

# PROVIZIO® SEM SCANNER/SCANNER S

## **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.

## **RONLY**

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



### I.I. 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 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.



- 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, BBI) or a BBI Authorized Service Center. Please contact your BBI Product Specialist or Customer Service 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 Base slot before placing the scanner in the Charging Base.

#### 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 BBI Webserver Virtual Machine (VM).



#### 2.3. Nomenclature

Virtual Machine: The BBI Webserver VM that is installed on the institution-provided server and provides a working environment for the BBI 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 know 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 (BBI) warrants the Provizio SEM Scanner against defects in materials and workmanship for three (3) years from the date of purchase from BBI or its subsidiaries. This warranty is given only to the original purchaser of the SEM Scanner. BBI's 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 BBI in unsuitable packaging, any physical damage present in the Product on receipt and inspection by BBI, and not previously



reported, will be presumed to have occurred in transit and will be the responsibility of the Purchaser.

#### 2.8.1. Exclusions

Table I, below.

The use of the instrument in a manner different that 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 BBI Instructions for Use, (d) on which the serial number has been removed or made illegible, (e) that have been modified by anyone other than BBI or its authorized service center, unless authorized prior to such service by BBI, (f) that are equipment sold as used, or (g) that are exposed to agents listed in

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 Nitric Acid - 70% Benzene Cyclohexane Kerosene Perchloroethylene Carbon tetrachloride Ethyl Chloride Trichloroethylene Chlorobezene 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 BBI, or to assume for BBI 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** 

	T		
Symbol	Meaning		
REF	Manufacturer's Catalog designation or number		
SN	Serial number		
LOT	Lot Number		
CE	CE mark in accordance to the European Medical Device Directive		
EC REP	European Union Authorized Representative		
R, ONLY	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		
<u>.</u>	Caution or warning		
Dispose of this equipment according to local regulations for ele electronic waste disposal			
444	Manufactured By		
IPX1	Drip Proof Equipment-IPXI: The Provizio SEM Scanner enclosure provides protection against the harmful effects of the ingress of liquids. (IPXI, per IEC 60529)		
Type BF Applied Part with IEC-60601-1			
Keep away from sunlight			
<del>*</del>	Keep dry		
Do not use if package is damaged and the device inside appears physically cracked, or does not charge and start up following the Instructions for U			
Temperature limits (example limits shown)			
Humidity limits (example limits shown)			
1	Package contents		
2	Single Patient Use Only		
NON STERILE	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 I Gateway Login Screen

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

If you have a single role as a Clinical User, you will be taken straight to the Patient List (Section 4.1).

If you have multiple roles, you will be asked to select which one to use for this session (Section 3.2).

#### 3.2. Select a Role

If your credentials are approved by the institution authentication server and you have multiple privileges within the Gateway, you will be presented with a screen to allow you to select what role you are using for this session.





Figure 2 Gateway Role Selection

Clicking on CONITINUE will take you to the first screen of your selected Role.



#### 4. Clinical Role

#### 4.1. Patient List

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

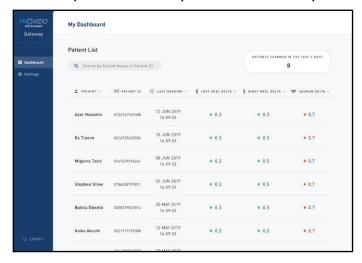


Figure 3 Patient List Screen

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



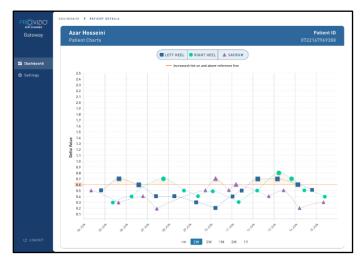
Figure 4 Patients Scanned in Last Three Days

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.

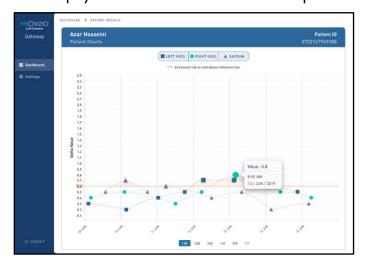


Figure 6 Data Point Details

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.



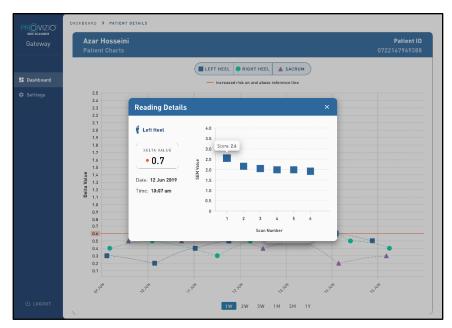


Figure 7 SEM Values For a Data Point

Close the browser window to exit the session.



#### 5. Admin Role

The first screen lists various sub-topics, described in the following sections, as well as the total number of **Active Devices** in the field and the total number of **Readings Per Week** that have been conducted.

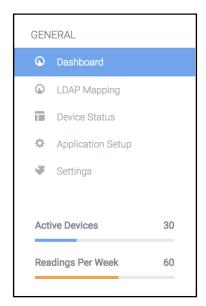


Figure 8 Sub-topics Menu

#### 5.1. Dashboard

The Dashboard shows the percentage of patients who are above and below the 0.6 threshold.

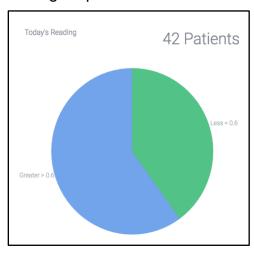


Figure 9 Dashboard Chart

The **Overall Analysis** line chart displays the total number of readings divided by SEM readings on a day by day basis.





Figure 10 Analysis Chart

## 5.2. LDAP Mapping

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

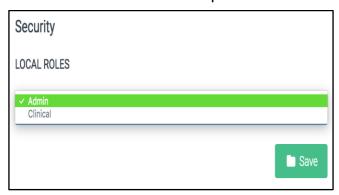


Figure I I Select Role to Map

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



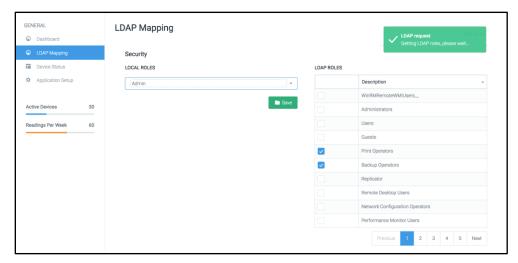


Figure 12 Role Mapping

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

#### 5.3. Device Status

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

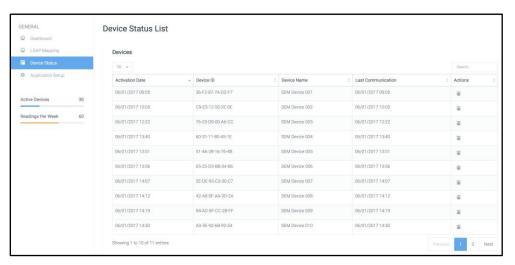


Figure 13 Device Status

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 14 Device Search Results

## 5.4. Application Setup

The **Database Info** screen displays information for the **Server Address**, **Server Port**, **Username**, and **Password** initially set.

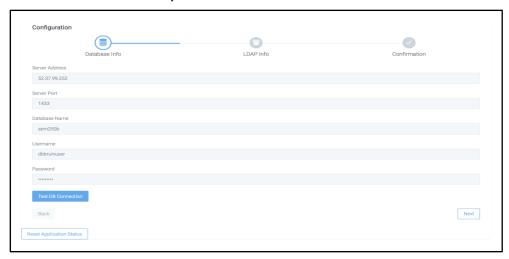


Figure 15 Database Info Screen

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** button in the lower left. If correct, a green confirmation message will appear in the upper right.



Figure 16 Test DB Connection Success

Click on the **Next** button in the lower right to progress to the **LDAP Info** screen.

The LDAP Info screen displays information for the LDAP Address, LDAP Port, LDAP Username, and LDAP Password initially set.



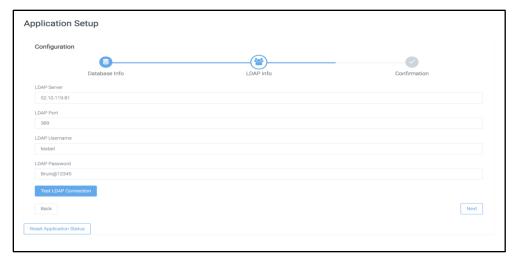


Figure 17 LDAP Info Screen

If you need to make sure the **LDAP Info** is correct, click on the **Test LDAP Connection** button. If correct, a green confirmation message will appear in the upper right.



**Figure 18 Test LDAP Connection Success** 

If incorrect, a red error message will appear in the upper right.

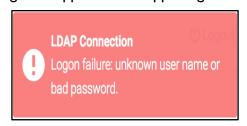


Figure 19 Test LDAP Connection Failure

Make any edits if needed and click on the **Next** button in the lower right to progress to the **Confirmation** screen. You can also click on the **Back** button in the lower left to return to the **Database Info** screen if needed.



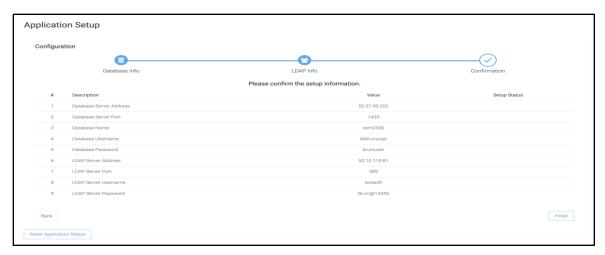


Figure 20 LDAP Set-Up Screen

Review the information displayed on the **Confirmation** screen.

Click on the **Finish** button in the lower right to save all changes.

## 5.5. Settings

The **Settings** page allows a user to set or make changes to the blue **Reference Line Value** viewed on the **Patient Chart** when logged in as a **Clinical** user and also controls the global **Time** and **Date** formats throughout the application.

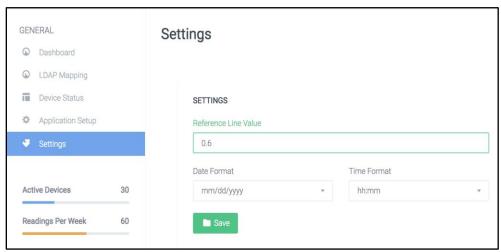


Figure 21 Settings Screen

**Reference Line Value**: (The default is 0.6 but is editable.)

Date Format: Select "mm/dd/yyyy" or "dd/mm/yyyy" from the drop-down menu.

Time Format: Select "hh:mm:ss" or "hh:mm" from the drop-down menu.

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



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
Harmonic emissions IEC 61000-3-2	Complies	and in establishments connected to a low-voltage power supply network which supplies
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	buildings used for domestic purposes.



## 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 Vrms	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any



Radiated RF IEC 61000-4-3 $ \begin{array}{c} 3 \text{ V/m} \\ 80 \text{ MHz to 2.7} \\ \text{GHz} \end{array} $ $ \begin{array}{c} 3 \text{ V/m} \\ 80 \text{ MHz to 2.7} \\ \text{GHz} \end{array} $ $ \begin{array}{c} 3 \text{ V/m} \\ 80 \text{ MHz to 2.7} \\ \text{GHz} \end{array} $ $ \begin{array}{c} 3 \text{ V/m} \\ 80 \text{ MHz to 2.7} \\ \text{GHz} \end{array} $ $ \begin{array}{c} 4 = 1.2 \cdot \sqrt{P} \\ 80 \text{ MHz to 800 MHz} \\ \text{d} = 2.3 \cdot \sqrt{P} \\ 800 \text{ MHz to 2.7 GHz} \end{array} $ 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).} \\ \text{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.} \\ \text{Interference may occur in the vicinity of equipment marked with the following}	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.
symbol:	80 MHz to 2.7	3 V/m	$d=1.2\cdot\sqrt{P}$ 150kHz to 80 MHz $d=1.2\cdot\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\cdot\sqrt{P}$ 800MHz to 2.7 GHz 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). 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. Interference may occur in the vicinity of equipment marked with the following



#### 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	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.



## 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*1	+/- 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>&</sup>lt;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 BBI 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.	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 Gate way role. Ask your system administrator to check that you have been assigned a Gateway role.



Problem	Resolution	
Patient Listings & Data		
I do not see a patient listed.	The data may not have been uploaded yet. Data is only uploaded when the 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 scanner must be registered with the Gateway before data can. Ensure the scanner is listed in the Device Listings.	
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 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 scanner must be registered with the Gateway before data can. Ensure the scanner is listed in the Device Listings.	
Device Listings		
A scanner is not listed.	Each scanner must be registered with the Gateway before data can. Ensure the scanner is listed in the Device Listings.	





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.	



BBI products are protected by one or more patents. Refer to <a href="https://sem-scanner.com/patents">https://sem-scanner.com/patents</a> for more information

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