

# **PROVIZIO<sup>®</sup> SEM SCANNER**

## **GATEWAY SYSTEM**

### **USER MANUAL**

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## I. Warnings and Safety Precautions

The Provizio SEM Scanner and Provizio SEM Scanner S has been designed and constructed in accordance with applicable 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.

### **Rx ONLY**

Caution: Federal (US) law restricts this device to sale by or on the order of a physician or other licensed health practitioner.



#### **I.1. 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 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 this document after it is used on a patient.
- **WARNING:** To prevent cross-contamination of patients, use a new, unopened single-use 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.

- **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 there is no foreign material in the Charging Hub slot before placing the scanner in the Charging Hub.

## **1.2. 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.

## **2. General**

### **2.1. 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.

### **2.2. Requirements**

The Bruin Biometrics Webserver Virtual Machine (VM).

### **2.3.      *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.

### **2.4.      *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.

### **2.5.      *Contraindications***

Do not use on broken skin.

### **2.6.      *Intended User Profile***

The system is intended for use by healthcare professionals.

### **2.7.      *Adverse Effects***

There are no known adverse effects using the scanner.

### **2.8.      *Warranty and Disclaimer***

This manual is intended to provide instructions on the proper use of the SEM. It should be used in conjunction with the appropriate training. Bruin Biometrics LLC warrants the Provizio SEM Scanner against defects in materials and workmanship for three (3) years from the date of purchase from Bruin Biometrics or its subsidiaries. This warranty is given only to the original purchaser of the SEM Scanner. Bruin Biometrics obligation under the warranty is to provide for repair, or at its option, to provide a replacement product. No other remedy is obligated by this warranty. All special, incidental, and coincidental damages are excluded.

There are no conditions associated with varnishing, enameling, oxidation and similar protective finishes, as well as covering with sealing compounds that can re-plasticize at temperatures to be expected during normal operation.

To request repair or replacement under this warranty, purchasers should contact their local Customer Service provider.

Warranty conditions may differ in some countries. Contact your Customer Service provider for warranty terms.

Risk of loss or damage during shipments under this warranty shall be borne by the party shipping the Product. Products shipped by the Purchaser under this warranty shall be suitably packaged to protect the Product. If Purchaser ships a product to Bruin Biometrics in unsuitable packaging, any physical damage present in the Product on receipt and inspection by Bruin

Biometrics, and not previously reported, will be presumed to have occurred in transit and will be the responsibility of the Purchaser.

### **2.8.1. Exclusions**

The use of the instrument in a manner different than that described in this manual may result in improper function. This warranty is limited to defects and materials that can be attributed to a fault or defect within the SEM Scanner.

This warranty does not extend to any Warranted Products or parts thereof: (a) that have been 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 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 or its authorized service center, unless authorized prior to such service by Bruin Biometrics, (f) that are equipment sold as used, or (g) that are exposed to agents listed in

Table I, below.

Table I is not an exhaustive list of agents which may compromise the integrity of the SEM Scanner.

**Table I. Agents That Should Never Be Used on the 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





















### **2.8.2. Disclaimer of Additional Warranties**

No distributor, dealer or other party is authorized to make any warranty on behalf of Bruin Biometrics, or to assume for Bruin Biometrics any other liability with respect to the SEM Scanner.

The contents of these Instructions for Use do not constitute a warranty.

## 2.9. Table of Symbols

Table 2. Table of Symbols

Symbol	Meaning
	Manufacturer's Catalog designation or number
	Serial number
	Lot Number
	CE mark in accordance to the European Medical Device Directive
	European Union Authorized Representative
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed health practitioner
	Instructions are included and must be followed
	Caution or warning
	Dispose of this equipment according to local regulations for electrical and electronic waste disposal
	Manufactured By
	Drip Proof Equipment-IPX1: The Provizio SEM Scanner enclosure provides protection against the harmful effects of the ingress of liquids. (IPX1, per IEC 60529)
	Type BF Applied Part with IEC-60601-I
	Keep away from sunlight
	Keep dry
	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
	Temperature limits (example limits shown)
	Humidity limits (example limits shown)
	Package contents
	Single Patient Use Only
	Non-Sterile

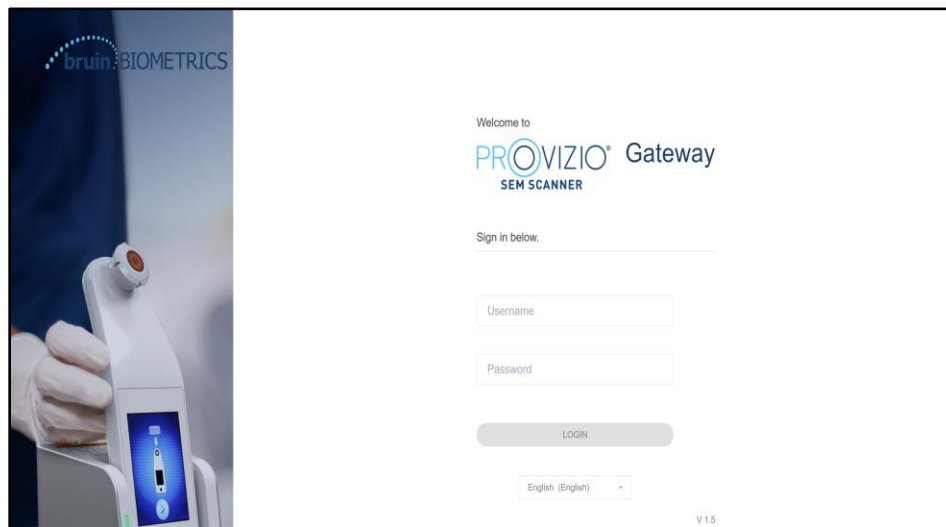


### 3. Logging In

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

#### 3.1. *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.

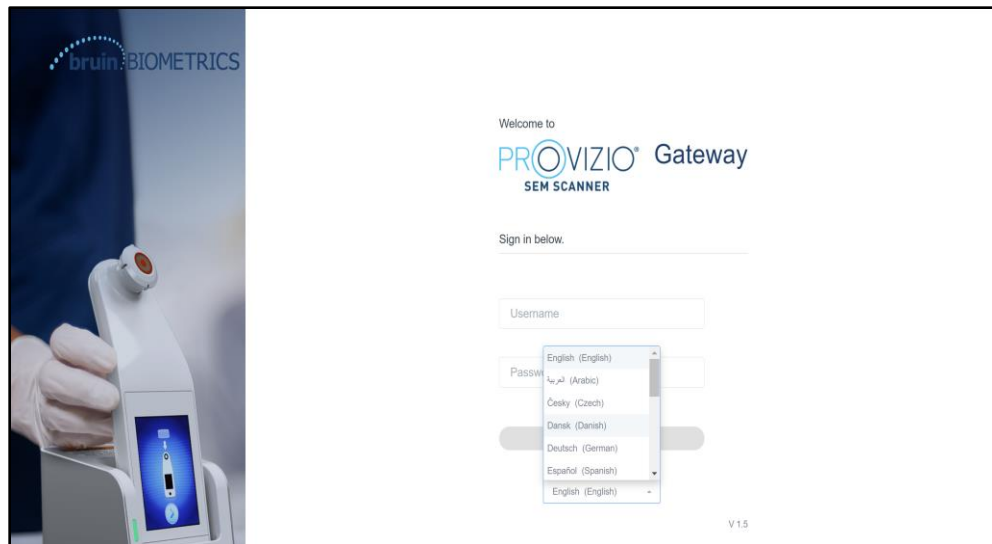


**Figure 1 Gateway Login Screen**

Enter the username and password that you use for other applications within your institution. Click on the LOGIN button.

#### 3.2. *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 2 User Language Selection**

Clicking on LOGIN will take you to the first screen for your Role.

## 4. Clinical Role

### 4.1. Patient List

This screen displays a list of all patients currently under care within your institution.

PATIENT	PATIENT ID	LAST READING	LEFT HEEL DELTA	RIGHT HEEL DELTA	SACRUM DELTA
Azar Hosseini	0722167967388	12 JUN 2019 14:09:53	0.3	0.5	0.7
Ea Tipene	0814725422806	10 JUN 2019 14:09:53	0.3	0.5	0.7
Miglena Tadic	0367629296661	08 JUN 2019 14:09:53	0.3	0.5	0.7
Stephen Shaw	0186538797811	02 JUN 2019 14:09:53	0.3	0.5	0.7
Babila Ekwé	035837867816	20 MAY 2019 14:09:53	0.3	0.5	0.7
Iruka Akuchi	0521911792088	12 MAY 2019 14:09:53	0.3	0.5	0.7

Figure 3 Patient List Screen

The **Patient List** displays columns of the Name, Patient ID, date of the last reading, and last delta values for the Left Heel, Right Heel, and Sacrum. Every column is sortable by clicking on the heading. There is a SEARCH box to find the name and PID fields. Hovering your mouse over the “PATIENTS SCANNED IN THE LAST 3 DAYS” brings up a pop-up window

PATIENT	PATIENT ID	LAST READING	LEFT HEEL DELTA	RIGHT HEEL DELTA	SACRUM DELTA
Azar Hosseini	0722167967388	12 JUN 2019 14:09:53	0.3	0.5	0.7
Ea Tipene	0814725422806	10 JUN 2019 14:09:53	0.3	0.5	0.7
Miglena Tadic	0367629296661	08 JUN 2019 14:09:53	0.3	0.5	0.7
Stephen Shaw	0186538797811	02 JUN 2019 14:09:53	0.3	0.5	0.7
Babila Ekwé	035837867816	20 MAY 2019 14:09:53	0.3	0.5	0.7
Iruka Akuchi	0521911792088	12 MAY 2019 14:09:53	0.3	0.5	0.7
Dashante Clarke			0.3	0.5	0.7
Shirai Subaru			0.3	0.5	0.7

Figure 4 Patients Scanned in Last Three Days

Click on a patient’s name to view the Patient Chart.

## 4.2. 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. The icon legend is shown at the top of the page.

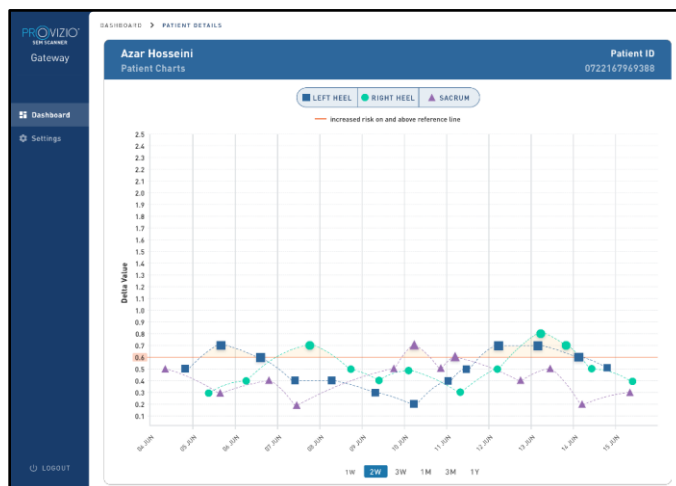


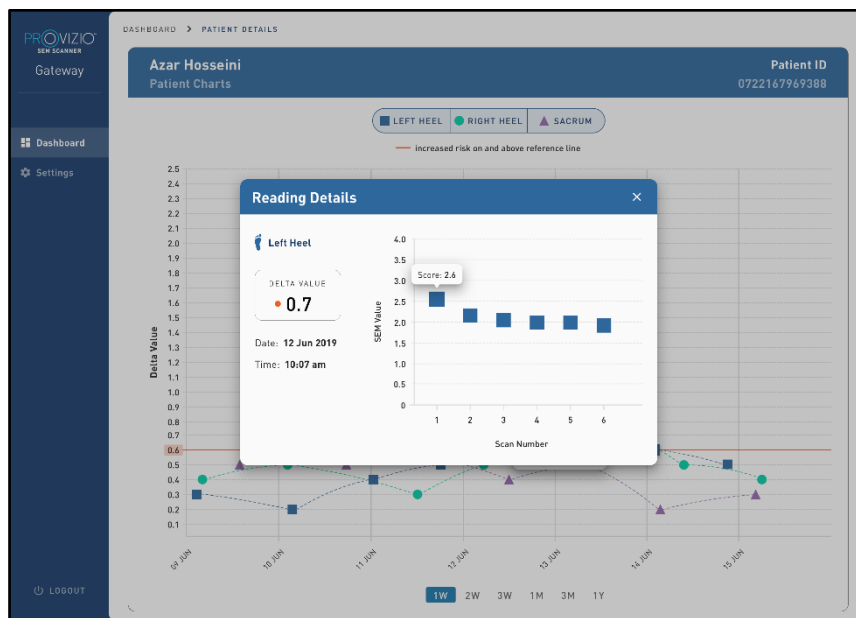
Figure 5 Patient Chart

Hovering over an icon will display the numeric details of that data point.



Figure 6 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 7 SEM Values For a Data Point**

Close the browser window to exit the session.

### 4.3. **Export Data**

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

The screenshot shows the 'My Dashboard' page with the 'Export Data' section active. It includes filters for 'Export Data For All Patients', 'Encrypt Data', 'Filter By Patient ID(s)', 'Filter By Date Range' (06/01/2021 to 06/01/2021), and 'Filter By Reading Type' (Sacrum, Right Heel, Left Heel). Below the filters is a table with columns: PATIENT, PATIENT ID, READING DATE/TIME, SACRUM DELTA, RIGHT HEEL DELTA, and LEFT HEEL DELTA. The table contains two rows of data.

PATIENT	PATIENT ID	READING DATE/TIME	SACRUM DELTA	RIGHT HEEL DELTA	LEFT HEEL DELTA
90YR8KJyt	9WfagK06x	6/1/2021 10:50:12 AM	0.0	0.0	54.3
90YR8KJyt	X0LNS+5TB9	6/1/2021 4:21:44 PM	0.4	0.3	0.1

**Figure 8a Export SEM Data View**

The available filters and options for Data Export are:

- All Patients or Selected Patients
- Unencrypted (Real Patient ID & Patient Name) or Encrypted Data (Non-identifiable Patient ID & Patient Name)
- For Unencrypted data, the following warning will be displayed:
  - Exported patient data will be UNENCRYPTED. Proper safeguards should be in place to secure data.
- Filter by Date Range
- Filter by Reading Type (SEM, Right Heel, Left Heel)
- View Data on Screen
- Export Data in CSV format

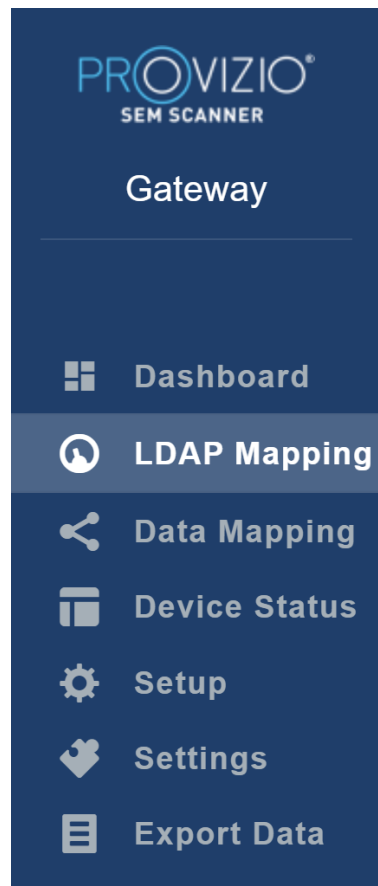
Clicking on left menu “Export Data” will launch the above screen. Select the desired options and click on “View Data” to refresh the data on the screen.

“Download CSV” will be enabled once you have “Refreshed Data” by clicking on “View Data”.

Clicking on “Download CSV” will download the file (csv or zip) on your computer hard drive in the download folder. This can also be opened in Excel.

## 5. Admin Role

The Admin Menu lists several options to allow management of **Dashboard**, **Devices**, **Language Settings**, **Database Setup**, and **Data Mapping**.

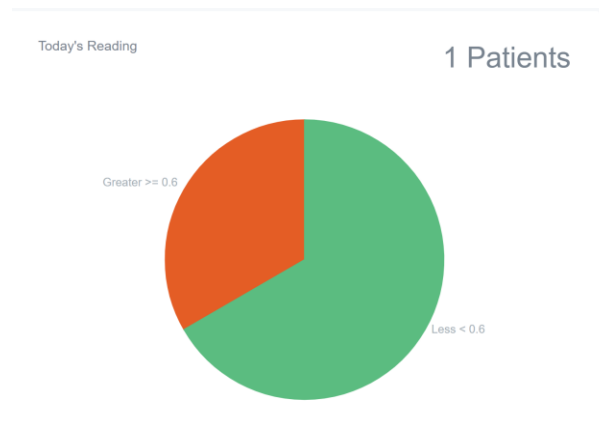


**Figure 9 Admin Menu**

### 5.1. *Dashboard*

The Dashboard shows the percentage of patients who have been scanned using the Provizio SEM Scanner and are wither above or below the 0.6 threshold on that day.

**For example:** In the Picture below, A single patient was scanned, the SACRUM was scanned as higher than 0.6 while both Right & Left heels were scanned as lower than 0.6



**Figure 10 Dashboard Chart**

The **Overall Analysis** line chart displays the total number of delta readings for the past 7-day period, categorized as either low risk ( $<0.6$ ) or high risk ( $\geq 0.6$ ) on a day by day basis.

**For example:** In the Picture below, the Chart was created on July 09<sup>th</sup>. There were no readings on July 03, July 04, & July 05. Then, on July 06<sup>th</sup>, there were total of 5 readings. 01 reading was higher than 0.6 while 4 readings were lower than 0.6. There were no readings on July 07, July 08, and July 09.



**Figure 11 Analysis Chart**


## 5.2. LDAP Mapping

Select **Admin** or **Clinical** from the **Local Roles** drop down menu.



## LOCAL ROLES

Admin ▼

 Save

**Figure I2 Select Role to Map**

Search for **LDAP Roles** table on the right or scroll to the right LDAP role.

Check the applicable checkboxes to select roles from the **LDAP Roles** table on the right.

PROVIZIO<sup>®</sup>

SEM SCANNER

Gateway

Dashboard

LDAP Mapping

Data Mapping

Device Status

Setup

Settings

Export Data

Logout


My Dashboard

LDAP Mapping

Security

LOCAL ROLES

Admin ▼

 Save

LDAP ROLES

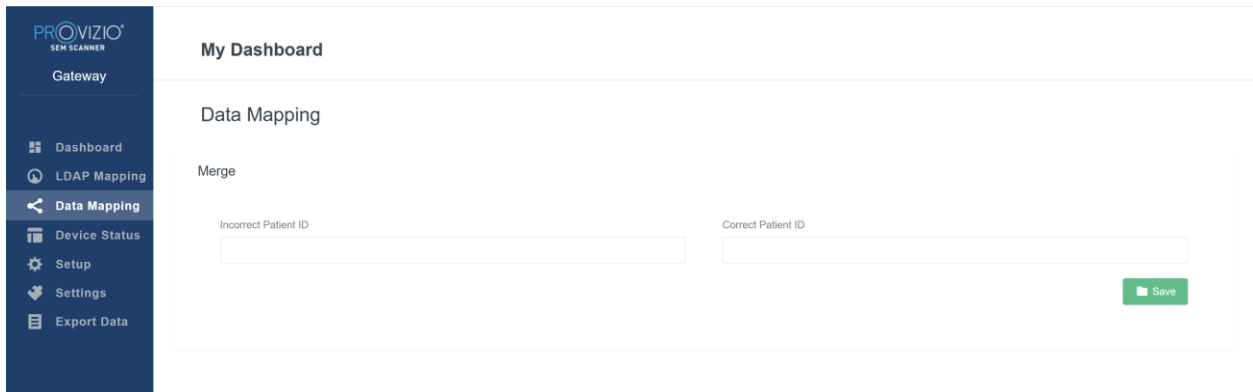
	Description
<input type="checkbox"/>	Administrators
<input type="checkbox"/>	Users
<input type="checkbox"/>	Guests
<input type="checkbox"/>	Print Operators
<input type="checkbox"/>	Backup Operators

**Figure I3a Role Mapping**

Click on the **Save** button to save your settings.

### 5.3. 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.

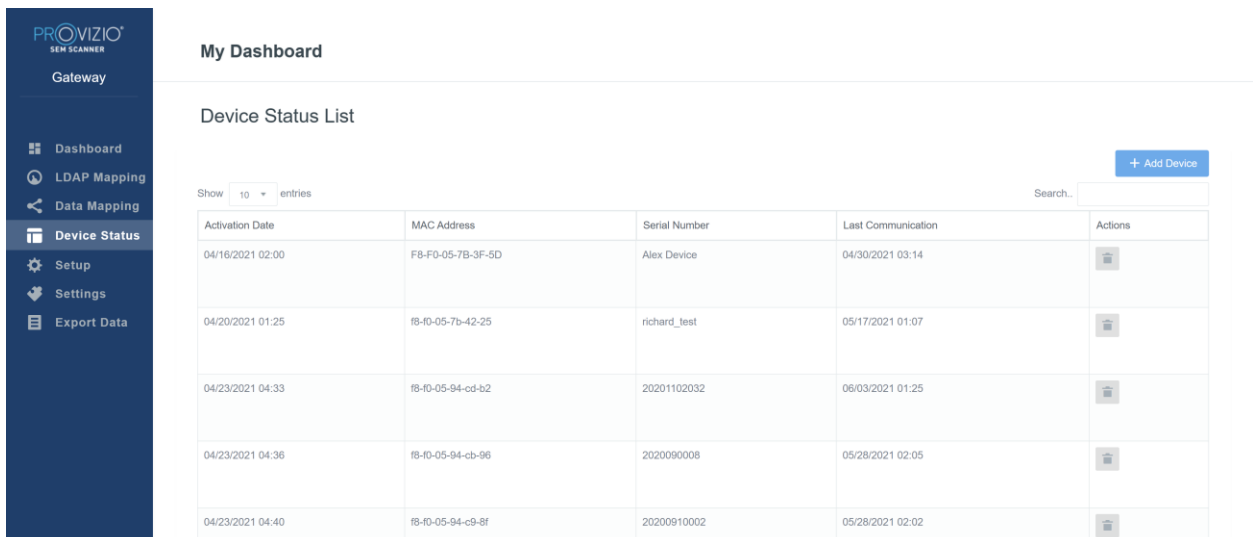







**Figure I3b Data Mapping**

Click on the **Save** button to save your Data Mapping.

### 5.4. Device Status

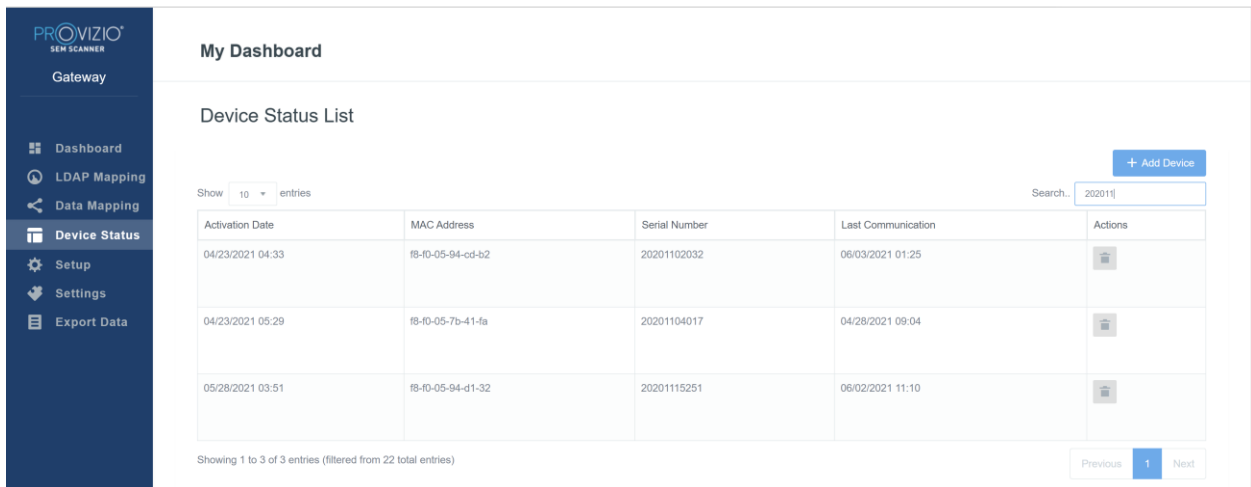
The **Device Status List** displays information for all activated devices including **Activation Date**, **MAC Address**, **Serial Number**, **Last Communication**, and **Actions**. All columns can be sorted.



Activation Date	MAC Address	Serial Number	Last Communication	Actions
04/16/2021 02:00	F8-F0-05-7B-3F-5D	Alex Device	04/30/2021 03:14	
04/20/2021 01:25	F8-F0-05-7B-42-25	richard_test	05/17/2021 01:07	
04/23/2021 04:33	F8-F0-05-94-cd-b2	20201102032	06/03/2021 01:25	
04/23/2021 04:36	F8-F0-05-94-cb-96	2020090008	05/28/2021 02:05	
04/23/2021 04:40	F8-F0-05-94-c9-8f	20200910002	05/28/2021 02:02	

**Figure I4 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.



**My Dashboard**

**Device Status List**

Show 10 entries Search: 202011

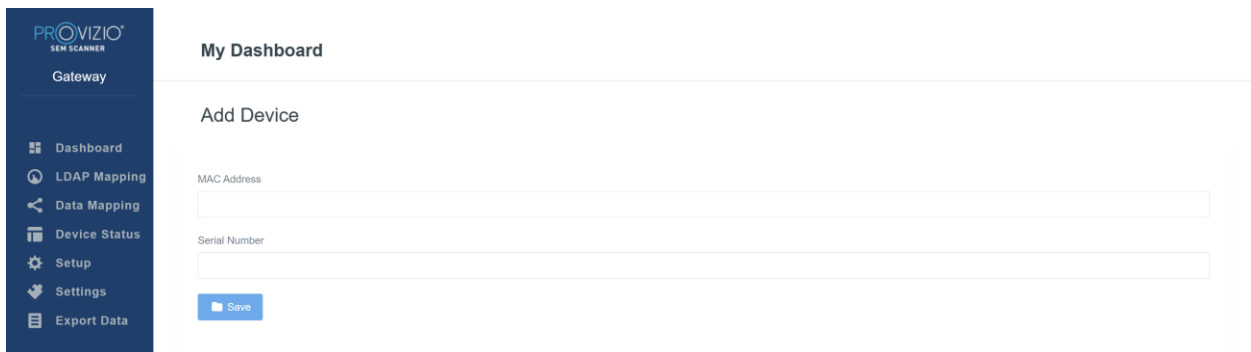
Activation Date	MAC Address	Serial Number	Last Communication	Actions
04/23/2021 04:33	18-10-05-94-cd-b2	20201102032	06/03/2021 01:25	
04/23/2021 05:29	18-10-05-7b-41-fa	20201104017	04/28/2021 09:04	
05/28/2021 03:51	18-10-05-94-d1-32	20201115251	06/02/2021 11:10	

Showing 1 to 3 of 3 entries (filtered from 22 total entries)

Previous 1 Next

**Figure 15 Device Search Results**

Click on **Add Device** to enter a new SEM Scanner with MAC Address and Serial number.



**My Dashboard**

**Add Device**

MAC Address

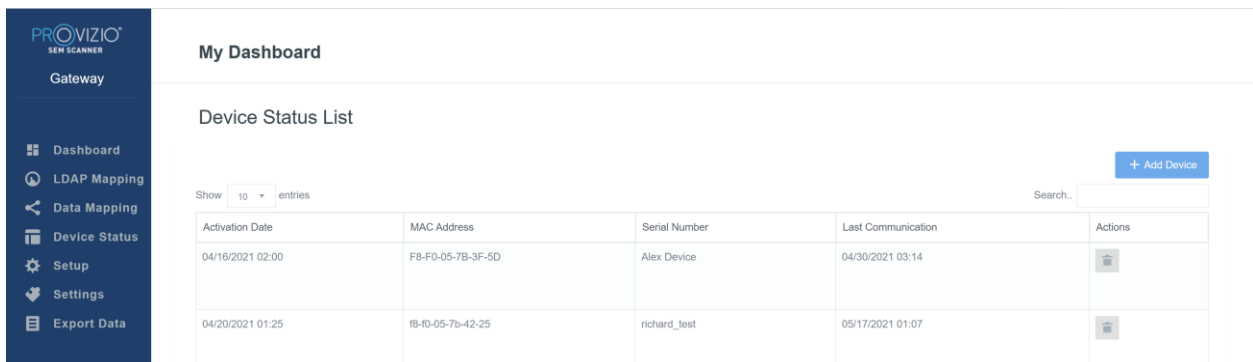
Serial Number

**Save**

**Figure 16 Add Device**

Click on the **Save** button to Save the new Device.

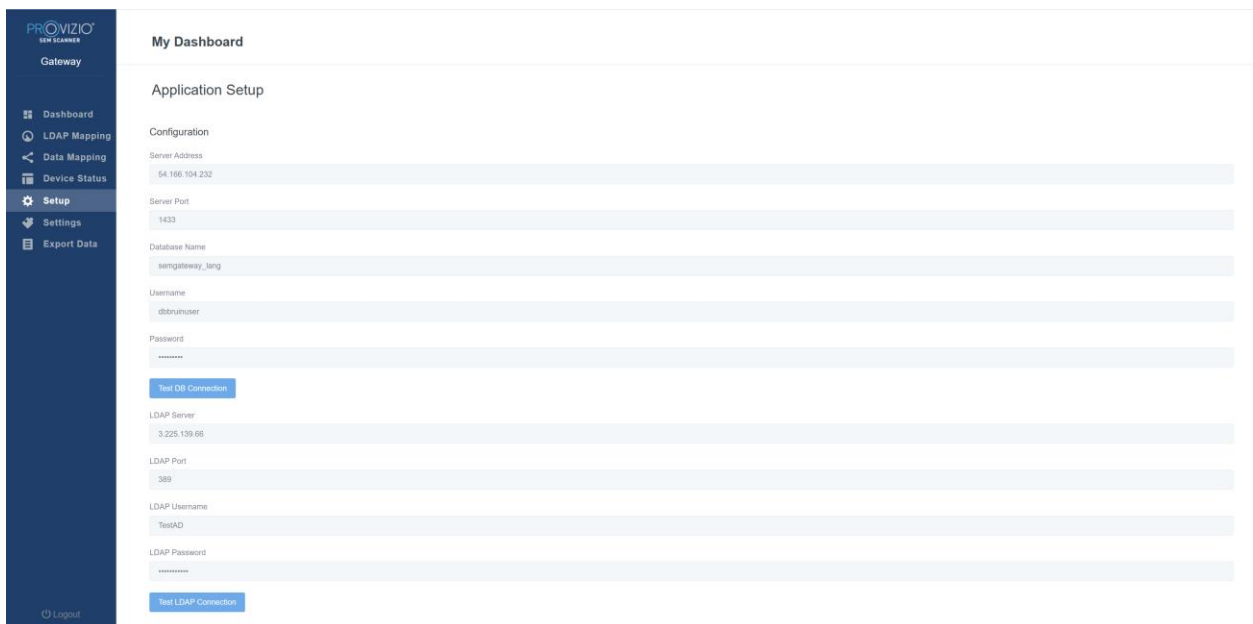
**Warning! Irreversible:** Click on **Actions** to Remove a device from the Gateway.



**Figure 17 Remove Device**

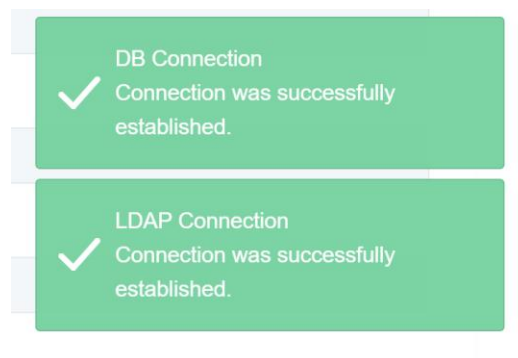
## 5.5. Setup

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



**Figure 18 Database & LDAP Info Screen**

No edits can be made here but if you'd 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.

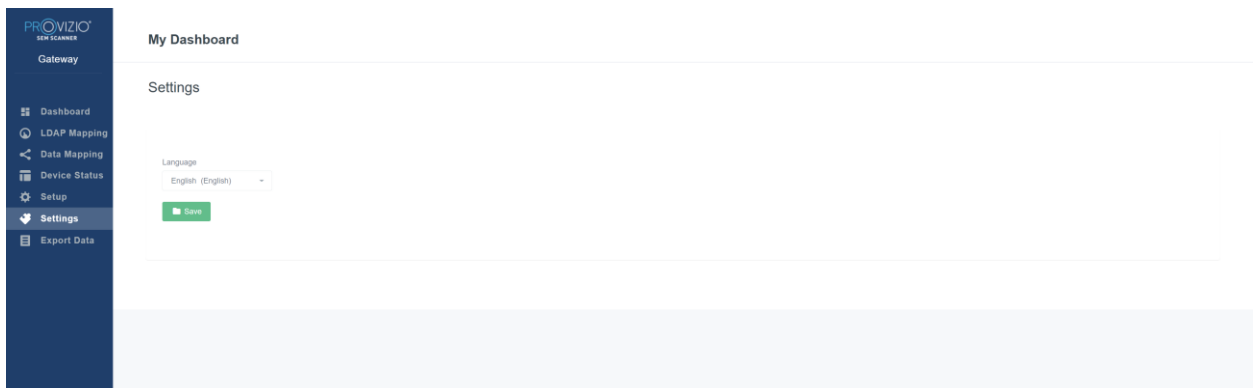


**Figure 19 Test DB & LDAP Connection Success**

**Note:** This is a read-only screen where an **Admin** user can verify connection but, user cannot change any setup data.

## 5.6. 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.



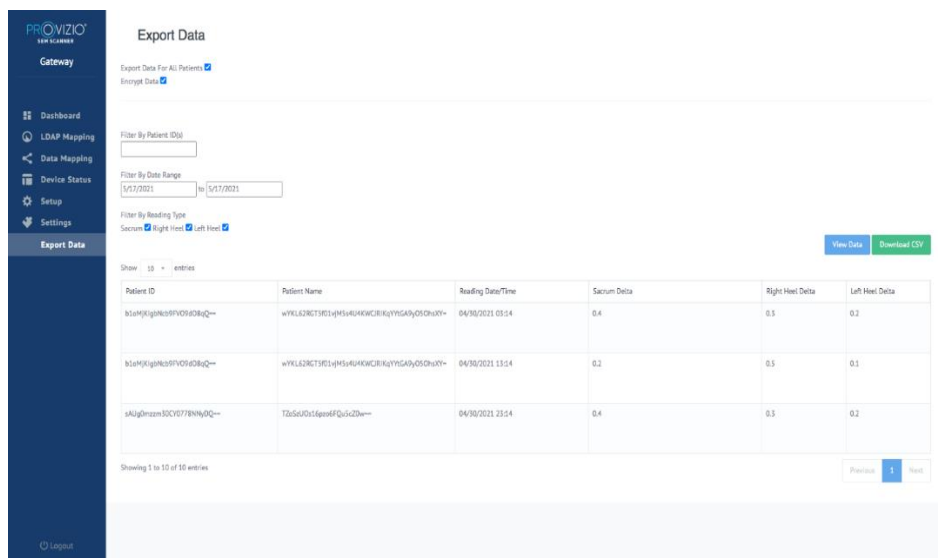
**Figure 20 Settings Screen**

Select the Desired Language

Click on the **Save** button to save the settings.

## 5.7. Export Data

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



**Figure 21 Export SEM Data View**

The available filters and options for Data Export are:

- All Patients or Selected Patients
- Unencrypted (Real Patient ID & Patient Name) or Encrypted Data (Non-identifiable Patient ID & Patient Name)
- For Unencrypted data, the following warning will be displayed:
  - Exported patient data will be UNENCRYPTED. Proper safeguards should be in place to secure data.
- Filter by Date Range
- Filter by Reading Type (SEM, Right Heel, Left Heel)
- View Data on Screen
- Export Data in CSV format

Clicking on left menu “Export Data” will launch the above screen. Select the desired options and click on “View Data” to refresh the data on the screen.

“Download CSV” will be enabled once you have “Refreshed Data” by clicking on “View Data”.

Clicking on “Download CSV” will download the file (csv or zip) on your computer hard drive in the download folder. This can also be opened in Excel.

Close the browser to exit the session.

## 6. Handheld Support

These data are included pursuant to IEC 60601-1 labelling requirements.

### 6.1. *Electromagnetic Environment*

The Provizio SEM Scanners are intended for use in the electromagnetic environment specified in **Table 3. Electromagnetic Environment**. Users should ensure that the Provizio SEM Scanners are used in such an environment.

**Table 3. Electromagnetic Environment**


Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR11	Group 1	The Provizio SEM Scanner 250 device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The Provizio SEM Scanner 250 is suitable for use in all establishments other than domestic and in establishments connected to a low-voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

## 6.2. Electromagnetic Immunity

**Table 4. Electromagnetic Immunity**

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines n/a (unit does not contain any signal, control, or telcom lines)	Mains power quality should be that of a typical commercial or institution environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV lines to earth	± 1 kV line(s) to line(s) ± 2 kV lines to earth	Mains power quality should be that of a typical commercial or institution environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 30 cycles <5% UT (>95% dip in UT) for 5s	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 30 cycles <5% UT (>95% dip in UT) for 5s	Mains power quality should be that of a typical commercial or institution environment. If the user of the SEM Scanner 200 charging system requires continued operation during power mains interrupts, it is recommended that the SEM Scanner 200 system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be a level characteristic of a typical location in a typical commercial or institution environment.
Conducted RF IEC 61000-4-6	3 V <sub>rms</sub>	3 V <sub>rms</sub>	Portable and mobile RF communications equipment should be used no closer to any



	150 kHz to 80 MHz		part of the SEM Scanner 200 system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m  80 MHz to 2.7 GHz	3 V/m	<p>Recommended separation distance:</p> $d = 1.2 \cdot \sqrt{P} \quad 150\text{kHz to } 80 \text{ MHz}$ $d = 1.2 \cdot \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \cdot \sqrt{P} \quad 800\text{MHz to } 2.7 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b.</p> <p>Interference may occur in the vicinity of equipment marked with the following</p> <p>symbol: </p>

### 6.3. Separation Distance

The Provizio SEM Scanner is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Provizio SEM Scanner can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Provizio SEM Scanner as recommended below, according to the maximum output power of the communications equipment. The recommended separation distance between portable and mobile RF communications equipment and the Provizio SEM Scanner is listed in **Table 5**.

**Table 5. Separation Distance**

Separation distance according to frequency of transmitter (meters)			
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \cdot \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			

## 6.4. Specifications

**Table 6. Specifications**

Item	Specifications
Applied Part	Type BF
Battery Life	3 hours (typical)
Method of Cleaning and Disinfection	Clean the device as defined in User Manual
Water ingress protection	IPX1
Duty Cycle	Continuous operation
Power Source	Internally powered equipment
SEM Value Range	0.3 to 3.9 SEM Value units
SEM Value Repeatability* <sup>1</sup>	+/- 0.2 SEM Value units
Storage	The Provizio SEM Scanner should only be stored at temperatures ranging from -4°F (-20°C) to 113°F (45°C) at 5% to 90% relative humidity (non-condensing).
Operating Conditions	The Provizio SEM Scanner should only be operated at temperatures ranging from 59°F (15°C) to 95°F (35°C) at 5% to 90% relative humidity (non-condensing).
Charging Mat AC Mains Voltage	100-240 V
Charging Mat Mains Current	0.5 A

<sup>1</sup> Repeatability is the variation of a single device in measuring the same location by the same person when multiple measurements are taken one after the other (“repeat”) at that time.

## 7. 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 Bruin Biometrics Customer Service.

**Table 7. Troubleshooting**

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.	<p>Ensure you have the correct URL from your system administrator.</p> <p>Ensure with your system administrator that your computer and intranet is configured to connect to this URL.</p>
My login does not work.	<p>The Gateway uses the same login information as you use for other activities.</p> <p>You may not have been assigned a Gateway role. Ask your system administrator to check that you have been assigned a Gateway role.</p>

Problem	Resolution
<b>Patient Listings &amp; Data</b>	
I do not see a patient listed.	<p>The data may not have been uploaded yet. Data is only uploaded when the scanner is placed back into the Charging Hub.</p> <p>The Gateway uses the entered/scanned patient ID to gather patient name. Ensure that the patient ID has been entered correctly.</p> <p>Each scanner must be registered with the Gateway before data can. Ensure the scanner is listed in the Device Listings.</p>
There is a Patient ID listed, but no patient name.	<p>The Gateway uses the entered/scanned patient ID to gather patient name. Ensure that the patient ID has been entered correctly.</p>
A scan for a patient is not listed.	<p>The data may not have been uploaded yet. Data is only uploaded when the scanner is placed back into the Charging Hub.</p> <p>The Gateway uses the entered/scanned patient ID to gather patient name. Ensure that the patient ID has been entered correctly.</p> <p>Each scanner must be registered with the Gateway before data can. Ensure the scanner is listed in the Device Listings.</p>
<b>Device Listings</b>	
A scanner is not listed.	<p>Each scanner must be registered with the Gateway before data can. Ensure the scanner is listed in the Device Listings.</p>

Problem	Resolution
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.

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

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