.

Exporting System Logs

Open Simple Plex Runner CE

Clicking Tools > Export Diagnostic Data for Technical Support is used to export diagnostics information to a compressed zip file if requested to do so by Technical Support.

Maintenance and Cleaning

Ella requires a yearly preventative maintenance carried out by a Bio-Techne representative. Otherwise, no user calibration is required. That said it is recommended to perform periodic inspections of the system. Take note of any damage to Ella's enclosure or the insulation of associated cables. If the enclosure damage indicates that protection of the electronics from moisture intrusion or laser light is compromised or that compromise is imminent, or if the cable damage suggests that cable electrical shorts or opens are imminent, then take the appropriate corrective action depending on the situation— up to and including removal of the product from service until repairs have been performed. Contact Customer Support for information regarding repairs and spare parts.



CAUTION: Do not use the system if power cable is damaged in any way

Materials required to properly maintain, and clean Ella are as follow:

1. 10% household bleach solution

2. 70% ethanol solution

3. Mild detergent

4. Clean, lint free cloths

5. Disposable lens wipes (optional)

Fan Filter Cleaning and Maintenance

Ella must always receive adequate ventilation for cooling. Proper cooling is required for Ella to meet specifications, and to avoid overheating. Periodic instrument maintenance should include inspection and cleaning of the fan filter every six months.

To clean the filter:

1. Remove the fan guard and fan filter.
2. Vacuum the fan filter to clean it.
3. If necessary, replace worn-out or damaged fan filters (PN 541401).
4. Reinstall the fan filter and fan guard.

External Surface Cleaning

Turn off and unplug Ella prior to cleaning. If required, wipe down all of Ella's external surfaces exterior only with a damp non-abrasive cloth that may be moistened with mild detergent. Additionally, if accessories, like the USB cable or barcode scanner require cleaning, you may do so, again using only a damp non-abrasive cloth that may be moistened with a mild detergent.

⚠ CAUTION: Do not clean the exterior surface with ethanol.

Cartridge Nest and Objective Window Cleaning

Cartridge Nest

If required, Ella's cartridge nest can be cleaned using a non-abrasive lint-free wipe dampen with 70% ethanol.

⚠ CAUTION: When cleaning the nest, care should be taken not to contaminate the objective window.

Objective Window

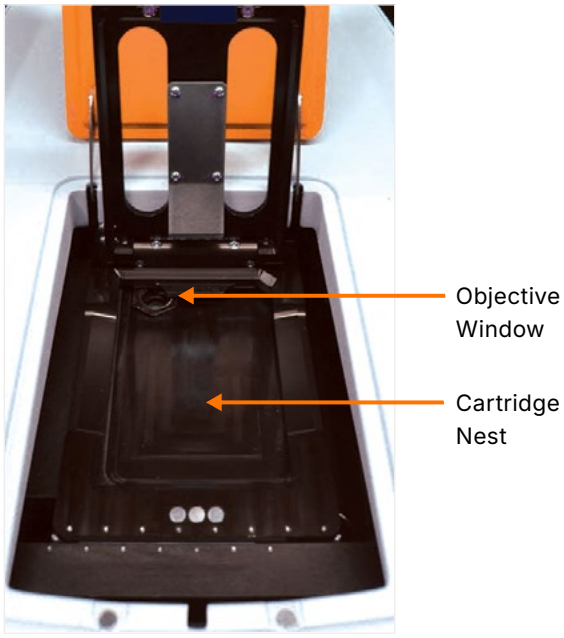
Care should be taken to ensure the objective window is clean. If cleaning is required, use a clean, non-abrasive lint-free wipe dampened with either a mild detergent, or 70% ethanol until the window is 'streak free'. Multiple one-time use wipes are recommended to ensure the objective window is cleaned (streak- free), see Figure 13.

⚠ CAUTION: When cleaning the Objective Window

- Do not use bleach
- Do not touch the Objective Window other than with the non-abrasive cloth

FIGURE // 13

Cartridge Nest and Objective Window.



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