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SEM250 Provizio SEM Scanner GATEWAY User Manual

Contents

SEM250 Provizio SEM Scanner GATEWAY

Warnings and Safety Precautions

The Provizio SEM Scanner and Provizio SEM Scanner S have been designed and constructed in accordance with applicable European Medical Device Directives and United States (US) regulations and requirements, as well as U.S. and international standards for operation of electrical equipment, electromagnetic compatibility, and stipulated safety requirements. Improper use or handling, however, can result in damage and/or injury. To prevent damage to the equipment, please read these operating instructions carefully before using your Provizio SEM Scanner system. Keep these instructions in a safe place. Follow the instructions below to ensure safe and trouble-free operation of your system.
Caution: Federal (US) law restricts this device to sale by or on the order of a physician or other licensed health practitioner.

Warnings

- **WARNING:** The standard of care should be followed for reducing the risk of developing pressure ulcers. Readings from the Provizio SEM Scanners can be used to support increased intervention; but should never be the basis for decreasing intervention.
- **WARNING:** This device is not intended to be used for detecting or diagnosis of pressure ulcers.
- **WARNING:** Do not use the Provizio SEM Scanners on broken or otherwise compromised skin.
- **WARNING:** Only use with Provizio SEM Scanner System components.
- **WARNING:** To prevent the spread of infection, the Provizio SEM Scanners should be properly cleaned and disinfected according to the instructions provided in the Provizio SEM Scanner User Manual.
- **WARNING:** To prevent cross-contamination of patients, use a new, unopened singleuse sensor per patient, per session. Multiple anatomic locations may be scanned using the same sensor in one session, however, ensure a new sensor is used for each new session. A session can be defined as scanning the sacrum, left heel and right heel for the same patient.

- **WARNING:** Do not attempt to clean or disinfect a contaminated single-use sensor.
- **WARNING:** Should the device contact contaminated surfaces (for example, if it falls on the floor) it should be cleaned and disinfected before obtaining another patient reading.
- **WARNING:** Do not attempt to disassemble or otherwise modify the Provizio SEM Scanner as this can result in unintended hazards. The Provizio SEM Scanner System can only be serviced by the manufacturer (Bruin Biometrics) or a Bruin Biometrics Authorized Service Center. Please contact your Product Specialist or Customer Service Representative regarding any device that is not functioning correctly.
- **WARNING:** To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- **WARNING:** To avoid the risk of explosion, the Provizio SEM Scanner should not be used in the presence of flammable anesthetic agents.
- **WARNING:** The Provizio SEM Scanner S will not operate correctly without first installing a single-use sensor head.
- **WARNING:** Ensure the is no foreign material in the Charging Hub slot before placing the scanner in the Charging Hub.

Cautions

- **CAUTION:** Examine the Provizio SEM Scanner for damage or sharp edges prior to each use. If any damage or sharp edges are found, please contact Customer Service or your Product Specialist. Do not attempt to use the device.
- **CAUTION:** Ensure the power cord is plugged into the supply main and the device is fully charged prior to use.
- **CAUTION:** Do not immerse the Provizio SEM Scanner. Immersion may damage the scanner and prevent it functioning normally.
- **CAUTION:** Ensure that the sensor connector is completely dry before attaching a single-use sensor to the device.

General

1. **Purpose**
   This document describes how to connect to the Gateway application that is installed at an institution and guides a user through the various screens.
2. **Requirements**
   The Bruin Biometrics Webserver Virtual Machine (VM).
3. **Nomenclature**
   Virtual Machine: The Bruin Biometrics Webserver VM that is installed on the institution provided server and provides a working environment for the Bruin Biometrics Web application. Pressure ulcers also are called pressure injuries, decubitus ulcers, bed sores or pressure sores.
4. **Indications for Use**
   The Provizio SEM Scanner and Provizio SEM Scanner S are intended to be used by healthcare professionals as an adjunct to the standard of care when assessing the heels and sacrum of patients who are at increased risk for pressure ulcers.
5. **Contraindications**

Not to be used on broken skin and intended for use on adult population only.

6. **Intended User Profile**

The system is intended for use by healthcare professionals.

7. **Adverse Effects**

There are no know adverse effects using the Provizio SEM Scanner.

8. **Warranty and Disclaimer**

This manual is intended to provide instructions on the proper use of the Provizio SEM Scanner. It should be used in conjunction with the appropriate training. To request repair or replacement under warranty, purchasers should contact their local Customer Service provider. Warranty conditions may differ in some countries. Contact your Customer Service provider for warranty terms.The use of the instrument in a manner different that that described in this manual may result in improper function. Warranty is limited to defects and materials that can be attributed to a fault or defect within the Provizio SEM Scanner. Warranty does not extend to any Warranted Products or parts thereof: (a) that havebeen subject to misuse, neglect or accident, (b) that have been damaged by causes external to the Warranted Product, (c) that have been used in violation of the Bruin Biometrics LLC Instructions for Use, (d) on which the serial number has been removed or made illegible, (e) that have been modified by anyone other than Bruin Biometrics LLC or its authorized service center, unless authorized prior to such service by Bruin Biometrics LLC, (f) that are equipment sold as used, or (g) that are exposed to agents listed in Table 1, below. Table 1 is not an exhaustive list of agents which may compromise the integrity of the Provizio SEM Scanner.

Severe Effect – NOT Recommended

Benzene	Cyclohexane	Kerosene	Nitric Acid – 70%
Carbon tetrachloride	Ethyl Chloride	Trichloroethylene	Perchloroethylene
Chlorobenzene	Freon	Lacquer	Toluene
Chloroform	Gasoline, unleaded	Naphtha	Xylene

Table 1 Agents That Should Never Be Used On The Provizio SEM Scanner

Note – No distributor, dealer or other party is authorized to make any warranty on behalf of Bruin Biometrics LLC, or to assume for Bruin Biometrics LLC any other liability with respect to the Provizio SEM Scanner. The contents of this User Manual do not constitute a warranty.

Table of Symbols

Symbol	Meaning
REF	Manufacturer's Catalog designation or number
SN	Serial number
LOT	Lot Number
CE	CE mark in accordance with the European Medical Device Directive
EC REP	European Union Authorized Representative
Rx ONLY	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed health practitioner
(symbol)	Instructions are included and must be followed
(symbol)	Caution or warning
(symbol)	Dispose of this equipment according to local regulations for electrical and electronic waste disposal
(symbol)	Manufactured By
IPX1	Drip Proof Equipment-IPX1: The Provizio SEM Scanner enclosure provides protection against the harmful effects of the ingress of liquids.(IPX1, per IEC 60529)
(symbol)	Type BF Applied Part with IEC-60601-1
(symbol)	Keep away from sunlight
(symbol)	Keep dry
(symbol)	Do not use if package is damaged and the device inside appears physically broken, cracked, or does not charge and start up following the Instructions for Use
(symbol)	Temperature limits (example limits shown)
(symbol)	Humidity limits (example limits shown)
(symbol)	Package contents
(symbol)	Single Patient Use Only
NON STERILE	Non-Sterile
MD	Medical Device

Logging In

No matter what privileges you have within the Gateway, your login starts the same way.

1. **Enter Credentials**

   Open a browser and enter the URL of the Gateway within the institutions' network. This should bring up the login screen from the Gateway. Enter the username and password that you use for other applications within your institution. Click on the LOGIN button.

2. **Select a Language**

   The Gateway language selection displays the language of the facility setup during configuration by the Admin. However, it allows each user to select language at their Login for their session.
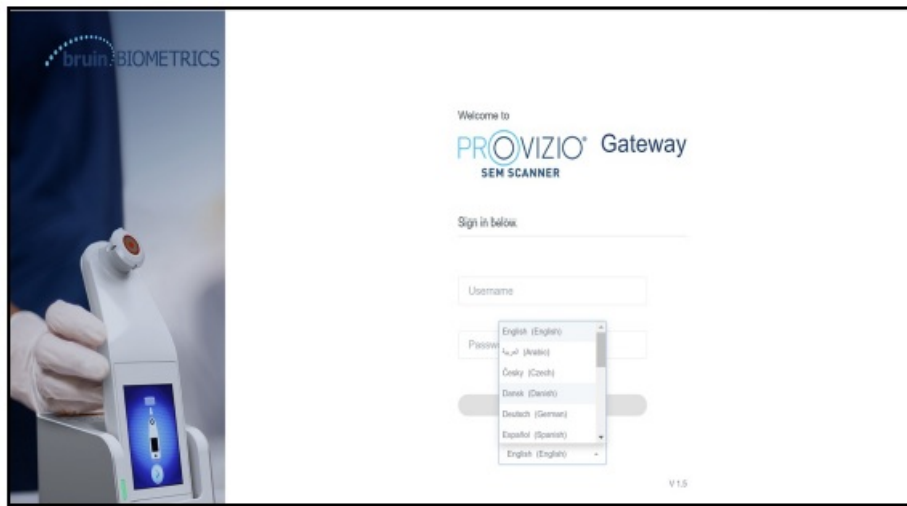
Figure 1 User Language Selection

Clinical Role

Patient List

This screen displays a list of all patients currently under care within your institution. The patient list is limited by the user's access rights to the facility and ward. These rights are configured by your system administrator based on your Job assignment and role. The patient list shows you 3 days of data by default. However, it allows you to filter by a date range to expand or contract your list of patients. It also allows you to see specific patient's data by entering a Patient name or Patient ID. You can also enter multiple Patient names or Patient ID's, separated by Comma.

After changing any options, you must click "Refresh data" to refresh data on your screen.

You can access additional filter options by clicking on Filter button. This will open a popup window with filter options to select.
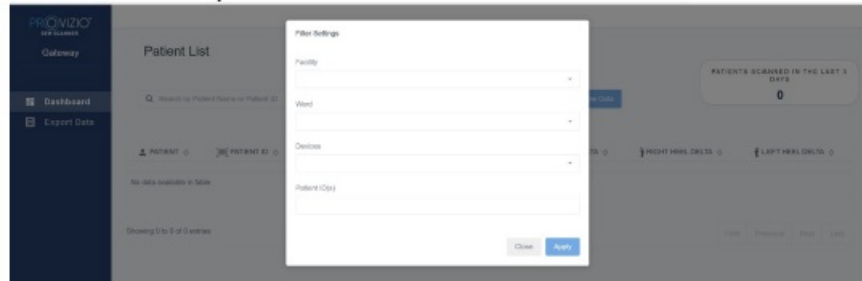

Figure 2 Patient List Filter Screen

The options are:

- **Facility –** Allows you to filter your data by a single facility
- **Wards –** Allows you to select multiple wards by which to filter your data
- **Devices –** Allows you to select multiple devices by which to filter your data – note device refers to individual Provizio SEM Scanners
- **Patient ID(s) –** Allows you to enter multiple patient IDs by which to filter your data
- **Reading Type –** Can be used independently to select Sacrum, Right Heel, or Left Heel

The filter screen will have 2 Actions:

- **Close –** To Discard your changes and close the Filter screen
- **Apply –** To Apply your filter and Close the Screen and update the Patient list

Patient list will allow you to "Click" on any row to view Patient Chart.

Patient Chart
The Patient Chart page displays a plot of the delta values over a period of time that can be selected by the button along the bottom of the page. This example is a 2-week plot. The orange line is the 0.6 threshold for an actionable delta i.e. delta D>0.6. The icon legend is shown at the top of the page. Hovering over an icon will display the numeric details of that data point.
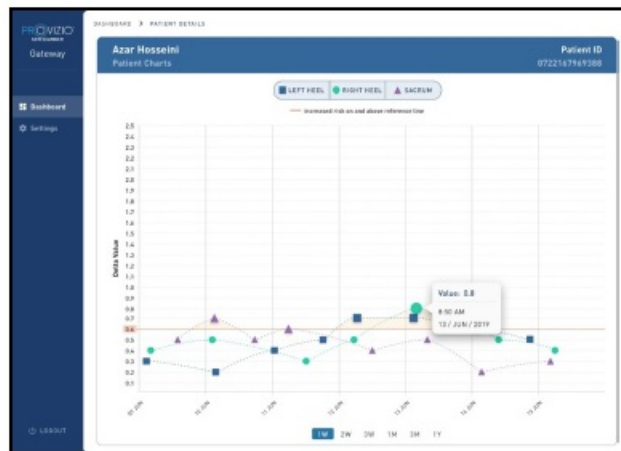

Figure 3 Data Point Details

Clicking on an icon will bring up a pop-up with a plot of the SEM values that were taken to generate this delta value.

Figure 4 SEM Values for a Data Point

Close the browser window to exit the session.

Export Data
The Export Data feature allows users to select criteria and Export SEM data in CSV format for the selected options.

Figure 5 Export SEM Data View

The Export Data screen allows you to view data based on your selections before exporting.
There are 2 options selected by default:

Export Data For All Patients
Encrypt Data – (Recommended, Non-identifiable Patient ID & Patient Name) A warning will display when Exporting patient data as UNENCRYPTED. Proper safeguards should be in place to secure the data. The Export Data list allows you to add date range to expand or contract your list of patients. It also allows you to see specific patient's data by entering Patient name or Patient ID. You can also enter multiple Patient names or Patient ID's, separated by Comma. After changing any options, you must click "Refresh data" to refresh data on your screen You can access additional filter options by clicking on Filter button. This will open a popup window with filter options to select.
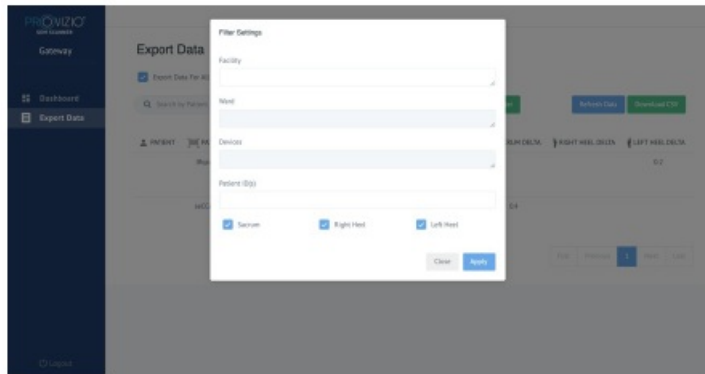

Figure 6 Filter Export Data

The options are:

- **Facility –** Allows you to filter your data by a single facility
- **Wards –** Allows you to select multiple wards by which to filter your data
- **Devices –** Allows you to select multiple devices by which to filter your data – note device refers to individual Provizio SEM Scanners
- **Patient ID(s) –** Allows you to enter multiple patient IDs by which to filter your data
- **Reading Type –** Can be used independently to select Sacrum, Right Heel, or Left Heel

The filter screen will have 2 Actions:

- **Close –** To Discard your changes and close the Filter screen
- **Apply –** To Apply your filter and Close the Screen and update the Patient list

"Download CSV" will only be enabled, if any data row is present in the Export Data Table. Clicking on "Download CSV" will download the file (csv or zip) on your computer hard drive in the download folder. This file can be opened in Excel. Close the browser window to exit the session.

Patient Name Edit (Configurable Feature)
The configurable feature for Editing Patient Name is only available if the facility's ADMIN has set up this feature on the Gateway Admin screen. It allows user to Add or Correct Patient Names, if needed.

Figure 7 Patient Name Edit (Configurable Feature)

When user clicks on the Edit icon on a patient row, a patient name edit screen allows the user to Add or Edit patient name, if available.

Figure 7a Patient Name Edit Screen (Configurable Feature)

Click on Update to apply Changes. A confirmation dialog will appear.

Figure 7b Patient Name Edit Confirmation (Configurable Feature)

Confirm or cancel the update to close the Dialog.

Admin Role

The Admin Menu lists several options to allow management of Dashboard, Facilities, LDAP, Data Mapping, Devices, Setup, & Settings for Language and Patient Name Options.
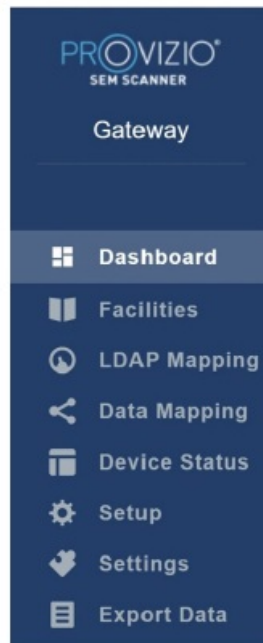
Figure 8 Admin Menu

- The "Settings menu" exposes the ability to "Enable" the "Configurable" Feature for Patient Name Edit.
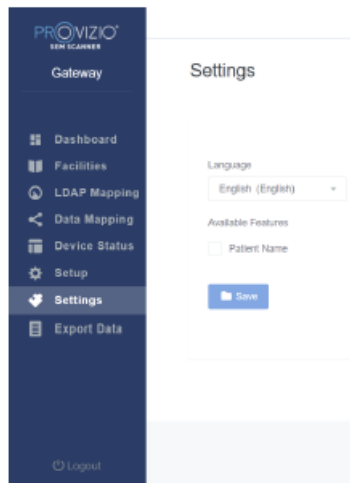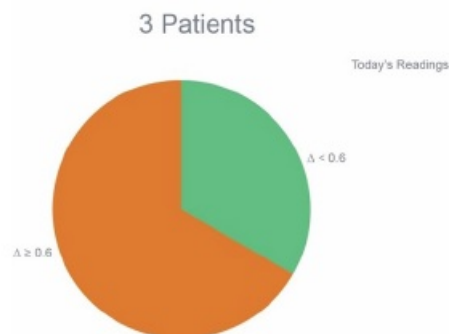

Figure 8a Patient Name

- Click on Save to Apply your changes.

Dashboard

The Pie Chart below shows the breakdown of patients who have been scanned using the Provizio SEM Scanner and are identified as being at increased risk (D>0.6) on a given day.

The Analysis line chart displays the total number of delta readings for the patients in the Pie Chart analysis for the past 7-day period, categorized as either low risk (green line, D<0.6) or increased risk (amber line, D>0.6) on a day by day basis.

OVERALL ANALYSIS
63

LOW RISK (△ < 0.6)
33

HIGH RISK (△ ≥ 0.6)
30

Figure 9a Analysis Chart

Enterprise (Facilities) Option
The Facilities screen will allow admin users to enter/edit facilities for their institution. Select Facilities Menu to manage Facilities and Wards

- To add a NEW Facility
- Click on Add Facility to Add a new facility record. The data required is:
- Facility Name
- Facility Description
- Active/Inactive Status

Figure 10 Add Facility Screen

Click on Save to Add the facility record and enter more, if needed by following the steps above.
To edit an EXISTING Facility
Click on Edit Facility to update an existing facility record. The data required is:

- Facility Name
- Facility Description
- Active/Inactive Status
- Click on Update will show confirmation of changes and close the Edit Screen.

Figure 11 Edit Facility Screen

Clicking on Wards will allow admin users to enter/edit Wards for their institution.

Figure 12 Wards Screen

To add a NEW Ward
Click on Add Ward to Add a new Ward record. The data required is:

- Ward Name
- Ward Description
- Facility Name that the Ward is assigned too
- Active/Inactive Status

Figure 13 Add Ward Screen

Click on Save to Add the Ward Record and enter more, if needed by following the steps above.
To edit an EXISTING Ward
Click on Edit Ward to Update an existing Ward record. The data required is:

- Ward Name

- Ward Description

- Facility Name that the Ward is assigned to

- Active/Inactive Status

- Click on Update will show confirmation of Changes and Close the Edit Screen.

Figure 14 Edit Ward Screen

LDAP Mapping
Allows the Admin user to apply Facility and Wards Access rights to the user roles in LDAP Mapping

Figure 15 LDAP Mapping Screen

- Admin user will first select the institution's LDAP role

- Admin User will then Select the Gateway role to associate Gateway role to the LDAP role

- Admin User will then select one or more Facilities (searchable) to allow access to the selected Gateway role

- Admin User will then select one or more Wards (Searchable) to allow access to the selected Gateway role

- Save Button will display a confirmation message and allow more mappings, if needed.

This setup controls how Gateway users will see patient(s) on their Patient list or Data Export list. The facilities and wards access will limit the list of patients to be ones in their allowed facilities and wards.

Data Mapping

The Data Mapping allows user to correct any Patient ID that may have been entered incorrectly or updated after the scan such as from a temporary ID to a permanent ID.

Figure 16 Data Mapping

Device Status
The Device Status List displays information for all activated devices including Activation Date, MAC Address, Serial Number, Last Communication, Facility, Ward, Active Status, and Actions. All columns can be sorted.

Figure 17 Device Status

Enter a keyword into the Search box in the upper right to display information matching the search string. Information from all columns can be searched.

Figure 18 Device Search Results

To add a NEW Device
Click on Add Device to enter a new Device. The data required is:

- **MAC Address –** without (:)

- **Serial number –** this can be found on the label on the back of the device. Allows Free text

- Facility Name (Select from List) that the Device will be assigned too

- Ward Name (Select from List) that the Device will be assigned too

- Active/Inactive Status

Figure 19 Add Device

Click on Save to Add the Device.
To edit an EXISTING Device
Click on Edit Device to edit an existing Device. The data required is:

- **MAC Address –** without (:)

- **Serial number –** this can be found on the label on the back of the device. Allows Free text

- Facility Name (Select from List) that the Device will be assigned to

- Ward Name (Select from List) that the Device will be assigned to

- Active/Inactive Status

Figure 20 Update Device

Click on Update Button to update the Device.

Setup

The Setup screen displays the Database Info & LDAP info for the Server Address, Server Port, Username, and Password initially set.

Figure 21 Database & LDAP Info Screen

No edits can be made here but if you would like to make sure the Database Info is correct, click on the blue Test DB Connection and/or Test LDAP Connection button in the lower left. If correct, a confirmation message will appear in the upper right.

Figure 22 Test DB & LDAP Connection Success

Settings

The Settings page allows a user to set Gateway's default Language. This will be used site-wide for any user unless the user changes it for a login session.
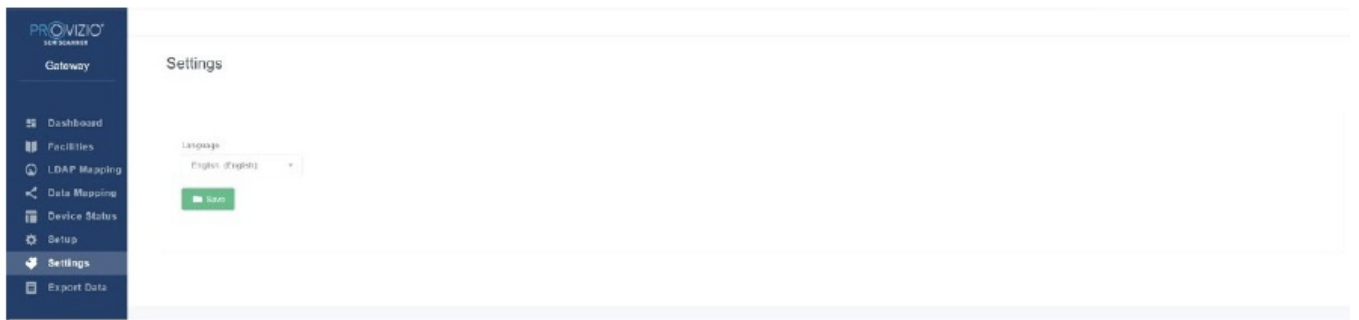
Figure 23 Settings Screen

Select the Desired Language
Click on the Save button to save the settings.

Export Data

The Export Data feature allows users to select criteria and Export SEM data in CSV format for the selected options.
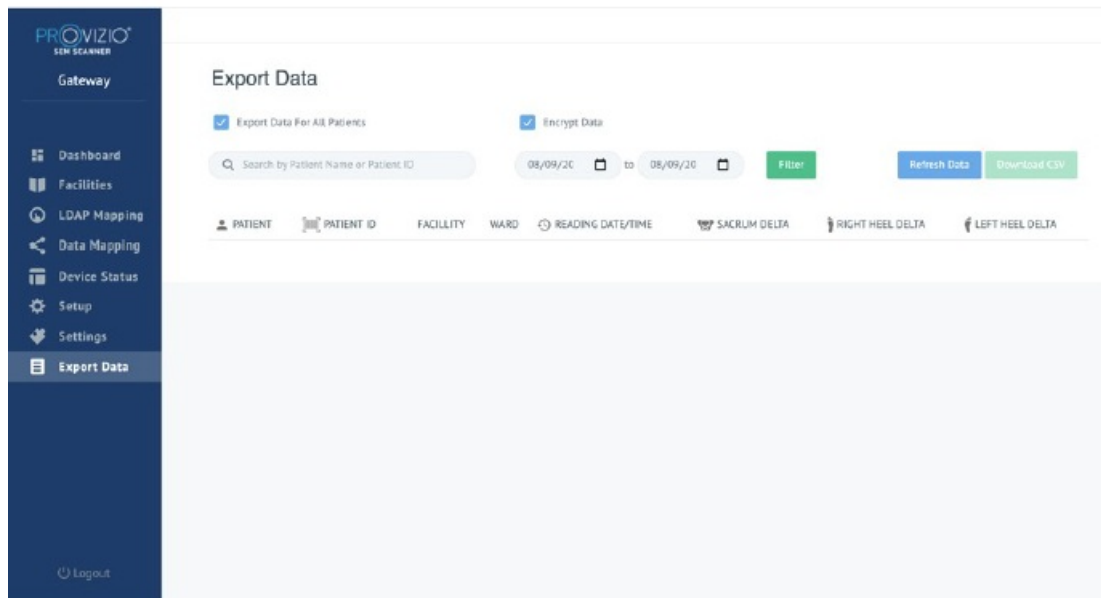
Figure 24 Export SEM Data View

The Export data screen allows you to view data based on your selections before exporting.

There are 2 options selected by default:

Export Data For All Patients

Encrypt data – (Recommended, Non-identifiable Patient ID & Patient Name)

A warning will display when Exporting patient data as UNENCRYPTED. Proper safeguards should be in place to secure data.

The Export data list allows you to add date range to expand or contract your list of patients.

It also allows you to see specific patient's data by entering a Patient name or Patient ID.

You can also enter multiple Patient names or Patient ID's, separated by Comma.

After changing any options, you must click "Refresh data" to refresh data on your screen.

You can access additional filter options by clicking on Filter button. This will open a popup window with filter options to select.

Figure 25 Export Filter Screen

The options are:

- **Facility –** Allows you to filter your data by a single facility
- **Wards –** Allows you to select multiple wards by which to filter your data
- **Devices –** Allows you to select multiple devices by which to filter your data – note device refers to individual Provizio SEM Scanners
- **Patient ID(s) –** Allows you to enter multiple patient IDs by which to filter your data Reading Type – Can be used independently to select Sacrum, Right Heel, or Left Heel
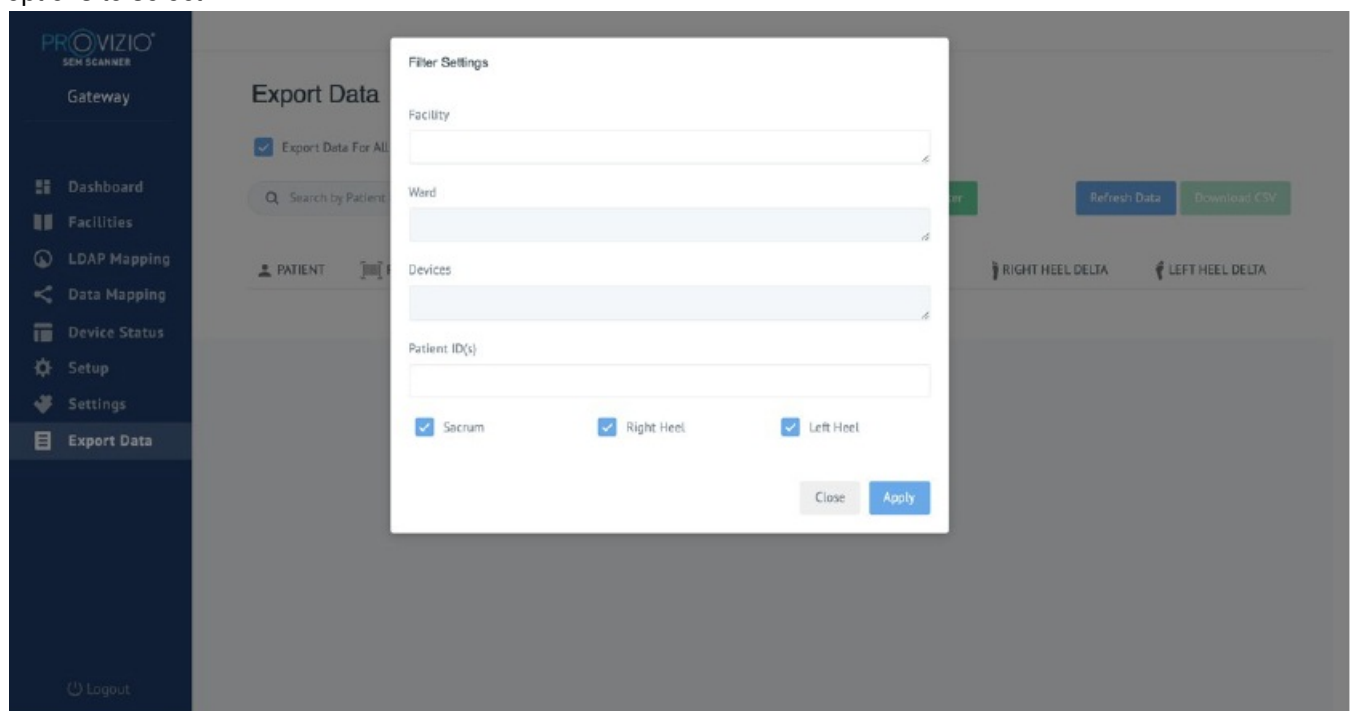
The filter screen will have 2 Actions:

- **Close –** To Discard your changes and close the Filter screen
- **Apply –** To Apply your filter and Close the Screen and update the Patient list "Download CSV" will only be enabled, if any data row is present in the Export Data Table. Clicking on "Download CSV" will download the file (csv or zip) on your computer hard drive in the download folder. This file can be opened in Excel.

Troubleshooting

If any situation cannot be resolved, please contact your system administrator or institutional Information Technology Department. If the situation can still not be resolved, please contact your Product Specialist or your Customer Service.

Problem	Resolution
Logging In	
I do not know the URL to connect to the Gateway.	Contact your system administrator for the correct URL for your institutions installation.
I have the Gateway URL, but my browser does not connect.	Ensure you have the correct URL from your system administrator. Ensure with your system administrator that your computer and intranet is configured to connect to this URL.

My login does not work.	The Gateway uses the same login information as you use for other activities. You may not have been assigned a Gateway role. Ask your system administrator to check that you have been assigned a Gateway role.
Patient Listings & Data	
I do not see a patient listed.	The data may not have been uploaded yet. Data is only uploaded when the Provizio SEM Scanner is placed back into the Charging Hub. The Gateway uses the entered/scanned patient ID to gather patient name. Ensure that the patient ID has been entered correctly. Each Provizio SEM Scanner must be registered with the Gateway before data can be uploaded. Ensure the Provizio SEM Scanner is listed in the Device Listings.

Problem	Resolution
There is a Patient ID listed, but no patient name.	The Gateway uses the entered/scanned patient ID to gather patient name. Ensure that the patient ID has been entered correctly.
A scan for a patient is not listed.	The data may not have been uploaded yet. Data is only uploaded when the Provizio SEM Scanner is placed back into the Charging Hub. The Gateway uses the entered/scanned patient ID to gather patient name. Ensure that the patient ID has been entered correctly. Each Provizio SEM Scanner must be registered with the Gateway. Ensure the scanner is listed in the Device Listings.
Device Listings	
A Provizio SEM Scanner is not listed.	Each Provizio SEM Scanner must be registered with the Gateway before data can be uploaded. Ensure the scanner is listed in the Device Listings.
Application Setup	
DB Connection test failed.	Contact your system administrator to ensure the database connection information in the Gateway is correct and current.
LDAP Connection test failed.	Contact your system administrator to ensure the LDAP connection information in the Gateway is correct and current.
I see an 'X' when I place the Provizio SEM Scanner in the Charging Hub after a patient scan.	Try 1 or 2 times as network connection could have been the issue and if the problem persists then contact your system administrator: they will refer to a Guide to get the decoded error message and troubleshoot this further.

Bruin Biometrics products are protected by one or more patents. Refer to **https://sem-scanner.com/patents** for more information.

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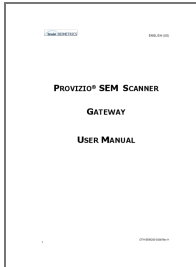**E-mail: info@bruinbiometrics.com**
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Documents / Resources

PROVIZIO® SEM SCANNER GATEWAY USER MANUAL	**SEM Scanner SEM250 Provizio SEM Scanner GATEWAY** [pdf] User Manual SEM250 Provizio SEM Scanner GATEWAY, SEM250, Provizio SEM Scanner GATEWAY, SEM Scanner GATEWAY, Scanner GATEWAY

References

- 🌐 **scanner.com/patents**
- ◎ **Pressure Injury Prevention Tool | Provizio® SEM Scanner**

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