LUCERNO DYNAMICS®

Ellexa® 3 Software

Operator's Manual

Lucerno Dynamics, LLC
140 Towerview Ct.
Cary, NC 27513
1-919-371-6800
www.lucerno.com

CMC Medical Devices & Drugs, S.L.
C/Horacio Lengo N 18
CP 29006, Malaga-Spain

CMC Medical Devices Ltd.
Office 32 19-21 Crawford Street
London, UK, W1H 1PJ

ACRA Regulatory Services Pty Ltd
7 / 84 Poinciana Avenue, Tewantin
QLD, Australia 4565

Resources (M) Sdn. Bhd.
No. 155, Jalan TU3
Taman Tasek Utama
75450 Ayer Keroh, Melaka, Malaysia
MDA Reg. No. GA4599423-115988

(01)00850014578152

U.S. Customer Support:

For technical support please contact Lucerno during business hours EST by calling (919)371-6800 x200 or via email at support@lucerno.com.

Outside the U.S. Customer Support:

Please contact Lucerno's authorized distributor for technical support. Contact details can be found on Lucerno's website https://lucerno.com/global-partners/.

TABLE OF CONTENTS

ABOUT THIS MANUAL

Please read these instructions completely in order to use the software safely and effectively. If you have any questions or concerns, please contact Lucerno or your local distributor.

For instructions regarding operation of the Lara System itself, please read the “Lara Operator’s Manual”.

In this manual, you will see this Attention symbol used where there is information for instructions that are particularly important.

Instructions that require you to interact with the system are shown in a shaded area.

SYMBOLS AND DEFINITIONS

You may encounter the following symbols in this manual and on product labeling.

 Caution

 Refer to the Operator's Manual

 Standby Power

 Type BF Applied Part

 Manufacturer Information

 Date of Manufacture

 SN Serial Number

 REF # Product Model

 Temperature Range (Storage or Shipping)

 Relative Humidity Range (Operating)

 Keep Away from Sunlight

 Keep Dry

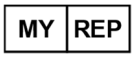
 Radioactive Materials

 Waste Electrical and Electronic Equipment (WEEE)

 EC REP Authorized Representative in the European Community

 UK REP Authorized Representative in the United Kingdom

 Australian Sponsor Authorized Sponsor in Australia

 MY REP Authorized Representative in Malaysia

 Complies with EU Medical Device Regulation

 MD Medical Device

 UDI Unique Device Identifier

INTENDED USE

The Lara System by Lucerno Dynamics is intended to dynamically assess the presence of a radiopharmaceutical in a patient's organ or body region as part of a nuclear medicine procedure. The system is indicated for use as a quality control tool to help assess whether a radiopharmaceutical remains near the administration site rather than circulating in the vascular system. The system is also indicated for use as a tool to help evaluate the biological clearance of a radiopharmaceutical. Additionally, the system is indicated for use as a quality assurance tool to monitor, evaluate, and help improve the radiopharmaceutical administration process.

The Lucerno Dynamics Ellexa Software ("LD Software"), discussed in this manual, allows a user to view and store the information recorded by the Lara System.

INTENDED LOCATION AND USERS

The LD Software is designed to be used by nuclear medicine physicians, nuclear medicine technologists, and other medical staff associated with a nuclear medicine center after they have been trained on the use of the Lara System.

INTENDED PATIENT POPULATION

The Lara System is indicated for use with any patients receiving a radiopharmaceutical as part of a nuclear medicine procedure.

SERIOUS INCIDENTS

For serious incidents concerning this device, notify Lucerno and, if applicable, your Competent Authority.

PRECAUTIONS

The Lara System is designed to be safe and reliable. However, the following points must be taken into consideration to ensure patient and operator safety as well as longevity of the device.

WARNING: No modification of this equipment or software is allowed.

SYSTEM REQUIREMENTS

Please ensure that your computer meets the following system requirements:

- Operating system: Microsoft Windows 10 or 11
- Microsoft .NET Framework version 4.6.2 or later
- Browser: current versions of Chrome, Firefox, or Edge

ABOUT THE LUCERNO DYNAMICS ELLEXA SOFTWARE

The Lucerno Dynamics Ellexa Software is a component of the Lara System and consists of two separate applications – the Ellexa Explorer and the Ellexa Web Application. For complete instructions regarding operation of the Lara System, refer to the Lara System Operator's Manual found online at scans.lucerno.com/ifu.

The Ellexa Explorer (Figure 1) is an application that transfers scan data from the Reader to your PC. It displays a time-activity curve (TAC) of the data, giving you timely feedback regarding the presence of a radiopharmaceutical near the administration site.

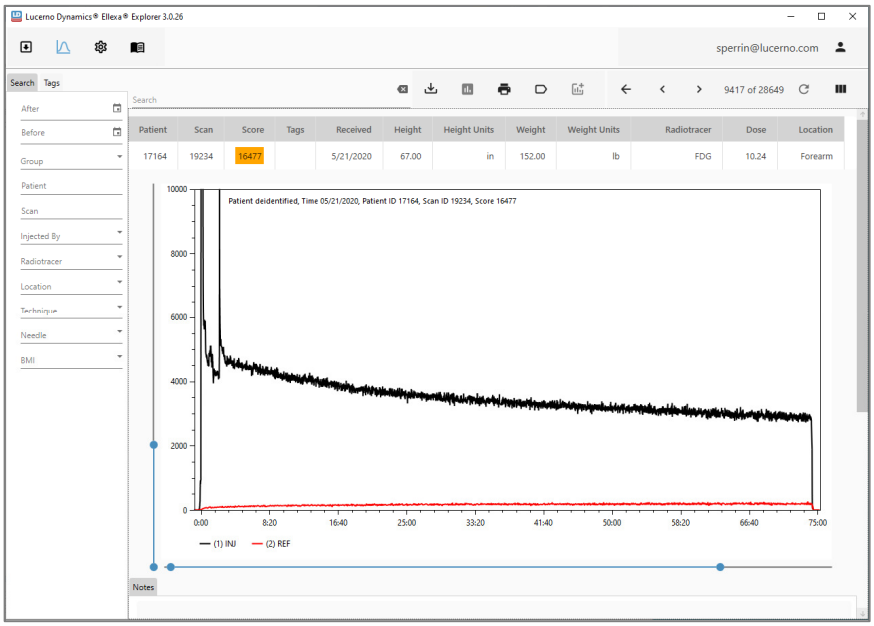


Figure 1 Lucerno Dynamics Ellexa Explorer

The Ellexa Explorer collects information about critical factors that may affect an administration procedure. This information, along with the scan data, can be reviewed in the Ellexa Web Application (Figure 2) by authorized users. The Web Application also helps to identify trends in the quality of a site's radiopharmaceutical injection procedures.

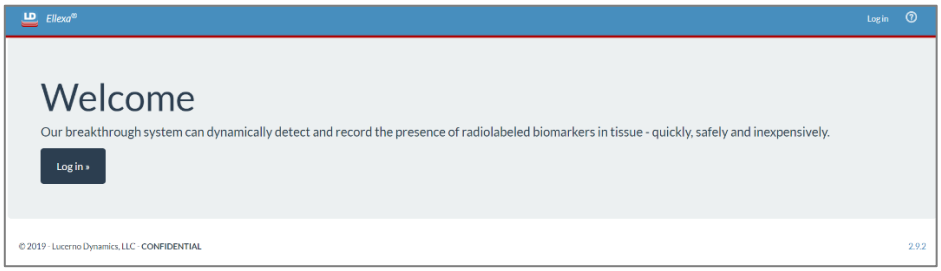


Figure 2 Ellexa Web Application

ABOUT THE LARA SCORING SYSTEM

The Lara System includes a scoring system which provides an assessment of the quality of a bolus injection for certain isotopes. A TAC's score reflects the likelihood that an expert observer would classify a case to be infiltrated. To develop the scoring system, numerous TACs were manually interpreted and classified. Algorithms were developed to quantify those features of the TACs which were examined during manual classification. The outputs of these algorithms, referred to as "scan metrics", are discussed in the Site Summary section, below. Finally, a statistical regression analysis was performed to select the weights that are applied to each metric in order to calculate a score.

By aggregating and analyzing scoring data, users may have the opportunity to assess and improve the injection procedures which are used at their site. See the Site Summary section, below, for more information.

The manual classification process was developed after analyzing over 1,700 human, canine, and murine TACs over 5 years. The process was informed by literature reviews, discussions with experienced, board-certified nuclear medicine physicians and physicists, and by testing with phantom models. Multiple examples of ideal and infiltrated injections (as assessed in static PET images) were considered.

TACs for ideal bolus injections show that activity at the injection site peaks immediately after administration, before rapidly declining to reference arm levels (Figure 3). In contrast, TACs for non-ideal bolus injections (such as that in Figure 1) indicate that radiotracer is present at the injection site for a much longer period of time.

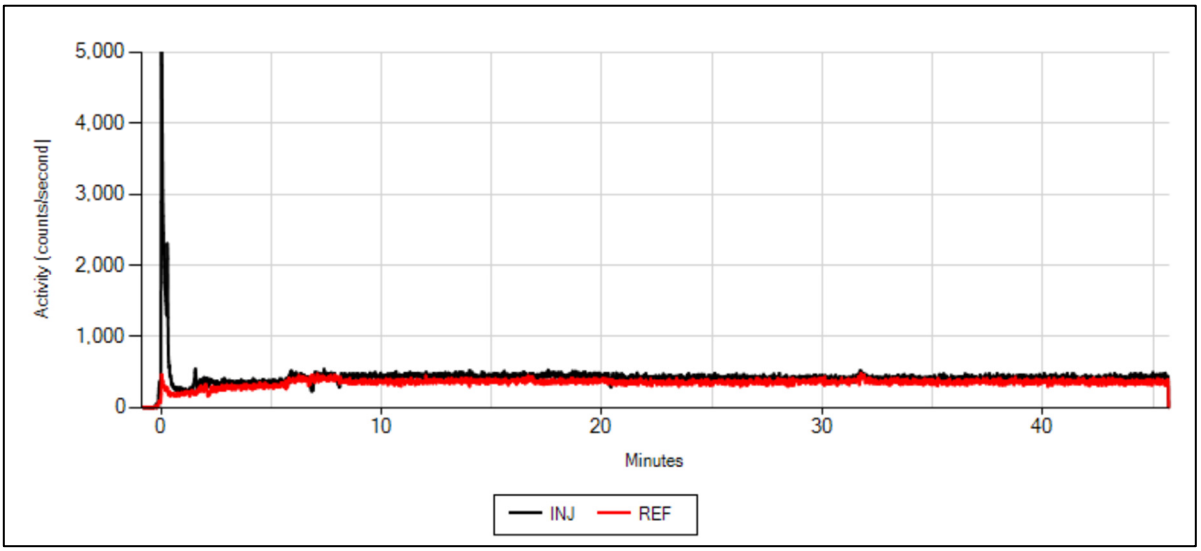


Figure 3 Ideal Lara Time-Activity Curve

The manual classification process considered the following factors:

- radiopharmaceutical and net administered dose
- patient height and weight
- administration location
- side of the patient's body on which the administration was performed (activity in nearby organs may contribute to TAC counts)
- shape of the injection TAC as the bolus passed the Sensor
- absolute injection TAC counts (considered at various points during the uptake period)
- area under the curve (AUC) ratios between injection and reference Sensor TACs, which are compared at various time intervals.

The shape and amplitude of a time-activity curve depends on the proximity of the Sensors to an infiltration. Please refer to the Lara System Operator's Manual for instructions on the placement of Sensors.

Scores are meant to bring attention to potential issues with an injection. Clinical decisions should be made based upon all available information including consideration of patient pathology, review of associated nuclear medicine images, and an understanding of how the Lara device was used.

SYSTEM SETUP

This section describes how to set up the LD Software for the first use.

This section assumes that Lara hardware has already been connected to your PC. For complete instructions detailing this setup, please refer to the Lara System Operator's Manual.

USER ACCOUNTS

You must have an account with Lucerno to use the software. For each installation site, Lucerno will provide at least one user account which can be used to log in to the software. This user may in turn create accounts for other users at the site.

User IDs for accounts will usually be a work email address.

To obtain an initial user account, please contact Lucerno or your local distributor.

SOFTWARE INSTALLATION

The Ellexa Explorer application must be installed on a PC to transfer measurement data from a Reader.

System administrator rights may be required to install the Ellexa Explorer.

1	Use a web browser to log in to the Ellexa Web Application help page.
2	Under "Download Software" select "LD Explorer Installer" to download the installation program named ExplorerSetup.exe.
3	After the download has completed, run the "ExplorerSetup.exe".
4	Windows will install the Ellexa Explorer software. After the installation is complete, there will be an icon to launch the "Ellexa Explorer" in a "Lucerno Dynamics" folder in the Windows Start Menu.

If you need assistance with the software or user accounts, please contact Lucerno or your local distributor.

ELLEXA EXPLORER

1	Launch the Ellexa Explorer by selecting “Ellexa Explorer” from the “Lucerno Dynamics” folder in the Windows Start Menu.
2	When the **Log in** window opens, enter a Lucerno Dynamics ID (most likely your work email address) and password. If log in is successful, the **Ellexa Explorer** window (Figure 4) will become active.

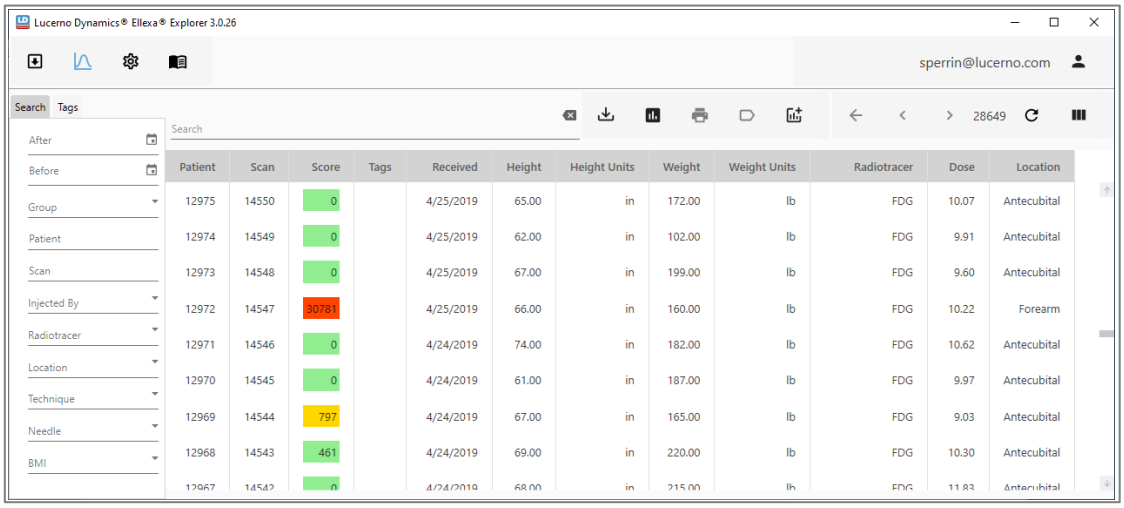


Figure 4 Ellexa Explorer Scans view

1	In the upper left corner of the Ellexa Explorer are buttons which will navigate to various views.  Download – Transfer data from a Lara Reader  Scans – Review Lara scans  Real-Time Visualization  Settings – Configure the Ellexa Explorer  Instructions For Use
2	The Ellexa Explorer opens to the “Scans” view which lists the Lara scans that have been collected by an organization. To view the time-activity curve for a Lara scan (Figure 1), double-click a row in the list.
3	You can search for scans which match certain criteria using the Search Panel to the left of the scan list. You can also enter search queries manually in the Search input above the list. See the section in this document titled “Search Queries” for information about the search query syntax.

REAL-TIME VISUALIZATION

Using the Ellexa Explorer, Lara data can be visualized in real-time as the administration is being performed.

When a Lara Sensor Docking Station is connected to a PC for Real-Time Visualization, a medical-grade USB isolator is required to protect patients from unacceptable risk of electric shock.

1	Configure the Lara hardware for Real-Time Visualization in accordance with the Lara Operator’s Manual.
2	Make sure the Lara Reader is seated in the Sensor Docking Station and the Docking Station is connected to the PC using a medical grade USB isolator.
3	Switch to the “Real-Time Visualization” view in the Ellexa Explorer.
4	In the panel on the left, select the Lara Reader and radiotracer from the drop-down lists.

5	Click “Start” to begin streaming live Lara data. The graph will update once per second. See Figure 5.
6	The Lara Reader will continue to operate as normal – data is still saved to its internal memory and real-time counts are still displayed on its screen (if enabled).
7	You can stop streaming real-time data by clicking the “Stop” button in the panel on the left. Clicking “Stop” will not stop the Lara Reader from recording data; it will only stop the Real-Time Visualization graph.
8	If you switch to any other view within the Ellexa Explorer, the Lara Reader **will** stop recording data.

Real-Time Visualization does not save the Lara data to your PC, you must still transfer the data from the Lara Reader as normal.

When using Real-Time Visualization, you still must transfer the recorded data to your PC using the “Download” view. See the Data Transfer Procedure on page 15 for further instructions.

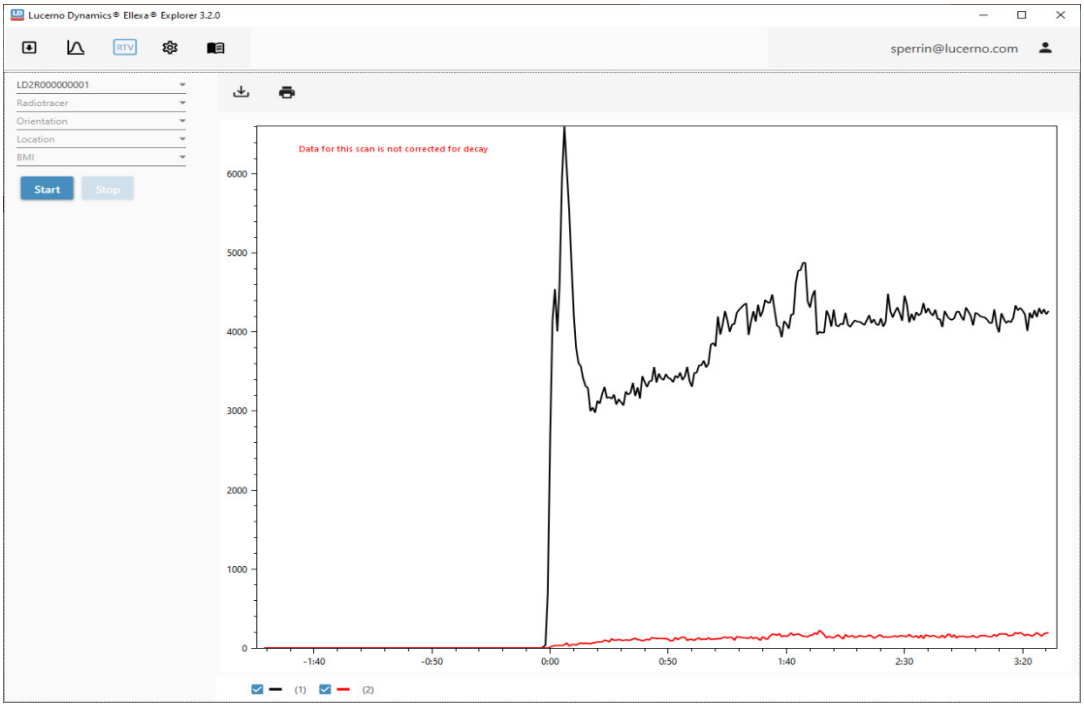


Figure 5 Real-Time Visualization View

DATA TRANSFER PROCEDURE

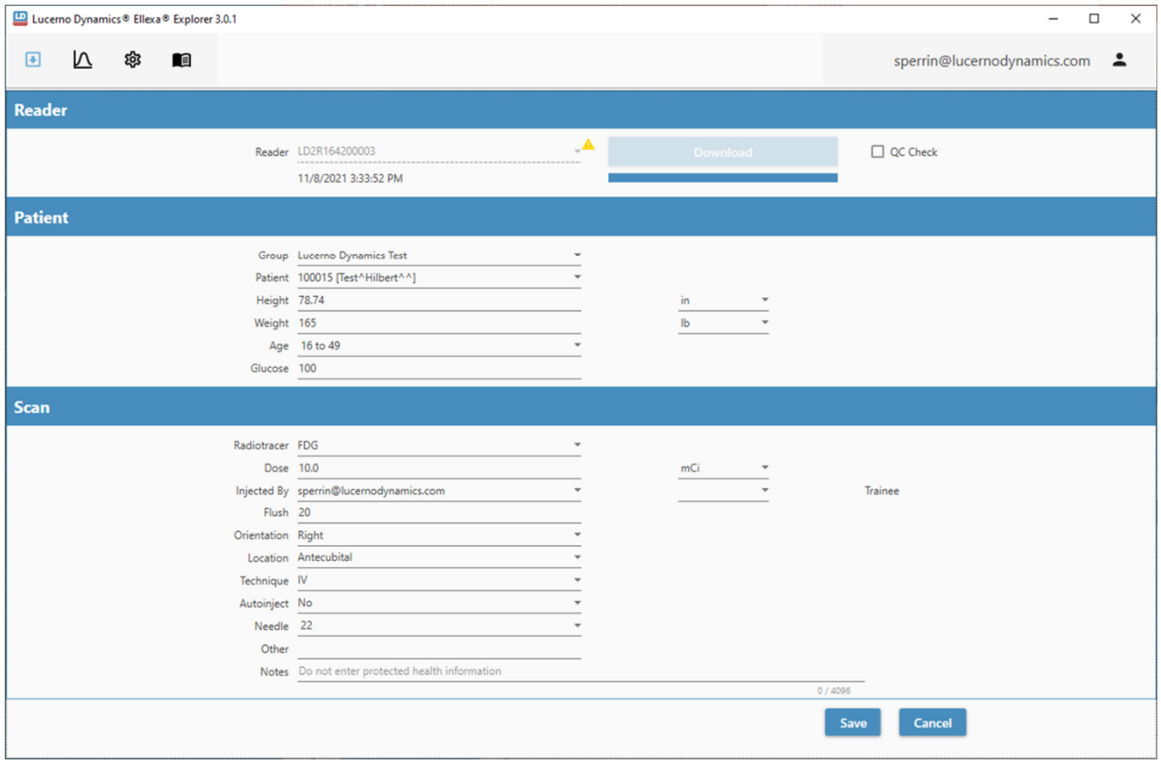


Figure 6 Ellexa Explorer Download view

After acquiring scan data on a Reader, use the following instructions to transfer the scan data to your PC for review.

1. Make sure the Lara Reader is seated in the PC Docking Station and the Docking Station is connected to the PC with a USB cable.

   Select the “Download” button in the upper left corner of Ellexa Explorer to open the Download view (Figure 6). If a Reader is attached to the PC, it will appear in the Reader field near the top of this window. If multiple Readers are attached, select a Reader from the Reader dropdown list. Readers in the list are identified by their serial number, visible on the display of the Reader.

   When a Reader is selected, its backlight will turn on. If the selected Reader has scan data available for download, the time of the scan will display beneath the Reader and the Download button will become enabled.

2. After selecting a Reader, click the Download button to begin transfer of data from the Reader.

3. While data is being transferred, enter additional information about the patient and procedure in the remaining fields. The “Notes” field can be used to document any other information. If required information is missing, a red icon will appear next to that input.
4. When all information has been entered, click the Save button.
5. Scan data and procedure information is now stored in the Web Application for further review.

Enter all data accurately.

Some fields in the Ellexa Explorer window may be disabled and therefore will not be displayed. For information about how inputs can be configured, please refer to the Ellexa Web Application section.

Some fields in the Ellexa Explorer window may be required and are highlighted. Data cannot be saved before this information has been entered.

Do NOT enter protected health information (PHI) in the Notes field.

SCAN DATA REVIEW

After a download, Ellexa Explorer will automatically display a graph of the scan data in the **Scan Data View** window (Figure 1). Directly above the graph is a menu with several buttons.

- **Download** – Save a copy of the time-activity curve data, either as a graph (.png) or raw sample data (.csv)
- **Print** – Print a copy of the graph
- **Tag** – Add a tag to the scan
- **Edit** – Edit the metadata for the scan. NOTE – you must be a superuser to edit scan metadata.

Additional buttons enable navigation between scans.

- **Return to list** – Return to the Scans view with a summary of all scans
- **Go to previous scan** – Navigate to the previous scan in the list
- **Go to next scan** – Navigate to the next scan in the list
- **Refresh** – Update the scan list with the newest scans
- **Select Columns** – Identify the columns which are viewable in the scan list

To magnify the graph, position the mouse pointer over the graph and roll the mouse scroll wheel. The smaller graph in the upper right corner displays the complete TAC data.

Included with the data for each scan is a “Score” metric which provides a composite assessment of the quality of the injection. Scores may not be available for all radiopharmaceuticals or procedures. For a complete description of the metrics, please refer to the information at the Lucerno Help page.

A site may request that the **Scan Data View** window be temporarily disabled as part of a blinded baseline assessment in a quality improvement study.

PERFORMING A SENSOR QC CHECK

Lucerno recommends that Quality Control (QC) checks be performed for every Lara Sensor on a periodic basis. To learn how to collect data from a Sensor, please see the section titled “Sensor QC Check” in the Lara System Operator’s Manual.

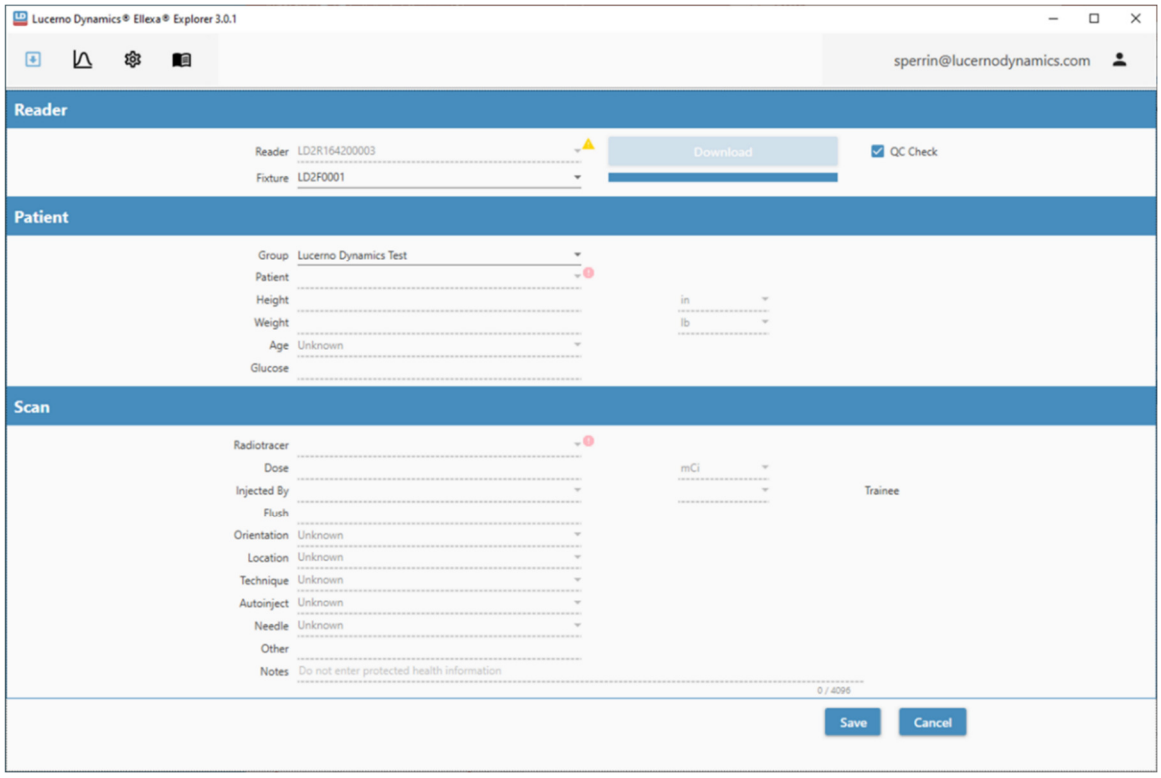


Figure 7 Downloading QC Check data

After QC check data has been collected in the Reader, the data can be analyzed automatically by the Ellexa Explorer.

1	Place the Reader in the PC Dock and start Explorer. Navigate to the **Download** view
2	Select the desired Reader from the **Reader** dropdown and select the **QC Check** box.
3	Type the serial number for the fixture which was used to perform the check. If the fixture has been used previously, its serial number should already be present in the drop-down list.
4	Select **Download** to transfer data from the Reader. Then select the name of the group which is using the Sensor(s) being analyzed.
5	When the data transfer is complete, the **Save** button will be enabled. Select **Save**.
6	Results of the constancy check appear in the **Sensor QC Check Status** window (Figure 8). For each Sensor, there is an indication of whether the QC check was acceptable or not. If not acceptable, there will be a message indicating the reason. The Counts column has the average counts per second recorded by the sensor during the check. The Error column has the difference between counts for this check and the baseline (initial) check. Chi Square is a test of the likelihood that the data acquired during the check came from a correct source. For a check to be considered valid, this value must be between 0.05 and 0.95.
7	For Sensors which are not acceptable, Lucerno recommends that the QC check procedure be repeated to confirm the result. Upon a second unacceptable result, contact Lucerno or your local distributor for assistance.

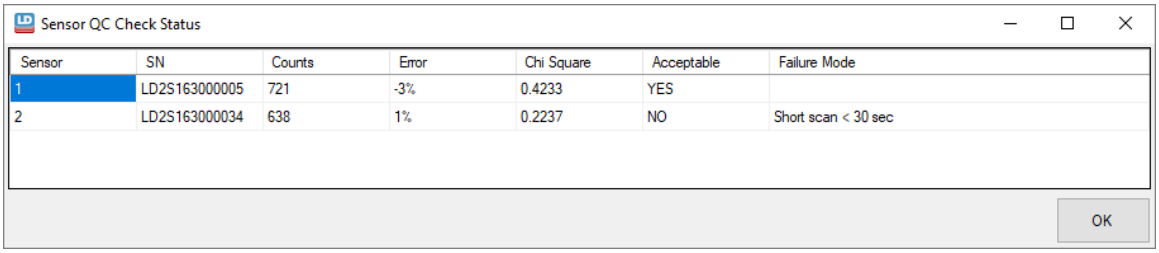


Figure 8 Sensor Constancy Status window

QC check results are valid for 30 days by default. To change the validity period for your site, please contact Lucerno or your local distributor.

If a Sensor has not passed a QC check within the validity period, a user downloading a scan from that Sensor will see a yellow icon beside the Reader input (as in Figure 7). If the user chooses to save the scan, the scan will be processed normally.

It is critical that you enter the correct fixture Serial Number in the Fixture dropdown list.

SCANS VIEW

Scan information can be reviewed in detail in the Scans View (Figure 4).

1	The Scans View displays a list of all scans that are available for review. By default, scans are sorted by Received Date. The scans' sort order can be changed by clicking on the header ("Patient", "Scan", "Score") at the top of each column. To synchronize this list of scans with the server, select the refresh button ↻. This button will appear blue when newer scans are available on the server.
2	The Search panel provides a straightforward way to search for scans matching specific criteria.
3	The Tags panel displays a list of tags which users have previously applied to scans. Clicking a tag in this panel will cause the list of scans to be filtered, displaying only those scans with this tag. The "Score" tags will select scans with scores between the values indicated by the tags.
4	The Search field can be used to search for scans containing particular text. All available data for the scan will be searched, including data in columns which are not currently visible. More information about entering search queries is provided in the section titled "Search queries".
5	Columns can be made visible or hidden using the column selector. To open the column selector, click on the 3 vertical bars ||| in the upper right of the screen.
6	To view details for a specific scan, click anywhere on the row corresponding to the desired scan. the Scan Data View window (Figure 1) includes the original image of the scan as it was displayed.

7 This Scans View also has controls that can be used to tag and navigate scans. From left to right, the controls are:

Download downloads metadata for the list of scans to the PC. Only scans matching the current search query are included in the download.

Summary displays a summary of injection quality scores (Figure 9). Again, only scans matching the current search query are included in the summary. The Summary View includes the following:

A histogram showing the frequency at which a scan's score falls within a given range.

A table of Scan Factors which might help identify the attributes of a scan which are most frequently associated with high scores. For each scan, an attribute will have one of several possible values. "Needle", for example, may have the value 20, 22, 24 or another value, depending upon the gauge of needle which was used for that scan. Factors with a significantly (p value < 0.05) high or low percentage of high scores are highlighted. Green text highlights low scores; red text highlights high scores.

A Decision Tree which might help to explain which factors contribute to high scores. It also might help to identify relationships between factors. Each node in the tree represents a subset of scans which has been selected based on the value of a single factor. N is the size of the subset. % indicates the fraction of scans in the subset with high scores.

Analyze allows a user to compare injection quality scores for two different sets of scans (Figure 10). The sets are selected using the search panels on the left and right of the view. In cases where factors on the right side of the panel have a significantly (p value < 0.05) higher or lower percentage of high scores (compared to the left side), that factor is highlighted. Green text highlights low scores; red text highlights high scores.

Tip – the search inputs for the Analysis View are pre-populated with values from the Summary View.

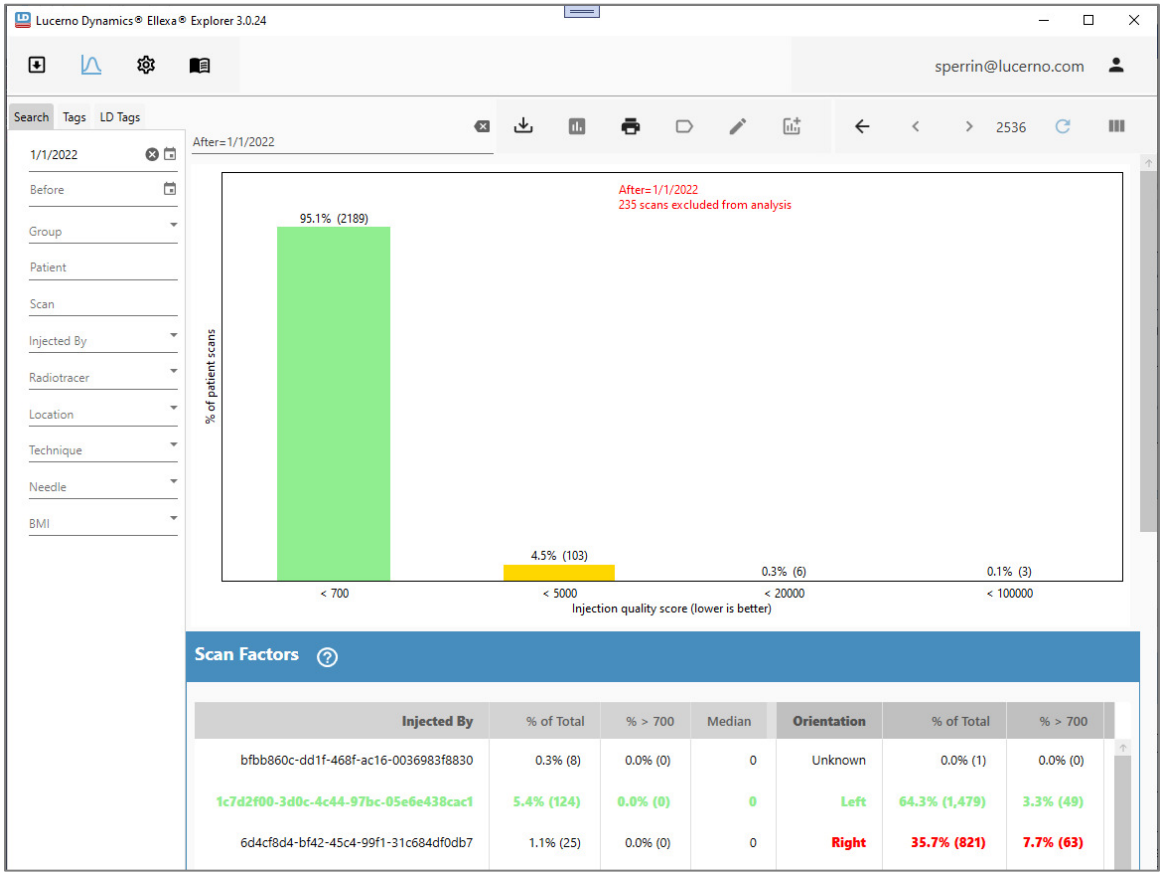


Figure 9 Scan Summary View

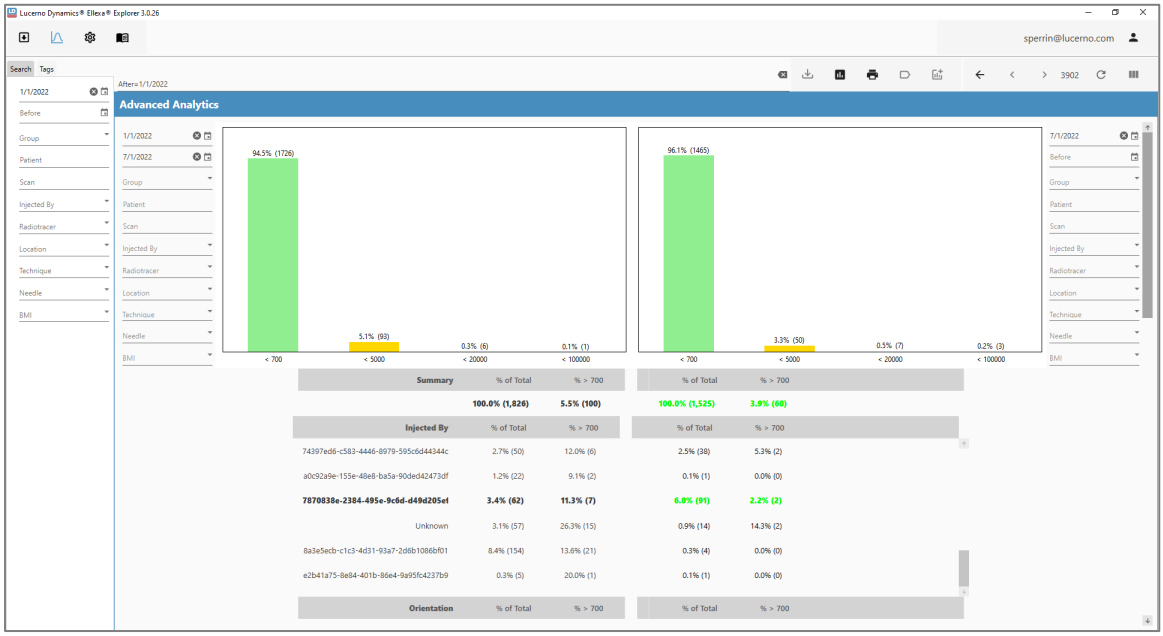


Figure 10 Scan Analysis View

SETTINGS VIEW

The Settings view (Figure 11) can be used to configure Lara Readers and The Ellexa Explorer application itself.

Site settings and DICOM settings can be modified by a superuser. Refer to the Ellexa Software Administrator's Manual for more information.

Some of the options described in this section must be enabled by Lucerno or your local distributor.

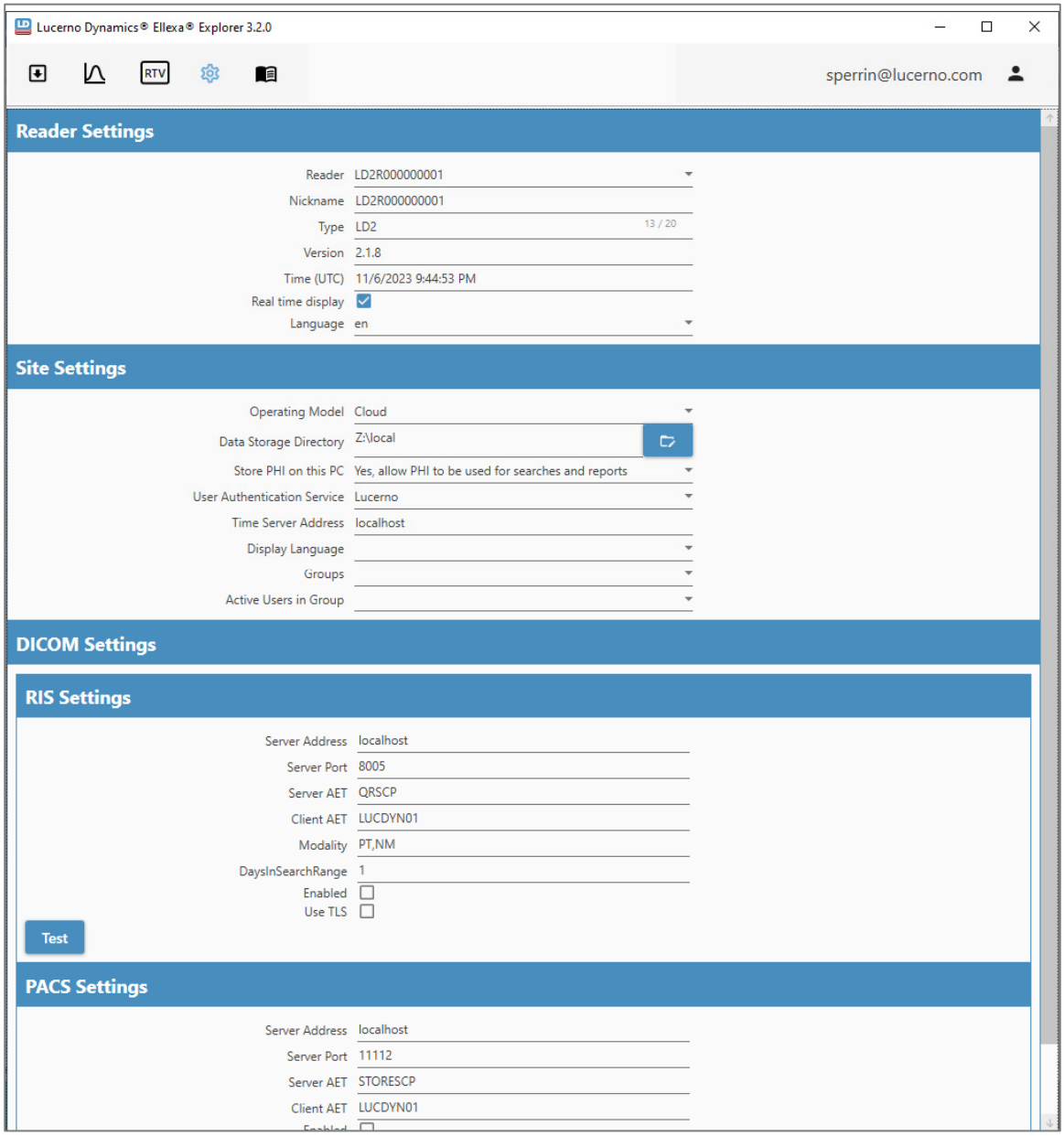


Figure 11 Settings view

READER SETTINGS

The Reader Settings panel provides basic information about Lara Readers that are attached to the PC. The **Reader** dropdown allows you to select a Reader to configure.

Readers can be given a unique nickname to allow easier tracking. Type a new nickname for the Reader in the **Nickname** input. The new name will appear on the Reader's screen.

A nickname may be up to 20 characters long.

Readers can be configured to enable or disable the display of Sensor counts. By displaying Sensor counts, a reader provides real-time feedback about the presence of a radiopharmaceutical near a sensor. It may be desirable to disable this feedback (during a quality improvement project, for example). When a check mark appears next to **Real time display**, the display of sensor counts is enabled. To change this setting on the Reader, select **Real time display**.

Readers can be configured to display information in different languages. Use the **Language** drop-down to select a language.

SITE SETTINGS

The Site Settings panel configures the behavior of the Ellexa Explorer application.

Patient Data Repository is used to select where scan data is stored after downloading. By default, data is stored in the Ellexa Web Application. Alternatively, scan data can be stored in a local shared file directory, the location of which is specified in the **Patient Data Storage Directory** input. The **Store PHI in repository** input can be used to determine whether protected health information is stored in the local file directory.

If you choose to store scan data in a local shared file directory, you are responsible for ensuring the security (e.g., access control, backup, encryption, etc.) of the stored information.

The Ellexa Explorer maintains a database of scan data on the PC where it is running. The information in the database allows scans to be searched in the Scan view. The information is also used to populate reports and printouts of scan data. To allow PHI to be included in this database, go to the input titled **Store PHI on this PC** and select **Yes, allow PHI to be used for searches and reports**.

To prevent unauthorized access to information, Ellexa Explorer requires users to sign in. By default, Explorer tests a user's credentials at the Ellexa Web Server. Organizations which use Azure Active Directory for authentication have the option of using this service to authenticate. To do so, go the **User Authentication Service** input and select **Microsoft**.

Lara Readers have an internal clock which is used to apply timestamps to recorded data. Ellexa Explorer verifies the setting of this clock by comparing it to a reference clock which supports the Network Time Protocol (NTP). By default, Explorer uses the reference clock operated by the US National Institute of Standards and Technology (NIST). To use an alternative reference, type the hostname or IP address in the **Time Server Address** input.

By default, the Ellexa Explorer will display text in the language which the Windows operating system is configured to display. If the Explorer does not support the Windows language, English is displayed. The user can select an alternate language from the Site Settings panel. Select the preferred language from the **Display Language** dropdown menu.

DICOM SETTINGS

The DICOM Settings panel allows the Ellexa Explorer to communicate with Radiology Information Systems (RIS) and Picture Archiving and Communication Systems (PACS). When configured to use RIS, Explorer will request a modality worklist from the server and use the response to populate fields in the Download view. The information from RIS, specifically the accession number, is used to create a DICOM image of the time-activity curve which is saved to the PACS server.

Verify that RIS and PACS settings have been entered correctly using the **Test** functions that are available with each panel.

RIS can be used without PACS. However, for DICOM files to be saved to PACS, RIS must also be enabled and correctly configured.

INPUT SETTINGS

This section applies to installations in which Explorer cannot communicate with the Ellexa Web Application (“Lara Local”). See the section on the Ellexa Web Application titled “CONFIGURING INPUTS IN THE EXPLORER APPLICATION” to learn how to manage inputs for other installations (“Lara Cloud” or “Lara Hybrid”).

If Explorer is licensed for “Lara Local” operation, Input Settings for the Download View can be configured here. See “CONFIGURING INPUTS IN THE EXPLORER APPLICATION” for a detailed explanation of these features.

INSTRUCTIONS FOR USE VIEW

In addition to links to this and other user's manuals, the Instructions For Use view provides access to maintenance records and software updates (Figure 12).

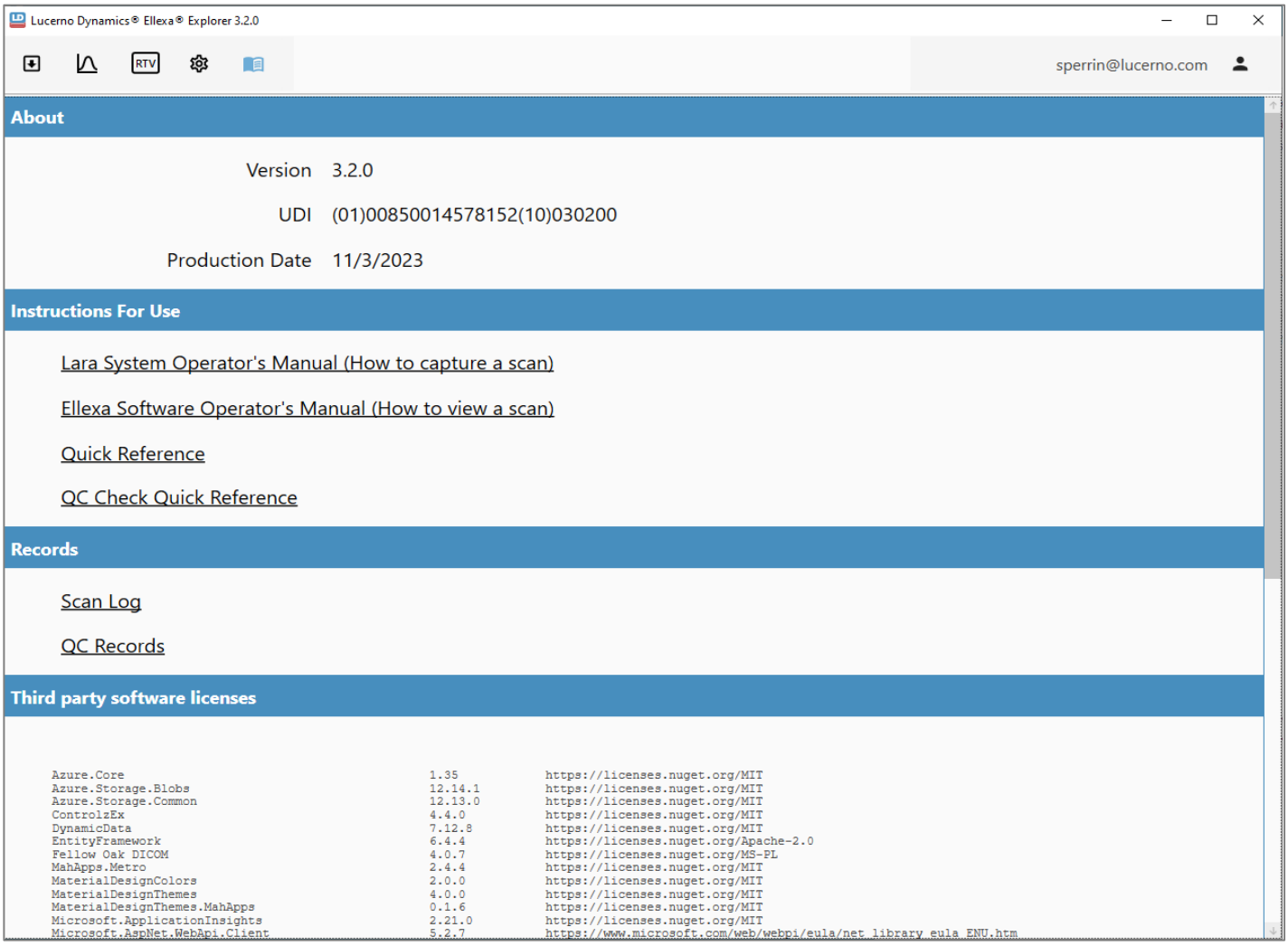


Figure 12 Instructions For Use view

The **Records** panel contains links which can be selected to review maintenance records. The **Scan Log** is a .csv file with a row recording each scan which has been downloaded on this PC. It can be used as a cross-reference between Lucerno identifiers and local identifiers. The **QC Records** link will open the Ellexa Web Application to the Sensor QC Records view which is described later in this document.

Lucerno will release periodic updates to the Ellexa Explorer software. When an update is available, a green flag will be visible in the menu at the top of the application window. Select this icon to download and install the software update. This process typically takes no more than five minutes.

Ellexa Explorer can be updated manually. To manually obtain the latest update, use a web browser to navigate to the link in the **Update is available** panel. If you are currently using the newest version of Explorer and Explorer has access to the Ellexa Web Application, this panel will not be visible. If Explorer cannot access the Web Application itself, a link to the latest version of Explorer can be found at https://scans.lucernodynamics.com/Home/Help.

Software updates from Lucerno will always be signed by Lucerno. When the update program is launched and the Windows operating system asks you for permission to make changes to the computer, the publisher of the software will be displayed. If the “Verified Publisher” is not “Lucerno Dynamics, LLC”, do not allow the update to proceed.

If you feel that the software is not performing as you expect, please contact Lucerno or your local distributor.

WEB APPLICATION

Scan information can be reviewed in detail on the Ellexa Web Application.

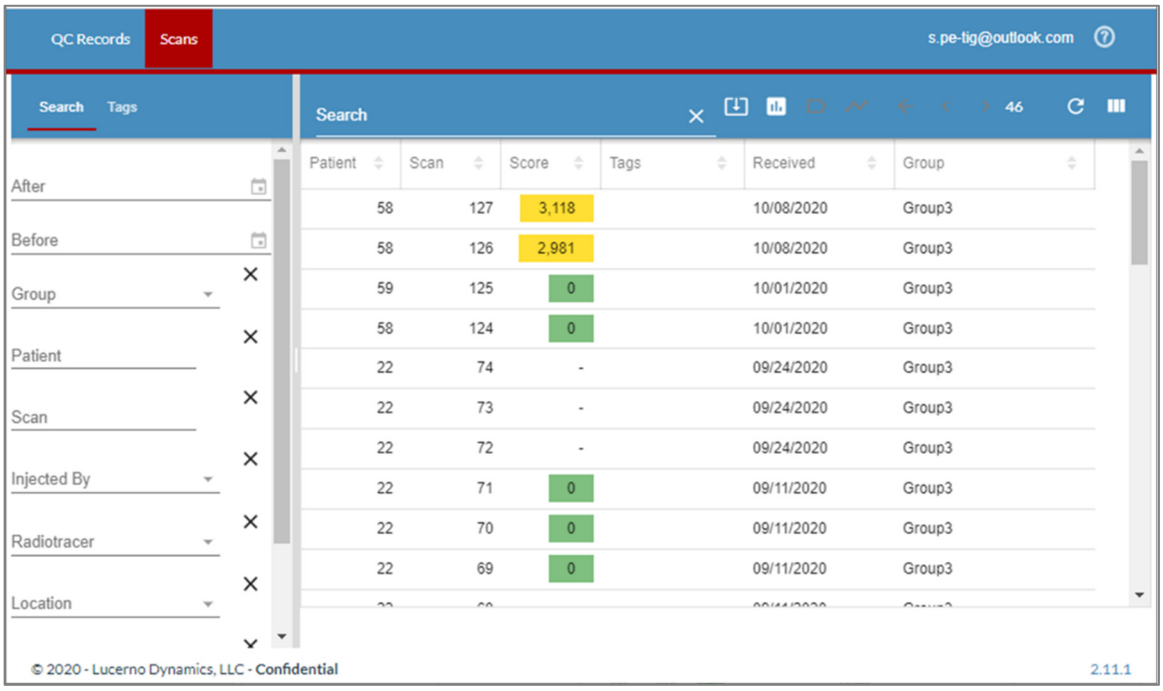


Figure 13 Scans View

1	Using a web browser, navigate to www.lucerno.com and select Log in.
2	Log in to the website using the User ID and Password which you received from Lucerno.
3	The Scans page displays a list of all scans that are available for review. By default, scans are sorted by Received Date. The scans' sort order can be changed by clicking on the header ("Patient", "Score", "Tags", "Received") at the top of each column (**Error! Reference source not found.**).
4	The Search panel provides a straightforward way to search for scans matching specific criteria.
5	The Tags panel displays a list of tags which users have previously applied to scans. Clicking a tag in this panel will cause the list of scans to be filtered, displaying only those scans with this tag. The "Score" tags will select scans with scores between the values indicated by the tags.

6	The Search field can be used to search for scans containing particular text. All available data for the scan will be searched, including data in columns which are not currently visible. More information about entering search queries is provided in the section titled “Search queries”.
7	Columns can be made visible or hidden using the column selector. To open the column selector, click on the 3 vertical bars in the upper right of the screen.
8	To view details for a specific scan, click anywhere on the row corresponding to the desired scan. The Scan Detail view (Figure 14) includes the original image of the scan as it was displayed on the PC. Also included in the Scan Detail view are the Scan Metrics (see below for more information) and a panel that allows you to record notes about the scan. This view also enables the controls that can be used to tag and navigate scans. From left to right, the controls are: Download: Downloads metadata for the list of scans to the PC. Only scans matching the current search query are included in the download. Summary: Displays a summary of injection quality scores, as described in the Site Summary section. If this feature is not active, please contact Lucerno or your local distributor. Apply a Tag: Allows you to add or remove tags from a scan. Analyze a Graph: Opens a view of the scan which can be panned and zoomed for more careful review. List: Returns to the list of all scans. Previous: Advances to the previous scan in the list. Next: Advances to the next scan in the list.

Figure 14 Scan Detail View

9 While analyzing a graph, additional controls allow you to pan and zoom the graph data (Figure 15).

Zoom: Used to zoom the graph in horizontal and vertical axes.

Download: Download or print an image of the scan.

Figure 15 Graph Analysis

When the Ellexa Explorer is configured to use a local shared file directory for its patient data repository, scan data is not available in the Ellexa Web Application.

When the Ellexa Explorer is configured to use the Ellexa Web Application for its patient data repository, protected health information (PHI) is removed from scan data before transmission to the web site.

SITE SUMMARY

The Site Summary view (Figure 16) compiles injection quality information for a set of scans for which scores are available and may help to identify factors which contribute to high quality injections.

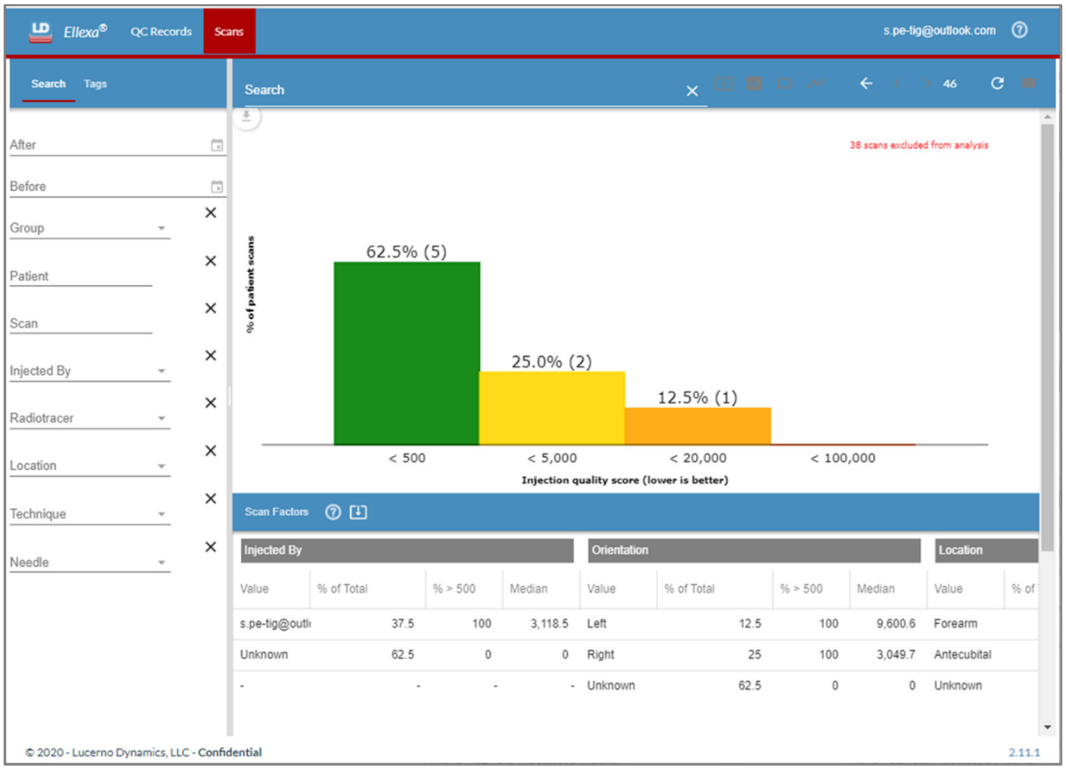


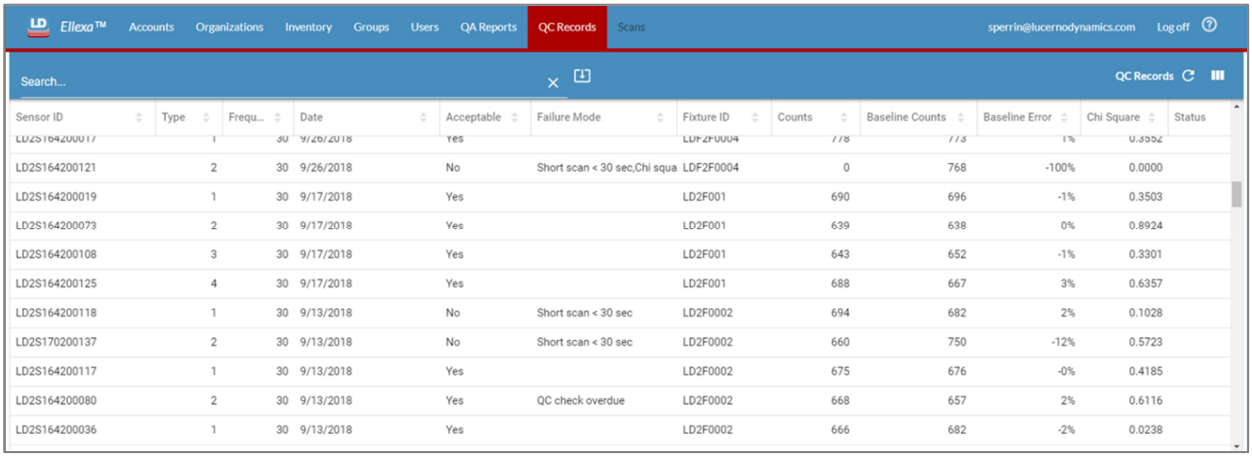
Figure 16 Site Summary View

1	Using the Search fields, identify a set of scans to review. Then select the Summary icon.
2	The histogram displays the number of scans from the set which fall within a given range of scores. The graph can be downloaded or printed by selecting the Download icon in the upper left corner of the histogram.
3	The Scan Factors table is intended to help identify the attributes of a scan which are most frequently associated with high Scan Metrics. For each scan, an attribute will have one of several possible values. "Needle", for example, may have the value 20, 22, 24 or another value, depending upon the gauge of needle which was used for that scan.

4 The table lists, for each of the possible values of each attribute, the percentage of scans ("% > N") which had high scores. Where a value is associated with a significant difference (p value < 0.05) from the other values, that value is highlighted. Green text highlights low scores; red text highlights high scores. The table also lists the percentage of all scans ("% of Total") that have high scores and median value of these high scores.

SENSOR QC RECORDS

The procedure for performing a Sensor QC check is described above in Performing a Sensor QC Check. Records can be reviewed and downloaded in the Sensor QC Record View (Figure 17). Select to download records.



Sensor ID	Type	Frequ...	Date	Acceptable	Failure Mode	Fixture ID	Counts	Baseline Counts	Baseline Error	Chi Square	Status
LD2S164200121	2	30	9/26/2018	No	Short scan < 30 sec,Chi squa	LDF2F0004	0	768	-100%	0.0000	
LD2S164200019	1	30	9/17/2018	Yes		LD2F001	690	696	-1%	0.3503	
LD2S164200073	2	30	9/17/2018	Yes		LD2F001	639	638	0%	0.8924	
LD2S164200108	3	30	9/17/2018	Yes		LD2F001	643	652	-1%	0.3301	
LD2S164200125	4	30	9/17/2018	Yes		LD2F001	688	667	3%	0.6357	
LD2S164200118	1	30	9/13/2018	No	Short scan < 30 sec	LD2F0002	694	682	2%	0.1028	
LD2S170200137	2	30	9/13/2018	No	Short scan < 30 sec	LD2F0002	660	750	-12%	0.5723	
LD2S164200117	1	30	9/13/2018	Yes		LD2F0002	675	676	-0%	0.4185	
LD2S164200080	2	30	9/13/2018	Yes	QC check overdue	LD2F0002	668	657	2%	0.6116	
LD2S164200036	1	30	9/13/2018	Yes		LD2F0002	666	682	-2%	0.0238	

Figure 17 Sensor QC Record View

MANAGING USERS

This section describes how to register new Users who will use either the Ellexa Web Application or the Ellexa Explorer.

Only designated users are allowed to perform the actions described below. If you require this capability but are not able to access this part of the web site, please contact Lucerno or your local distributor.

This section applies to installations in which Explorer can communicate with the Ellexa Web Application ("Lara Cloud" or "Lara Hybrid"). See the Ellexa Software Administrator's Manual to learn how to manage users for other installations ("Lara Local").

Data that is stored in the Ellexa Web Application is organized by groups. To read or write data belonging to the group, a User must be a member of that group. A User may belong to more than one group. For example, a site that has two nuclear medicine labs might choose to create a group for each lab. A technologist who works in only one of the labs might be added to only one group. However, a physician who reviews cases from both labs might be added to both groups.

1	To view the list of people who are registered at your site, select Users (Figure 18).
2	To create a new User, select +. Enter the User's information, as shown in Figure 19. Optionally, you may define an initial password for the User. When you select "Register", an invitation will be sent to the User's email address, along with instructions for setting their own password. NOTE – It is not necessary to define a password. By default, the User is assigned a random password which is subsequently updated by the user after receiving their email invitation.
3	To modify a User, select "Edit" in the "Actions" column. While editing a User, you can prevent that User from accessing Lucerno software by selecting the "Lock" button. Future attempts by the User to log in will fail while the User's account is "locked". A "locked" user account can subsequently be re-enabled by editing the User and selecting the "Unlock" button.

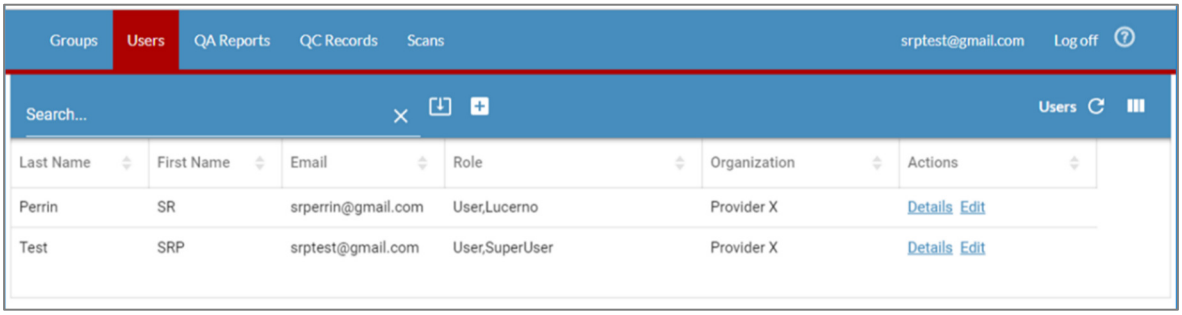


Figure 18 Users View

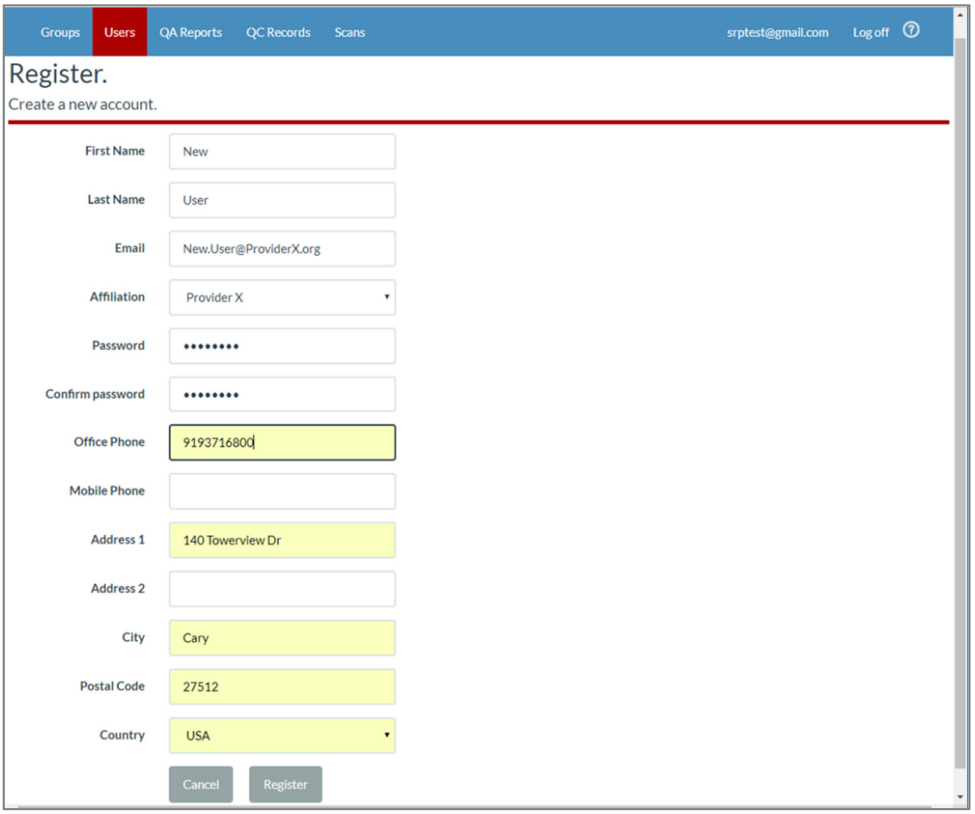


Figure 19 Creating a New User

MANAGING GROUP MEMBERSHIP

This section describes how to modify the set of users who have access to data belonging to a group.

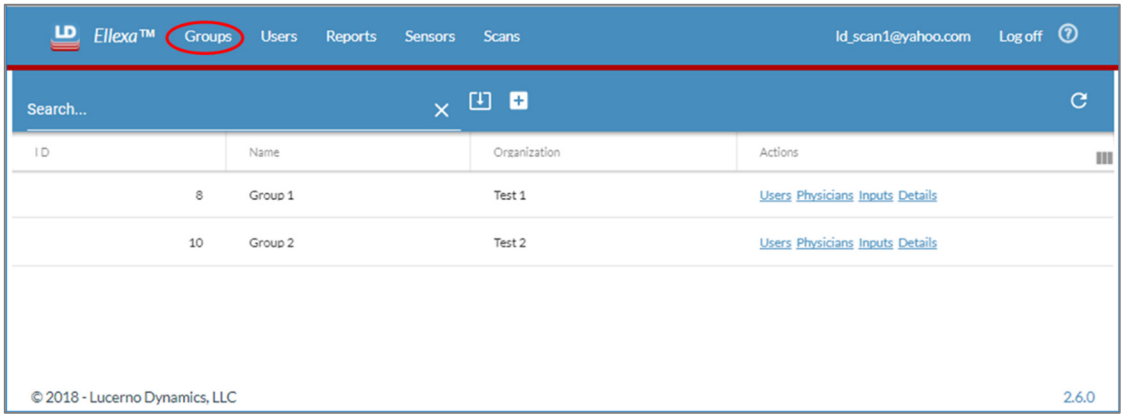


Figure 20 Group Settings View

1	From the Group Settings View (Figure 20), select Users
2	To deny access to an existing member of the Group, select Remove
3	To allow access to a new User, select +, then select Add

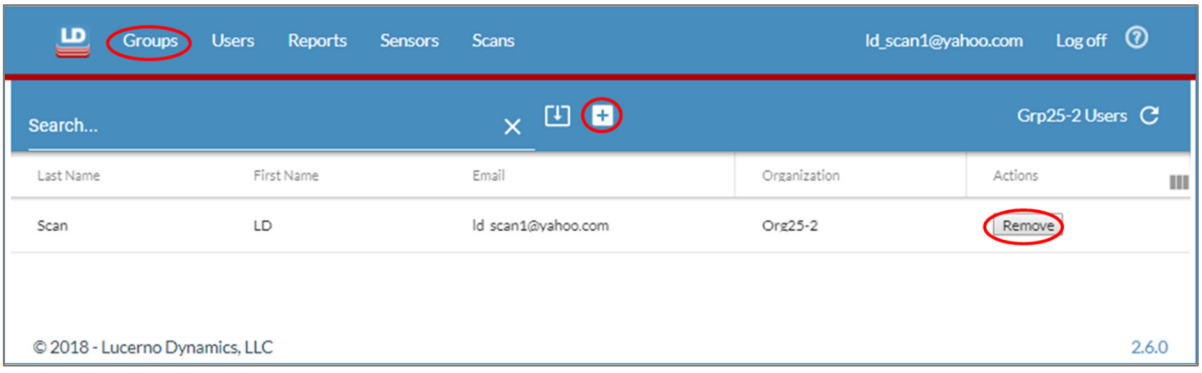


Figure 21 Removing and adding Users to a Group

Similarly, it is possible to identify certain users as Physicians belonging to a Group. A Physician has greater access to data than an ordinary User. Where ordinary Users may occasionally be prevented from viewing scan data (e.g., during a quality improvement study), a Physician is always able to view scan data.

REVIEWING QA REPORTS

The Ellexa Web Application will generate a monthly Quality Assurance (QA) report for each Group.

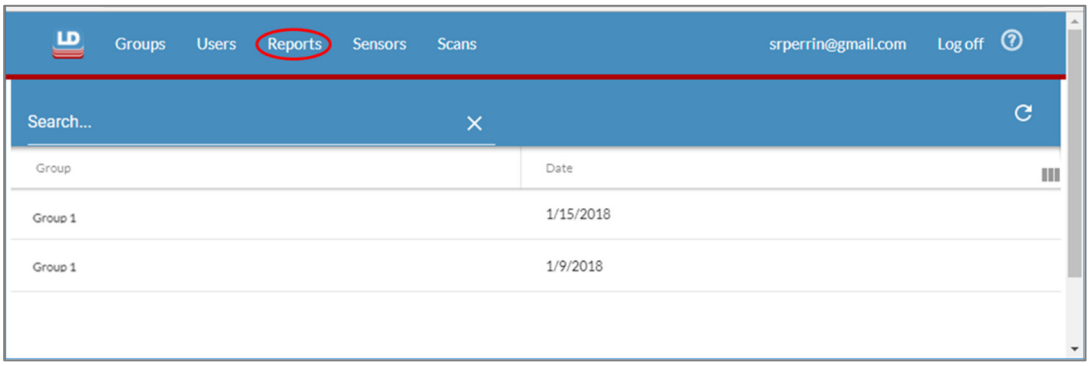


Figure 22 QA Report View

1	To view all available QA Reports, select Reports as shown in Figure 22.
2	Select a row to see the contents of a report (illustrated in Figure 23). NOTE – No report will be generated if a Group has not generated new scans in the prior week.

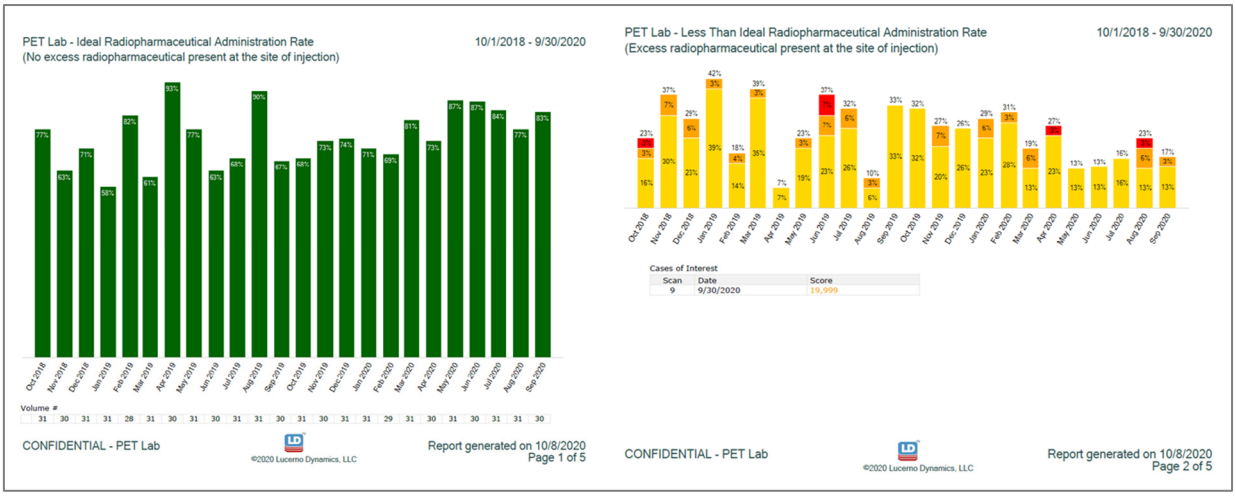


Figure 23 Example QA Report

CONFIGURING INPUTS IN THE EXPLORER APPLICATION

The input fields in the Download view of the Ellexa Explorer can be configured in the Ellexa Web Application. By default, input fields in the Download view (Figure 6) require that data be entered before the scan can be saved. However, the web application can be used to override this. Inputs can be made optional or be disabled so that they will not accept data.

1	To configure how inputs are displayed in the Ellexa Explorer, select Groups. A group represents a set of users who share access to scan data. Input fields can be enabled or disabled for a group by selecting Inputs.
2	Elect one of the following configuration options from the dropdown provided for each input field (Figure 24) Disabled – Users are not allowed to enter information in the Ellexa Explorer Software. Optional – Users may enter information if desired, but the field can also be left blank or unselected. Required – Users must enter this information. The inputs labeled DeidentifyPCData and RepeatPatientID do not apply to the Ellexa Explorer. These features have been replaced by similar options in the rules for an Organization. See the “Ellexa Software Administrator’s Manual” for details. Some of the inputs are used to calculate the score for an injection. If this information is not entered in the Explorer, Ellexa will not display a score.
3	After modifying the Input Settings, select Save at the bottom of the page. Changes to the Input Settings must be saved, and the Ellexa Explorer Software must be restarted for these settings to take effect.

This section applies to installations in which Explorer can communicate with the Ellexa Web Application (“Lara Cloud” or “Lara Hybrid”). See the section on the Explorer Settings View to learn how to manage inputs for other installations (“Lara Local”).

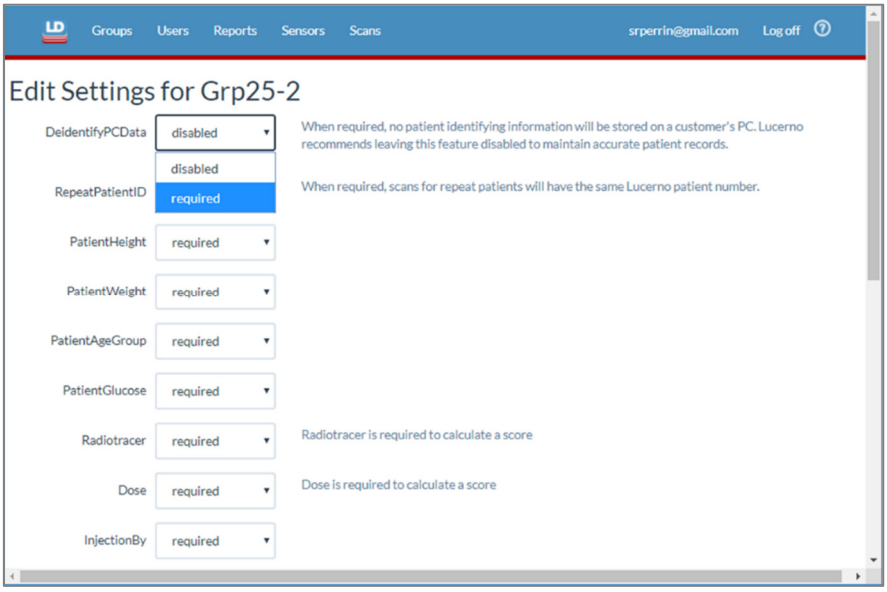


Figure 24 Group Input Settings View

SELECTING A LANGUAGE

By default, the Ellexa Web Application will display text in the language requested by the web browser. If the Web Application does not support the browser language, English is displayed. The user can select an alternate language from the Settings dialog (Figure 25). To open the settings dialog, select the user ID in the upper right corner of the Web Application.

Figure 25 - Settings Dialog

SEARCH QUERIES

To make it easier to find a particular scan, the list of scans that appear in the **Scan View** (Figure 4, **Error! Reference source not found.**) and **Site Summary View** (Figure 16) can be filtered. To filter the list, type a query in the **Search** input. The table below describes how to create valid queries and provides some example queries.

Query	Examples	Meaning	Description
<word> <word>	left arm	any scan that includes all these words in any column	Searches all columns for the words. If all the words appear in any column, the scan is a match.
'<phrase>'	'left arm'	any scan that includes the exact phrase in any column	Searches all columns for the entered phrase. If the text in any column includes the phrase, the scan is a match. **Use single quotes (') to group words into a phrase.**
<columnName>=<phrase>	tags=minor group='PET Lab'	any scan for which the value in the column exactly matches the phrase	Searches the column identified by columnName for the text identified by phrase. If the text in that column exactly matches the phrase, the scan is a match. If the text in the column includes the phrase but has additional text, the scan is NOT a match. Column names can be entered in all lower-case text. Phrases that contain multiple words should be surrounded with quotation marks.
<columnName><<phrase> **<columnName>><phrase>**	score>200 score<200	any scan for which the value in the column is greater than or less than the phrase	Searches the column identified by columnName. If the value in that column is greater than (or less than) the phrase, the scan is a match.

Query	Examples	Meaning	Description
<columnName>=<phrase1>,<phrase2>	tags=moderate,severe age='70_and_over','50_to_69'	any scan for which the values in a column exactly match either phrase	Searches for multiple phrases in a single column. If the text in the column exactly matches one of the entered phrases, the scan is a match. For the first example query, scans which match will have the "moderate" tag OR the "severe" tag. For the second example query, scans which match will have the age group "70_and_over" OR the age group "50_to_69"
<columnName>=<phrase1> **<columnName>=<phrase2>**	tags=severe tags=test	any scan for which the values in a column exactly match both phrases	Searches for multiple phrases in a single column. If the text in the column exactly matches both of the entered phrases, the scan is a match. For the example query, scans which match will have the "severe" tag AND the "test" tag.
<columnName>=-<phrase>	group='-PET Lab' tags=CAD,-negligible	all scans that do not include the phrase	Searches for columns that do NOT contain the phrase which is preceded by a "-". If the text in a column contains the phrase that was preceded by "-", the scan is not a match. The two example queries return: •scans which are NOT from the "PET Lab" group. •scans which have the "CAD" tag AND do NOT have the "Negligible" tag.
<columnName1>=<phrase1> **<columnName2>=<phrase2>** **<columnNameN>=<phraseN>**	tags=CAD group='PET Lab'	any scan which matches all of the query terms	Searches for scans in which all of the phrases entered match the text in the associated column. If the text in every entered column matches the phrase(s) entered, the scan is a match. If any column's text does not match the phrase entered, the scan is not a match. The example query returns scans which have the "CAD" tag AND which are from "PET Lab" group.

Query	Examples	Meaning	Description
<columnName>=<phrase1> <phrase2>	tags=CAD 'left arm'	any scan which matches all of the query terms	Searches for scans in which all query terms are a match. If every entered search query is a match in a scan, the scan is a match. If any search query is not a match, the scan is not a match. The example query returns scans which have the "CAD tag AND which include the text "left arm" anywhere in any column.
before=<date> **after=<date>**	before:2016-8-1 after=2016-7-14	any scan with a received date before/after the specified date	Searches for scans with a received date before or after the specified date. The queries can be combined to get scans between a range of dates, e.g., after July 14 AND before August 1. For **before:<date>**, if the received date of a scan is before the specified date, the scan is a match. For **after:<date>**, if the received date of a scan is on or after the specified date, the scan is a match. For **before=<date1> after=<date2>**, if the received date is within the range of the specified date(s), the scan is a match. All searches use local date – the date on the PC on which the application is running.
above=<number> **below=<number>**	above=0 below=1000	any scan with a Score that meets the specified criteria	Searches for scans whose Score is within the range bounded by the above/below values.

ERRORS AND TROUBLESHOOTING

While the Lucerno Ellexa Software is designed to be trouble-free, you may encounter the occasional problem. Please refer to the following table for troubleshooting tips.

Please contact Lucerno or your local distributor for additional help.

Lucerno Dynamics
+1-919-371-6800
www.lucerno.com

Symptom	Likely Cause	Possible Solution
PC Software displays "Error loading…"	The software cannot find a required file.	Contact Lucerno or your local distributor for assistance.
PC Software displays "No Reader found!"	The computer is unable to communicate with the Reader.	Check that the USB cable is plugged into both the PC and the Reader. Make sure the Reader is turned ON and positively seated in the PC dock. If using a powered USB hub, make sure that the hub is plugged into the PC, Reader, and AC power.
PC Software displays "No data available"	Scan data is deleted from the Reader after a successful download. The Reader has not been used to record a scan since the previous download.	Record a new scan.
PC Software displays "WARNING: Scan could not be saved!"	The software is unable to save the file to your computer.	Contact Lucerno or your local distributor for assistance.

Symptom	Likely Cause	Possible Solution
PC Software displays "Error: Cannot communicate with…"	The software cannot communicate with the internet.	The computer is not connected to the internet. Check the connection and restart the software to try again. Alternatively, connections to the Lucerno web service may be blocked by a firewall on your local network. Configure the firewall to allow connections to the following addresses: https://lucerno.com https://scans.lucernodynamics.com/ https://lucernostorage.blob.core.windows.net/ time.nist.gov Also, verify that the Microsoft Root Certificate Program is enabled and running on the computer. By running certmgr.msc, verify that "Go Daddy Root Certificate Authority – G2" is listed among the Trusted Root Certification Authorities. If not present, download it from the GoDaddy.com SSL certificate repository and install manually.
PC Software displays "Error: Cannot register…"	The software cannot communicate with the internet.	The computer is not connected to the internet. Check the connection and click OK to try again.
PC Software displays "WARNING: Cannot communicate with the Reader…"	The computer is unable to communicate with the Reader.	Check to make sure that the Reader is ON, and that the USB cable is plugged into both the computer and Reader. Click OK to try again. If using a powered USB hub, make sure that the hub is plugged into the PC, Reader, and AC power.

Symptom	Likely Cause	Possible Solution
PC Software displays "Error: USB device drivers have not been installed"	Windows Update has been disabled on the PC, preventing the Lara Reader device drivers from being installed automatically.	Install the device drivers manually. NOTE – This procedure may require admin privileges on the PC. 1. Download the zip file containing the device drivers from here. Extract the contents of zip file to a directory on your PC. 2. Attach a Lara Reader to the PC. 3. Start the Windows Device Manager by typing "devmgmnt.msc" at a command prompt. 4. Under "Other devices", find the "USB serial port" associated with the Reader (it will have a yellow triangle indicating that it has not been configured). Right click on the USB serial port. Select "Update driver". 5. Select "Browse my computer…". Under "Search for drivers in this location:", select "Browse". Navigate to the directory in which you extracted the device drivers. Select "Next" to start the installation. After the installation is complete, Device Manager will show a "Lucerno Docking Station" under "Ports".
PC Software displays "Checking system clock" for many seconds	The software is unable to get the time from a standard time server. By default, it will attempt to get the time from time.nist.gov. Access to this server might be blocked by a firewall.	Configure an alternative IP address for the PC Software to get the time. See the section titled "Advanced Configuration Options".

Symptom	Likely Cause	Possible Solution
PC Software displays "Failed to get worklist data from …" or PC Software does not have any entries in the Patient ID dropdown list	The software is unable to get a DICOM modality worklist from the RIS server.	Verify PC Software configuration settings. See the section titled "Advanced Configuration Options".
PC Software displays "Failed to store file to archive system"	The software is unable to store a DICOM file to the PACS server.	Verify PC Software configuration settings. See the section titled "Advanced Configuration Options". A backup copy of the DICOM file is stored on the PC under "Documents\Lucerno Dynamics\Patient Data". The file will have a .dcm file extension.
PC Software displays "This user cannot upload scans because the user is not a member of any group"	The user has not been granted membership in a group.	A Superuser for the site can add the user to a group. See the section titled "Managing Group Membership".
PC Software displays "License file cannot be opened"	License file has been modified or corrupted	See the Ellexa Software Administrator's Manual for information about configuring and installing the license file
PC Software displays "License for this system has expired"	Lara Local license has expired	Contact your Distributor to renew the license
PC Software displays "License file requires that a user group be defined in the Windows registry"	PC administrator needs to configure Lara Local users	See the Ellexa Software Administrator's Manual for information about configuring users

Symptom	Likely Cause	Possible Solution
PC Software displays "License file requires that a superuser group be defined in the Windows registry"	PC administrator needs to configure Lara Local superusers	See the Ellexa Software Administrator's Manual for information about configuring superusers
PC Software displays "Cannot access folder"	In the Site Settings, the Data Storage Directory settings is invalid or inaccessible	Review Site Settings. Confirm that all Explorer users have access to the designated Data Storage Directory.

Terms of Use

The Lara System (which includes the Lara hardware, Ellexa software, Operator's Manuals and other Lucerno documentation, sensor pads, and associated intellectual property) is sold by Lucerno Dynamics, LLC ("Lucerno") directly or through Lucerno's authorized distributors to the Customer.

License. Lucerno grants the Customer a limited, nonexclusive, nontransferable license to use the Ellexa software exclusively with the Lara hardware for the Permitted Use (as defined below). All right, title and interest in and to any intellectual property rights in the Lara System shall remain with Lucerno or its third-party licensors, as applicable. Customer has no right, license, or authorization with respect to the Lara System (including any individual components thereof) except as expressly provided herein. All other rights in and to the Lara System are expressly reserved by Lucerno or its third-party licensors, as applicable.

Permitted Use. Lucerno grants Customer's Authorized Users the right to use the Lara System in accordance with the Operator's Manuals for Customer's internal purpose ("Permitted Use"). "Authorized Users" are those users: (i) properly trained to use the Lara System, (ii) permitted by the Customer to access Customer Data (as defined below), and (iii) that consent to share with Lucerno their Personally Identifiable Information ("PII"), as defined by the EU General Data Protection Regulation ("GDPR"). PII will be handled according to Lucerno's Privacy Policy which can be found at https://lucernostorage.blob.core.windows.net/ifu/POLICY%20-%20Privacy.pdf.

License Restrictions. Customer shall not use the Lara System for any purposes beyond the scope of the Permitted Use. Customer shall not at any time, directly or indirectly, and shall not permit any Authorized Users to: (i) copy, modify, or create derivative works of the Lara System, in whole or in part; (ii) rent, lease, lend, sell, license, sublicense, assign, distribute, publish, transfer, or otherwise make available the Lara System; (iii) reverse engineer, disassemble, decompile, decode, adapt, or otherwise attempt to derive or gain access to any software component of the Lara System, in whole or in part; (iv) remove any proprietary notices from the Lara System; or (v) use the Lara System in any manner or for any purpose that infringes, misappropriates, or otherwise violates any intellectual property right or other right of any person, or that violates any applicable law.

Data. Use of the Lara System with a Lara Cloud license involves transmitting to Lucerno data that: (i) is de-identified and contains no PII or Protected Health Information ("PHI") as defined by the US Health Insurance Portability and Accountability Act ("HIPAA"); (ii) contains no confidential or personal information or trade secrets; and (iii) contains no financial information or credit information, ((i) through (iii), together "Customer Data"). Lucerno retains the right to use Customer Data in de-identified form ("Lucerno Data"). Any use of the Lucerno Data will be done in a manner that does not attribute any of such data to Customer. Customer will comply with applicable laws and regulations and will be responsible for the privacy and security of its patients' PHI or PII.

Customer may choose (with purchase of optional Lara Hybrid or Lara Local license) to store some Lara System data in a local shared file directory defined in the software as the Data Storage Directory ("Local Repository"). Depending upon the rules defined for an Organization, the files in the Local Repository may include PII and/or PHI. Customer assumes full responsibility for ensuring the security (e.g., access control, backup, encryption, etc.) of data stored in the Local Repository.

Infrastructure. Lucerno utilizes Microsoft Azure ("Azure") infrastructure (https://azure.microsoft.com). Data uploaded through the Lara System is securely stored in Azure facilities according to industry best practices with respect to computer software security and privacy. See the Azure Security site (https://docs.microsoft.com/en-us/azure/security/azure-security) for

information about Azure security and privacy capabilities and policies, including information on physical site security and data redundancy/availability capabilities.

Service Guarantee. The Lara System is covered by the service guarantee set forth in the following paragraphs. Such service guarantee is extended only with respect to the purchase of this Lara System directly from Lucerno or through Lucerno's authorized distributors, and is extended to the Customer thereof, other than for the purpose of resale.

Lucerno represents that the Lara System will:

(i) meet the written specifications in the Lara System's Operator's Manuals and the Ellexa software platform will be reasonably accessible;

(ii) be free from known defects and will be suitable for the Permitted Use (the "Service Guarantee").

If the Lara System is defective or becomes unsuitable for the Permitted Use, not based on the misuse of Customer, Lucerno's sole obligation under this Service Guarantee shall be to provide all parts and labor required to cause the Lara System to operate in accordance with the specifications at no charge to Customer. If the Lara System becomes unsuitable for the Permitted Use through the misuse of the Customer, Customer will purchase replacement parts or products.

The Service Guarantee will become immediately void in the event that any of the following conditions are not met or cease to be true:

(i) The Lara System must be operated and stored in accordance with the Operator's Manuals;

(ii) The Lara System must be kept in the proper operating environment as specified in the Operator's Manuals; and

(iii) The Lara System must be operated only by Authorized Users.

IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, CONSEQUENTIAL, INCIDENTAL, SPECIAL, OR PUNITIVE DAMAGES OR LOSSES OF ANY KIND, EVEN IF THE PARTY FROM WHOM DAMAGES ARE SOUGHT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. EACH PARTY'S MAXIMUM AGGREGATE LIABILITY FOR ANY CAUSE OF ACTION SHALL NOT EXCEED THE AMOUNT PAID BY THE CUSTOMER TO LUCERNO OR LUCERNO'S AUTHORIZED DISTRIBUTORS IN THE TWELVE (12) MONTH PERIOD PRIOR TO THE CAUSE OF ACTION. **LUCERNO MAKES NO WARRANTIES, EXPRESS OR IMPLIED. LUCERNO SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**