



ENGLISH

Provizio[®] SEM Scanner/Scanner S

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, 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 there 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 Nomenclature

Pressure ulcers also are called pressure injuries, decubitus ulcers, bed sores or pressure sores.

2.2 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.

2.3 Device Description

The Provizio SEM Scanner is a hand-held, portable device that consists of a single electrode sensor, an integrated pressure sensor, and hardware and software to run a user interface device screen that displays the device status, battery status, SEM Value, and SEM Delta (“SEMΔ”). The Provizio SEM Scanner is pre-calibrated. The Provizio SEM Scanner is provided with a Charging Hub and power supply for recharging the scanner.

The Provizio SEM Scanner assesses changes in electrical capacitance of tissue and expresses the result in a SEM Value of 0.3 to 3.9. SEM Value is unitless (not an International System of Units measurement). The Provizio SEM Scanner S displays a SEMΔ value after a minimum of three (3) SEM Values have been measured. The reported SEMΔ is used as an adjunct to the standard of care when assessing the heels and sacrum of patients who are at increased risk for pressure ulcers. See Section 8 for details of interpretation of the SEMΔ values.



Figure 1 Provizio SEM Scanner S showing Scanner and Charging Hub

The scanner can transmit collected SEM Values and SEMΔ, when associated with a valid patient identification number to a centralized, in-institution, data server for later review. Refer to the Gateway Software User’s Manual for more information.

2.4 **Provizio SEM Scanner**

The Provizio SEM Scanner System is provided in three versions:

- Provizio SEM Scanner S with a separately supplied single-use, non-sterile, single-use sensor and having manual patient ID entry only;
- Provizio SEM Scanner with the sensor head integrated into the handheld and having both manual patient ID entry and scanning patient ID barcodes; and
- Provizio SEM Scanner S with a separately supplied single-use, non-sterile, single-use sensor and having both manual patient ID entry and scanning patient ID barcodes.

The Provizio SEM Scanner is distinguished by the orange concentric rings on the sensor head.

The Provizio SEM Scanner S is distinguished by the green sensor with three gold connectors.



The Provizio SEM Scanner S will not operate correctly without first installing a single-use sensor head

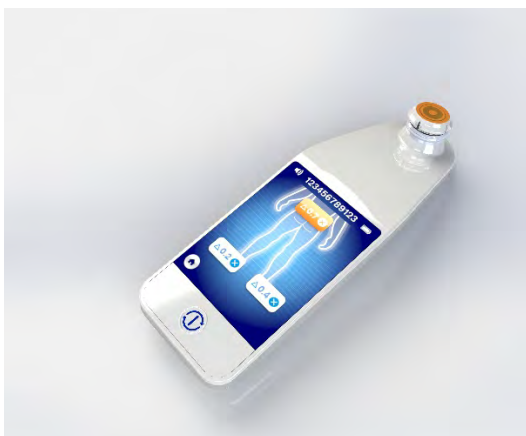


Figure 2 Provizio SEM Scanner



Figure 3 Provizio SEM Scanner S

2.5 **Additional Provizio SEM Scanner Components**

The Provizio SEM Scanner is packaged with a Charging Hub, power supply that is used when charging the scanner and provides a base for the scanner when not in use. The internal battery is recharged by wireless power transfer when the handheld is placed in the charging hub. See Section 3.2 for charging instructions.



2.6 Contraindications

Do not use on broken skin.

2.7 Intended User Profile

The system is intended for use by healthcare professionals.

2.8 Adverse Effects

There are no known adverse effects using the scanner.

2.9 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.

2.1.1 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 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 12, below. Table 1 is not an exhaustive list of agents which may compromise the integrity of 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

Table 1. Agents That Should Never Be Used on the SEM Scanner





















2.1.2 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.

2.10 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 Provizio SEM Scanner and Provizio SEM Scanner S Set-Up

3.1 *Unpacking and Inspection*

After the Provizio SEM Scanner is unpacked verify that the scanner has no signs of damage. If there are signs of damage, contact Customer Service. Figure 4 shows the packaged Scanner.



Figure 4 Packaging of Components

Follow your institutional policies and procedures regarding recycling and disposal of packaging.

3.2 *Charging the Device*



Ensure there is no foreign material in the Charging Base slot before placing the scanner in the Charging Base.

NOTE: During charging the scanner and/or Charging Hub may be warm to the touch. This is normal operation.

Charge the SEM Scanner before using it for the first time to at least four bars (five bars is the maximum). Follow the steps below to charge the scanner:

1. The Charging Hub is packaged with an AC to DC wall adaptor (Figure 5). The adaptor is provided with several regional pin configurations. Select the configuration suitable for your institution, insert into the face of the adaptor and twist to the right. A “click” indicates that the pins are inserted and locked.
2. Check that the pins are locked by gently turning to the left. The pins should not disengage from the adaptor.
3. Insert the cylindrical connector of the adaptor into the rear of the Charging Hub.
4. Plug the power adapter into the power outlet.
5. Verify the light on the front of the charging hub is displayed with the orange light.
6. Place the scanner into the charging hub. (Figure 6)
7. Verify that the light starts flashing green. If the green light is not flashing, then the Provizio SEM Scanner may not be positioned correctly in the cradle. Orange means an error has occurred.
8. When positioning the charging hub, ensure the hub is placed in a manner so that will make it difficult to disconnect the device.
9. While the handheld is in the charging hub, the touchscreen is disabled. The display shows the status of the data upload and the battery charge level. (Figure 7).
10. NOTE: When the Charging Hub is disconnected from mains power, the indicator light may remain on for a short time. This is normal behavior.
11. Refer to Section 6.3 for more information regarding the upload of patient data.



Figure 5 AC/DC Wall Adaptor (US Configuration)



Figure 6 Correct Positioning of the Provizio SEM Scanner on the Charging Hub



Figure 7 Display During Charging



3.3 Connecting the *Provizio* Scanners to Institution Wireless Networks

Please refer to your institutions Information Technology Department and the Gateway Configuration Manual for instructions on connecting the scanner to your network.



4 Provizio SEM Scanner and Provizio SEM Scanner S Operation

The Provizio SEM Scanner System is provided in two versions:

- Provizio SEM Scanner with the sensor head integrated into the handheld; and
- Provizio SEM Scanner S with a separately supplied single-use, non-sterile, single-use sensor.

The Provizio SEM Scanner is distinguished by the orange concentric rings on the sensor head.

The Provizio SEM Scanner S is distinguished by the green sensor with three gold connectors.



The Provizio SEM Scanner S will not operate correctly without first installing a single-use sensor head.

Both versions of the scanner operate in the same manner, with the same modes, methods of scanning and clinical interpretation. The Provizio SEM Scanner S has the additional steps of installing and removing the single use sensor. These steps will be noted as “S only” in this manual.

See Section 7 for cleaning and disinfection procedures.

4.1 Key Features

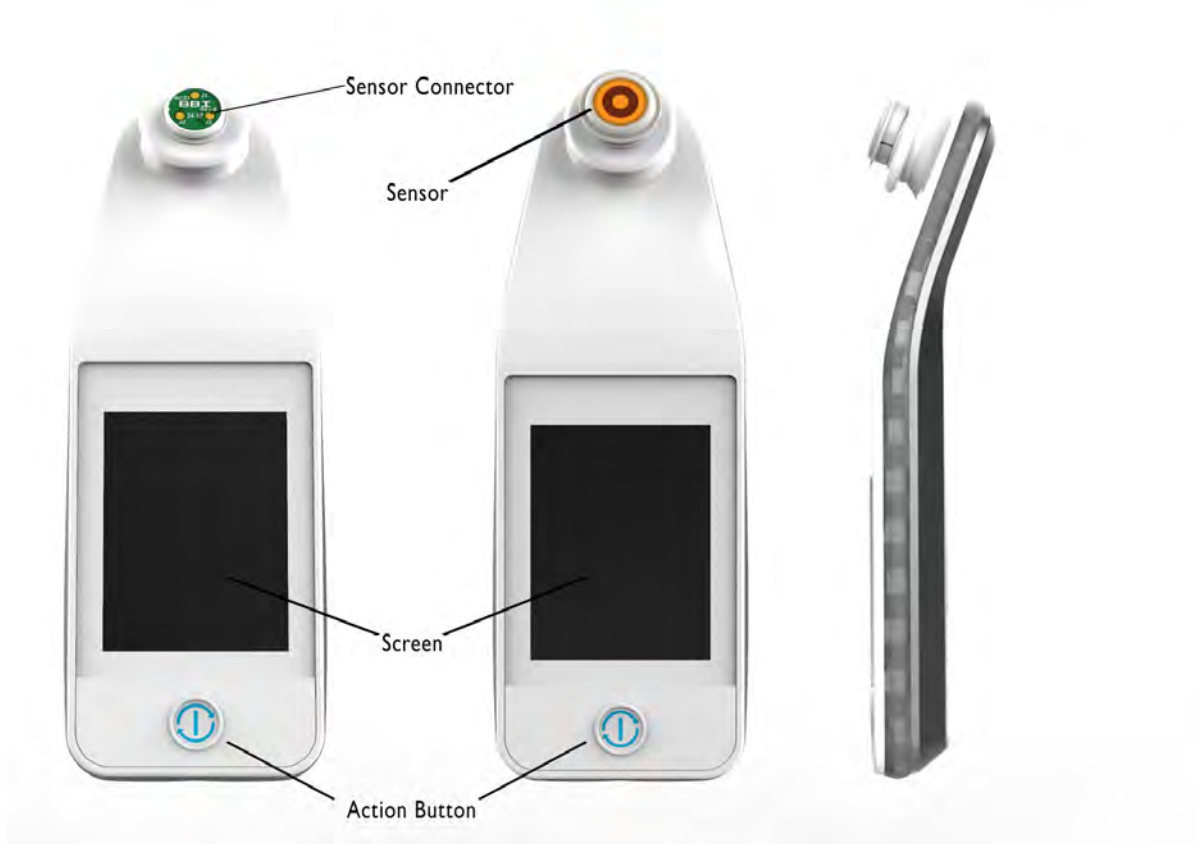


Figure 8 Key Features of the Provizio SEM Scanner S (left) and Provizio SEM Scanner (middle)

4.2 Key Controls and Icons

The following tables describe the controls and icons used throughout this manual and the Provizio System.

Table 3 Physical Controls


Control	Name	Description
	Action button	Turns the scanner ON and OFF

Table 4 Mode Selection Controls






Control	Name	Description
	Settings	Enters the setting and configuration screens
	Automatic upload	Enters barcode scanning (if available) and automatic upload mode
	Manual charting	Enters manual charting mode
	Manual patient ID	Enters manual patient ID entry
	Training	Enters training & research mode

Table 5 Navigation Controls








Control	Name	Description
	Home	Return to home and start a new scanning session
	Next screen	Go to the next screen
	Previous screen	Go to the previous screen
	Select	Select body area
	Body area	Return to body area selection
	Delete	On body area selection screen – deletes measurements for this body area
		On scanning screens – deletes last reading
	OK	Accept setting/selection and

Table 6 Other Controls



Control	Name	Description
	Sound	Enter sound setting screen
	Refresh	In training mode, clears the current set of scans and delta

Table 7 Battery Level Icons






Control	Name	Description
	Battery Indicator	Scanner docked but not charging
	Battery Indicator	Battery level low
	Battery Indicator	Intermediate battery levels
	Battery Indicator	Intermediate battery level, minimum for initial device
	Battery Indicator	Battery full

Table 8 Data Upload Icons





Control	Name	Description
	Data upload	Data upload in progress
	Data upload	Data upload complete
	Data upload	Data upload failed

Table 9 Other Icons

Control	Name	Description
	Calibration fail	Scanner self-calibration has failed

4.3 Turning the Scanner ON



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.



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.



Do not attempt to clean or disinfect a contaminated single-use sensor.

Follow the steps below to start a session with either version of the Provizio SEM Scanner:

1. Do not touch the sensor area (Figure 9) of the scanner during start up as the scanner is performing a self-calibration and touching the sensor could invalidate the results. There is no danger of electric shock or damage to the scanner. If the sensor is touched during start up, turn off the device and turn on the device to re-start.



Figure 9 Sensor of the Provizio SEM Scanner

2. If the scanner is in the Charging Hub, remove the Provizio SEM Scanner from the charging hub. The unit should automatically power on. If the screen is dark, press and hold the Action button (ⓘ) until the screen illuminates.
3. If the scanner is not in the Charging Hub, press and hold the Action button (ⓘ) until the screen illuminates.
4. Verify the scanner has no visible damage or sharp edge.
NOTE: DO NOT USE if the scanner is broken or any damage or sharp edges are found.
5. If required, clean and/or disinfect the unit per Section 7.

After turning on the SEM Scanner and the splash screen will be displayed (Figure 10).



Figure 10 Provizio SEM Scanner Splash Screen

Touching the Settings button (⚙️) enters the setting and configuration screens, allowing the user to configure the wireless and other settings of the scanner.

After four seconds the scanner will progress forward in the workflow.

4.4 Sleep Mode

During a period of inactivity, the unit may turn dark in sleep mode to save power. In sleep mode, the unit will not obtain readings and the screen will be off.

A scanner that is asleep may be brought back to action mode by pressing the action button. If a scanning session was underway, the scanner will return to the screen the user was last on, and resume operation from that point.

4.5 Install the Single-Use Sensor - S only

This section is only applicable to the Provizio SEM Scanner S.



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.

The sensor installation screen (Figure 11) will be displayed, prompting the installation of the single-use sensor.

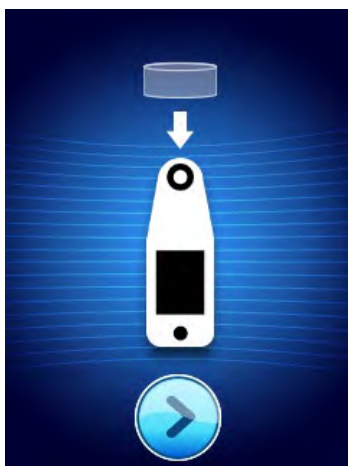


Figure 11 Install Sensor Screen



Figure 12 Sensor Calibrating

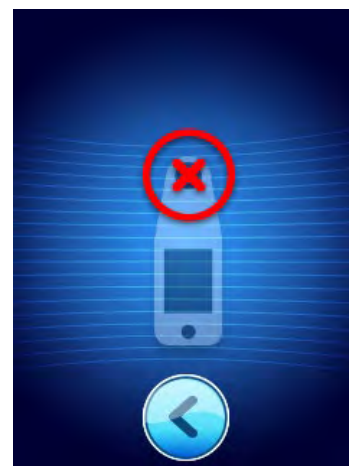


Figure 13 Failed Calibration

After you have installed the sensor (Section 4.5), press the Next Screen (➡). The scanner will then re-calibrate to the installed sensor (Figure 12). If the scanner fails calibration (Figure 13), remove the sensor and discard. Attempt calibration again by installing a new sensor.

If the scanner continues failing calibration, please contact Customer Service.

4.5.1 Installing the Sensor



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.



Do not attempt to clean or disinfect a contaminated single-use sensor.

The single-use sensor is provided clean, non-sterile in individually sealed pouches. Although not sterile, take care to not unnecessarily contaminate the sensor.

Remove the sensor from the pouch, and place on the sensor on the scanner connector (Figure 14). There is a notch in the sensor and a corresponding tab on the scanner connector to aid the alignment of the sensor. You will hear and feel a click when the sensor seats correctly on the connector.



Figure 14 Installation of the Single-Use Sensor

Once the sensor is installed, press the Next Screen (➡) to advance to next step, as described above.

4.6 Select Mode of Operation

After successful calibration, the scanner offers three possible workflows (Figure 15):

1. Pressing the Barcode button (📊) will implement the full data upload operational mode. Use this mode if the patient has a bar coded wrist band and the Gateway Software is installed on the institutions WIFI network.
2. Pressing the Manual charting button (📝) will implement the manual operation mode. This mode is appropriate when the patient does not have a bar coded wrist band, or the institution does not have the Gateway Software installed.
3. Pressing the Training button (🎓) in the lower left corner will implement a test mode for training and research.
4. Pressing the Manual Patient ID button (📋) in the lower right corner will allow the user the manually enter the Patient ID. Following the entry of the patient

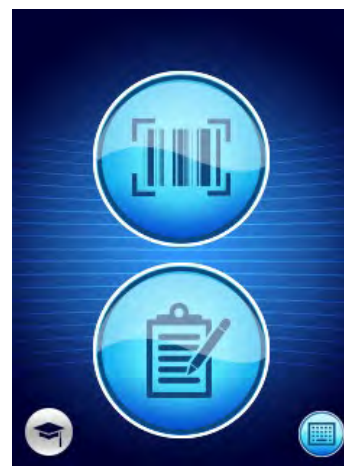


Figure 15 Mode Selection



ID, the system will move to the Select Body Location Screen.

In each of these modes, touching the Home icon (🏠) will return you to the Install Sensor Screen (Provizio SEM Scanner S only, Section 4.5) or the Mode Selection Screen (Provizio SEM Scanner only), and a new patient session will begin.

4.6.1 Automatic Upload Mode

Upon entering Automatic Upload Mode, if the scanner does not have a bar-code reader, the Manual Patient ID Entry screen (Section 4.6.4) will be displayed. This will allow you to key in the patient ID.

If the scanner has a bar-code reader, the display will show the barcode scanning screen(s) (Figure 16).



Figure 16 Barcode Scanning Screen

Position the patient barcode within the screen image. Patient wrist or chart barcodes may be used. Once the scanner has identified the barcode, the Body Selection Screen will be displayed (Section 4.7).

If the barcode fails to be identified, you may try again by repositioning the scanner, adding additional light or scanning another of the patient's barcodes.

If the barcode cannot be scanned, pressing the Manual Patient ID button (⌨️) in the lower right corner will allow you to manually enter the Patient ID. (Section 4.6.4) Following the entry of the patient ID, the system will move to the Select Body Location Screen.

4.6.2 Manual Charting Mode

Upon entering Manual Charting Mode, the Body Selection Screen will be displayed (Section 4.7).

NOTE: In this mode, even if the scanner is configured to connect to a Gateway Server, no patient data will be saved in the scanner or uploaded.

NOTE: Individual SEM and SEM Δ should be noted in the patient's physical or electronic medical record per your institutions policies and procedures.

4.6.3 Training Mode

Upon entering Training Mode, the Training Mode Screen will be displayed (Figure 17).



Figure 17 Training Mode Screen

Scan each body area as desired per Section 5.

Touch the Refresh Icon (🔄) to clear current data and commence a new scan.

Touch the Home icon (🏠) will return you to the Install Sensor Screen (Provizio SEM Scanner S only, Section 4.5) or the Mode Selection Screen (Provizio SEM Scanner only), and a new patient session will begin.

NOTE: In this mode, even if the scanner is configured to connect to a Gateway Server, no patient data will be saved in the scanner or uploaded.

NOTE: Individual SEM and SEM Δ should be noted in the patient's physical or electronic medical record per your institutions policies and procedures.

4.6.4 Manual Patient ID Entry

Figure 18 shows the screen to manually enter a patient identifier.

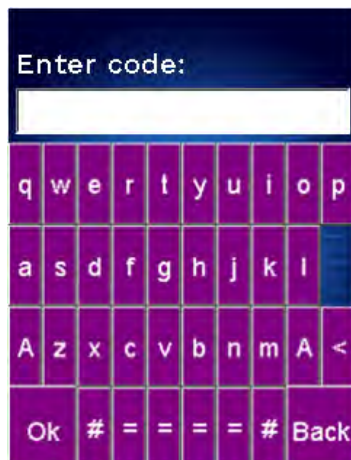


Figure 18 Manual Patient ID Entry Screen

Using the patient worn or chart barcode ID, enter all the characters of the ID.

Use the delete key (<) to erase errors.

To access numbers, press the number key (#).

When done, press the OK key (**Ok**) to proceed to the selection of body location.

If you wish to abandon manual ID entry and start over, press the back key (**Back**).

4.7 Select Body Location

In Barcode Scanning and Manual Charting Modes, the Body Location Selection Screen will be displayed (Figure 19). This screen provides the ability to scan the Sacrum, Left Heel and Right Heel, as well as display the final SEM Δ values for each area.

Touch the Select (+) icon over the body area you wish to scan. Body areas may be scanned in any order or omitted based on clinical judgement.

Once a set of SEM measurements have been made for a body area, the Select (+) icon will change and show the measured SEM Δ value for that area (0.2). The SEM Δ value for each body area may be deleted by touching the Delete icon (x) next to the SEM Δ value.



Figure 19 Body Location Selection Screen

Touch the Home icon (🏠) will return you to the Install Sensor Screen (Provizio SEM Scanner S only, Section 4.5) or the Mode Selection Screen (Provizio SEM Scanner only), and a new patient session will begin.

5 Making Measurements

5.1 General



DO not use the Provizio SEM Scanners on broken or otherwise compromised skin.



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.



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.



Do not attempt to clean or disinfect a contaminated single-use sensor.

A SEM Δ equal to or greater than 0.6 at an anatomical site may suggest increased risk for pressure ulcers.

The general layout of the measurement screen is shown in Figure 20.



Figure 20 Measurement Screen (Left Heel)

The number at the top is the Patient Identifier/Barcode that was scanned, if in Barcode Mode. In Manual Charting Mode, this will show “No Patient ID”. In Training Mode, this is blank.



In Barcode and Manual Charting Modes, the body area selected will appear next down. In Training Mode, this is blank.

Next below are indicators of the number of scans taken. Circles indicate a scan not yet performed, whereas the dot indicates that a scan has occurred. For the sacrum body area, six circles are initially shown. For the heels, four circles are initially shown. In training mode, no circles are initially shown and as measurements are made, dots will indicate how many. After nine (9) measurements, any subsequent measurement will be shown with a “plus” (+) sign, indicated that more than nine measurements have been completed.

The large circle on the left (0.6) is the SEM Δ . Initially, this will display as “-.-”. Once three or more measurements have been completed, the SEM Δ will display.

SEM Δ less than 0.6 have a green color. SEM Δ equal to or greater than 0.6 will be colored orange to indicate the increased risk of development of a pressure injury.

The smaller circle on the right (0.6) displays the current SEM value measurement. This measurement may be deleted by touching the Delete icon (X). You will then see the number of measurements circles/dots change accordingly.

At the lower right of the screen in either Barcode Scanning or Manual Charting Modes, the Previous Screen Button (←) will return you to the Body Location Selection Screen. In Training Mode, the Refresh Icon (↺) to clear current data and commence a new scan.

Ensure that any surface moisture or matter is removed from the area on the skin being assessed.

Ensure the sensor is flat against the patient’s skin in the area to be scanned.

Continuously increase pressure on the area until the scan is triggered.

The scanner will flash and beep when the measurement is made. After the beep, lift the scanner off the skin.

5.2 Making Measurements at the Sacrum

Ensure that any surface moisture or matter is removed from the area on the skin being assessed.

Ensure the sensor is flat against the patient’s skin in the area to be scanned.

Continuously increase pressure on the area until the scan is triggered.

The scanner will flash and beep when the measurement is made. After the beep, lift the scanner off the skin.

For the sacrum a minimum of six (6) SEM value measurements are recommended. These are made by moving directionally around the bony prominence to identify healthier tissue and other damaged areas around the bony prominence. The recommended positions for Provizio SEM Scanner readings to complete for an assessment of the sacrum are shown below (Figure 21).

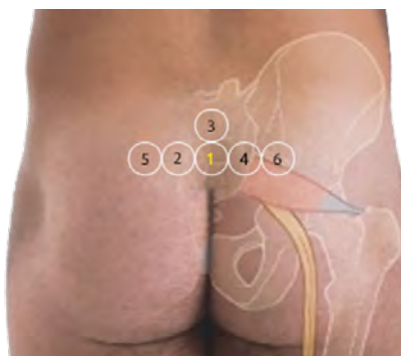


Figure 21 Recommended Sacral Measurement Locations

1. As a starting point, #1 is just above the gluteal cleft of the sacrum, around S3 of the sacral bone.
2. #2 through #6 are positioned side-by-side from #1. Variations with distances apart may arise due to positioning of the patient and restrictions prohibiting measurements at positions #5 and #6.
3. #3 should not be made higher than S1 of the sacral bone.

5.3 Making Measurements at Either Heel

Ensure that any surface moisture or matter is removed from the area on the skin being assessed.

Ensure the sensor is flat against the patient's skin in the area to be scanned.

Continuously increase pressure on the area until the scan is triggered.

The scanner will flash and beep when the measurement is made. After the beep, lift the scanner off the skin.

For heel scanning, a minimum of four (4) measurements are recommended. Measurements are made by moving directionally around the bony prominence to identify healthier tissue and other damaged areas around the bony prominence. The recommended positions for Provizio SEM Scanner readings to complete for an assessment of the left heel is shown below (Figure 22).

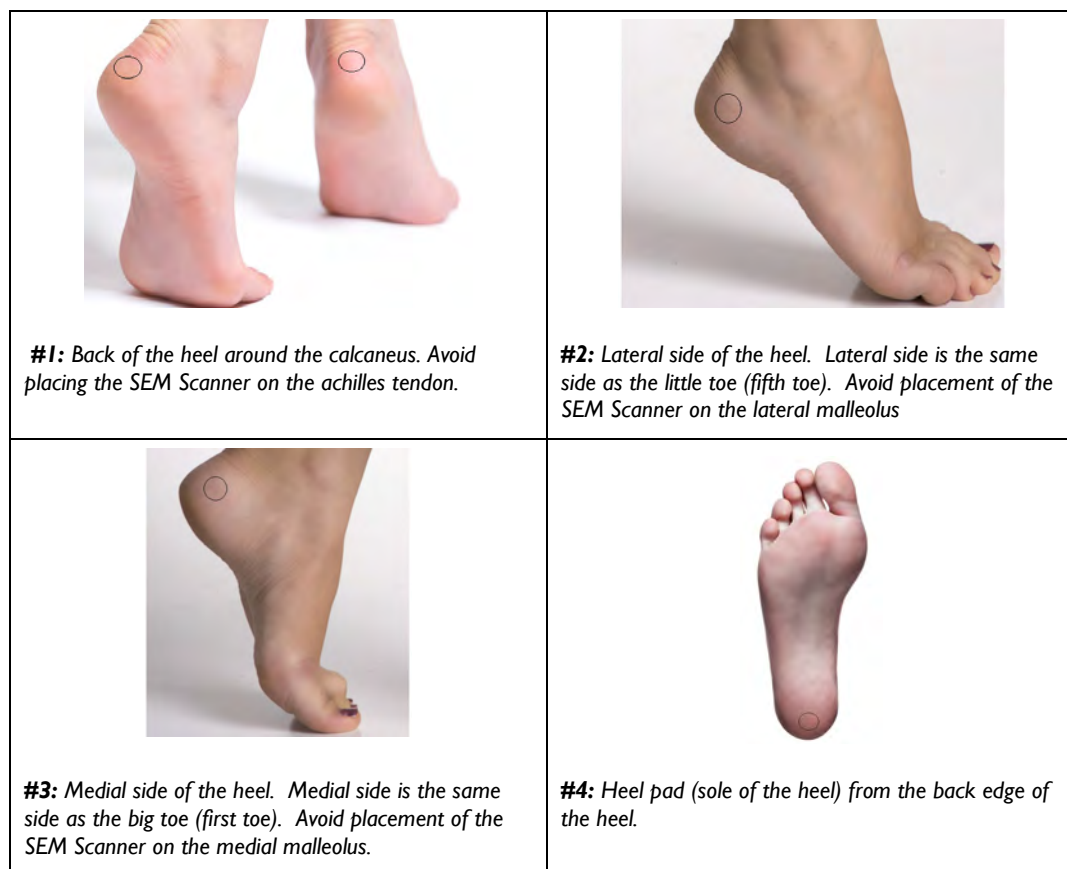


Figure 22 Recommended Heel Measurement Locations

1. #1 begins x of the left heel.
2. #2 through #4 are positioned side-by-side from #1.
3. If one of the measurement locations is calloused, do not take a reading there.

6 Finishing the Session

6.1 Remove the Single-Use Sensor - S only

This section is only applicable to the Provizio SEM Scanner S.



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.

The sensor is removed in the reverse manner of the installation. Firmly grip the scanner in one hand and gently pull the sensor away from the connector.

Follow your institutional policies and procedures regarding recycling and disposal of sensor.

6.2 Clean and Disinfect

Clean and, if needed, disinfect the scanner as directed in Section 7.



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.



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.



Do not attempt to clean or disinfect a contaminated single-use sensor.

6.3 Data Upload



Ensure there is no foreign material in the Charging Base slot before placing the scanner in the Charging Base.

Upon placement into the Charging Hub, the scanner switches into charging mode, and initiates wireless communications with the configured wireless network, and then connects to the Gateway Server. All communications are encrypted and secure.

Once the scanner has connected to the Gateway Server, all stored data sessions are uploaded to the Gateway server and then deleted from the handheld.



If interrupted during the data transfer, the scanner will resend the interrupted and unsent data the next time it is placed in the charger.

6.4 *Turning the Scanner OFF*

The scanner may be turned off by pressing and holding the action button.

After being turned off and then on, the scanner will re-start and begin a new patient scanning session.

7 Cleaning and Disinfection



Do not reuse single-use sensors for multiple patients or multiple sessions.



To prevent the spread of infection, the Provizio SEM Scanners should be properly cleaned and disinfected according to the instructions provided in this Instructions for Use after it is used on a patient.



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.



Should the device come in contact with contaminated surfaces (for example, if it falls on the floor) it should be cleaned and disinfected before obtaining another patient reading.



Do not immerse the Provizio SEM Scanner. Immersion may damage the scanner and prevent it functioning normally.

7.1 Cleaning and Disinfection Overview

BBI recommends manual cleaning and disinfecting the Provizio SEM Scanners between patients by using nonabrasive US EPA Registered cleaning and disinfection wipes described in the instructions below. The Provizio SEM Scanner should never be exposed to the chemical agents listed in the Warranty and Disclaimer section. Use of these agents will void the product warranty and could damage the scanner.

Single-use sensors should be disposed of following institutional policies and procedures for patient contacting materials.

The Provizio SEM Scanner should be cleaned and disinfected using nonabrasive cleaning and disinfection wipes containing intermediate-level chemical agents. Cleaning and disinfection are sequential processes. To achieve cleaning and disinfection requirements for intermediate risk level devices, BBI tested the use of wipes designed to perform both processes: a cleaner and chemical disinfectant in one wipe form.

Most healthcare-use wipes such as CaviWipe™ by Metrex Research are designed to both clean and disinfect. CaviWipe™ was tested by BBI.

7.2 Scanner Cleaning Instructions

The Provizio SEM Scanner should be cleaned using nonabrasive cleaning wipes and wetted with agents such as isopropyl alcohol or mild detergents.

- (1) Using a fresh wipe, verify the wipe is moist.
- (2) Thoroughly wipe all surfaces of the Provizio SEM Scanner for 45 seconds to remove dirt and debris from the SEM Scanner as shown in Figure 25 and Figure 26. Continue wiping for the entire 45 seconds even if there is no visible dirt and debris. Do not reuse the wipes.



Figure 23. Clean the Sides of the SEM Scanner



Figure 24. Clean the Front and back of the SEM Scanner

- (3) Dispense a fresh towelette wipe from the dispenser and verify the wipe is moist. Thoroughly wipe all surfaces of the Scanner for a minimum of 30 seconds to remove any remaining visible soil. Continue wiping for the entire 30 seconds even if there is no visible dirt and debris. The device surface should be fully coated with the wipe solution. Do not reuse the wipes.
- (4) Dispense a fresh towelette wipe from the dispenser and verify it is moist. Thoroughly wipe all surfaces of the SEM Scanner for a minimum of 30 seconds. Continue wiping for the entire 30 seconds even if there is no visible dirt and debris. The device surface should be fully coated with the wipe solution. Do not reuse the wipes.
- (5) Dispose the used wipe(s) as instructed by the wipe manufacturer. If no instructions are provided, the recommended disposal of used wipe(s) is medical waste; do not flush down the toilet.

7.3 Scanner Disinfection Instructions

To properly disinfect the external surfaces of the Provizio SEM Scanner using CaviWipe™ by Metrex Research, follow the steps below. Wearing gloves and an apron during cleaning and disinfection of the device is recommended. Please read the CaviWipe™ label instructions for a full list of precautions and use guidelines: manufacturers are periodically updated.

If other wipes are preferred, select nonabrasive intermediate-level cleaning and disinfection wipes. Users must follow the wipe manufacturer's cleaning and disinfection instructions. The selected wipe should not contain any of the chemical agents listed in the Warranty and Disclaimer section.

7.3.1 Disinfection Steps using CaviWipe

Note: When wiping the device with the wipe, you are applying the cleaning and disinfecting agent onto the device.

Before starting the disinfection, first clean the device as described above.

- (1) Dispense fresh CaviWipe™ towelette wipe from the dispenser and verify the wipe is moist.
- (2) Thoroughly wipe all surfaces of the Provizio SEM Scanner for 45 seconds to remove dirt and debris from the SEM Scanner as shown in Figure 25 and Figure 26. Continue wiping for the entire 45 seconds even if there is no visible dirt and debris. Do not reuse the wipes.



Figure 25. Disinfect the Sides of the SEM Scanner



Figure 26. Disinfect the Front and back of the SEM Scanner

- (3) Dispense a fresh towelette wipe from the dispenser and verify the wipe is moist. Thoroughly wipe all surfaces of the Scanner for a minimum of 30 seconds to remove any



remaining visible soil. Continue wiping for the entire 30 seconds even if there is no visible dirt and debris. The device surface should be fully coated with the wipe solution. Do not reuse the wipes.

- (4) Dispense a fresh towelette wipe from the dispenser and verify it is moist. Thoroughly wipe all surfaces of the SEM Scanner for a minimum of 30 seconds. Continue wiping for the entire 30 seconds even if there is no visible dirt and debris. The device surface should be fully coated with the wipe solution. Do not reuse the wipes.
- (5) Dispose the used wipe(s) as instructed by the wipe manufacturer. If no instructions are provided, the recommended disposal of used wipe(s) is medical waste; do not flush down the toilet.

For the second step, disinfection:

- (6) After completing Steps 1 – 5 for cleaning, repeat these steps to perform disinfection.
- (7) Place the cleaned scanner on a aseptic or disinfected surface after wiping for at least 2 minutes to properly disinfect the device before returning it to storage or using on another patient.
 - Note: Do not place the device with the sensor down onto a dirty surface. This will “dirty” your cleaned scanner.
 - For the highest level of disinfection, CaviWipe™ label instructions specify 3 minutes of continuous contact of the surface with the chemical agent during disinfection. The surfaces should be visibly wet for 3 minutes.
 - Continuous wiping of the scanner is not required.
 - If additional wipes are needed to keep the surfaces wet, wipe the device with a fresh wipe. Do not reuse wipes.
- (8). Allow the SEM Scanner to fully dry from cleaning and disinfection prior to use on a patient.

Metrex CaviWipe’s EPA Master Label (issued August 2018) states that, “repeated exposure may cause mild irritation” and that if a user should come in contact with the disinfectant they should “wash all affected and exposed areas with soap and water.”

Users of the wipes may be directly exposed to the wet liquid disinfecting solution. The user of the wipe is exposed to the wet liquid in several ways, including by touch, by splashing, and droplets. The User should wear gloves and an apron, and if not then washing hands is recommended.



7.4 *Cleaning the Charging Hub*

The Charging Hub is typically placed in a clean office environment or workstation with clean and disinfected scanners; and should be cleaned only as needed.

Follow the cleaning and disinfection recommendations above for more extensive cleaning if the system is accidentally soiled or contaminated.

8 Clinical Interpretation

Clinical interpretation of Provizio SEM Scanner scans begins by collecting a set of measurements described in Section 5 performed on each anatomical site under assessment. After the set of measurements have been collected, the SEM Δ value will be displayed.

A SEM Δ equal to or greater than 0.6 at an anatomical site may suggest increased risk for pressure ulcers.

The SEM Δ value should be considered in conjunction with other measures of standard of care and clinical judgment.



The standard of care should be followed for reducing the risk of developing pressure ulcers. Readings from the Provizio SEM Scanner can be used to support increased intervention but should never be to the basis for decreasing intervention.



This device is not intended to be used for detecting or diagnosis of pressure ulcers.

8.1 Deriving SEM Scanner Delta (Δ) Values

The measurement technology of the Provizio Scanner is the same as the SEM Scanner 200 and the clinical evaluation results of the SEM Scanner 200 are applicable to the Provizio SEM Scanner System.

Clinical study (SEM200-008 or “008”) results from 182 study subjects with 437 anatomical locations were used to derive clinical validity of the SEM Δ values. The 008 clinical study was a prospective, blinded study comparing the SEM Scanner to the current Standard of Care, Visual Skin Assessment (VSA), in identifying patients with tissue at increased risk of developing pressure ulcers at the heels or sacrum. SEM Scanner assesses the electrical capacitance of skin and tissue below the electrode when placed on the patient’s skin. VSA seeks to identify pressure ulcers (Stage I and beyond) once they are visible at the skin level.

8.1.1 SEM200-008 – Study Population

In the 008 Study there were 12 unique clinical-trial sites in the United States and United Kingdom that were included in the study. Each had their own Principal Investigator. Subjects in the 008-study received standard-of-care interventions for pressure ulcer prevention and management. These subjects were at varying risk for developing pressure ulcers (as defined by current risk assessment tools) and thus interventions were given.

According to the study protocol's inclusion criteria, these patients were defined as being “at risk” if they met one of the following criteria:

- Pressure Ulcer Risk Score – Braden < 15; Waterlow \geq 10; or Norton \leq 18;
- Poor mobility; e.g., Braden mobility sub-score \leq 2; Waterlow mobility sub-score > 2; Norton mobility sub-score \leq 2; or poor mobility according to clinical judgment (chair- or bed-bound);
- Poor nutrition; e.g., Braden nutrition sub-score \leq 2; Waterlow nutrition sub-score > 2; or other indicator of poor nutrition; and/or
- Medical procedure (e.g., surgery, x-ray, etc.) involving immobility and inability to change position lasting 4 hours or longer.

One hundred eighty-two (182) subjects were listed as Intent to Treat (ITT). Of those, 170 were included in the sensitivity and specificity calculations with 48 pressure ulcers forming in 36 subjects.

Subject enrollment occurred across a range of types of study institutions:

1. Orthopaedic Trauma: 14% (n=26 subjects)
2. Medical Surgery: 27% (n=50 subjects)
3. Long Term Care: 32% (n=58 subjects)
4. ICU: 9% (n=17 subjects)
5. Rehab: 4% (n=7 subjects)
6. Neurologic Care: 8% (n=15 subjects)
7. Other/Mixed: 5% (n=9 subjects)

8.1.2 SEM200-008 – Results

Sensitivity and specificity data presented in Table 10 and Table 11 show how the SEM Scanner 200 compares to visual skin assessment in identifying patients with tissue at risk of developing pressure ulcers at the heels or sacrum.

Table 10 Final Results for Individual Anatomical Locations

Total Patients in ITT Population (182) / Total Anatomical Locations (437)	Visible Pressure Ulcer	No Visible Pressure Ulcer
SEM Δ \geq 0.6	42	261
SEM Δ < 0.6	6	128

Table 11 Range of SEM Δ and Confidence Intervals Using Bootstrap Method

SEM Δ	Sensitivity ¹			Specificity ¹		
	n	%	95% CI	n	%	95% CI
≥ 0.6	42	87.4%	77.8%, 96.7%	124	33.0%	27.6%, 38.7%

¹ Sensitivity and specificity analysis was performed following an analysis rule of 2 of 3 consecutive observations of a SEM delta of 0.6 or above ("SEM positive") or SEM delta less than 0.6 ("SEM negative") from a five-day window from study exit or when a pressure ulcer is identified by visual skin assessment. This analysis rule was defined before study analysis was performed.

Forty-eight (48) pressure ulcers developed in 36 subjects in the Intent-to-Treat population (26% incidence in the ITT population) with several patients developing at least one pressure ulcer at separate anatomical sites.

Healthcare providers assessed 437 individual anatomical locations from 182 subjects in the ITT. These locations were classed as shown in Table 10. Results were classified as:

- True positives - a visible pressure ulcer and a SEM delta of 0.6 or above ("abnormal levels of SEM"). There were 42 anatomical sites in this category.
- True negatives - no visible pressure ulcer and a SEM delta below 0.6 ("flat values"). There were 128 anatomical sites in this category.
- False negatives - a visible pressure ulcer and a SEM delta below 0.6 ("flat values"). There were six anatomical sites in this category.
- False positives - no visible pressure ulcer and a SEM delta of 0.6 or above ("abnormal levels of SEM"). There were 261 anatomical sites in this category.

In order to appropriately account for the within subject correlation in the estimates of the 95% confidence intervals for sensitivity and specificity, the bootstrap method used. The bootstrap method was applied by sampling, with replacement, from the original dataset. The sampling was done on a per subject basis such that all records for a randomly chosen subject were extracted. One thousand datasets were generated using this method, each with the same number of subjects as the original dataset.

Estimates of sensitivity and specificity were then calculated across datasets by taking the median value. The confidence limits were generated from the 2.5th and 97.5th percentiles. This resulted in the following estimates (Table 11).

9 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

The Provizio SEM Scanners are intended for use in the electromagnetic environment specified in Table 12. Users should ensure that the Provizio SEM Scanners are used in such an environment.

9.1 Electromagnetic Environment

Table 12 Electromagnetic Environment


Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	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 CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	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.

9.2 Electromagnetic Immunity

Table 13 Electromagnetic Immunity – Part I

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.

Table 14 Electromagnetic Immunity – Part 2

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
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 _{rms} 150 kHz to 80 MHz	3 V _{rms}	Portable and mobile RF communications equipment should be used no closer to any 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>



9.3 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 15.

Table 15 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 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.</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>			



10 Specifications

Table 16 Specifications

Item	Specifications
Applied Part	Type BF
Battery Life	3 hours (typical)
Method of Cleaning and Disinfection	Clean the device as defined in Section 7
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

¹ 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.



II Disposal

II.1 *Packaging*

Follow your institutional policies and procedures regarding recycling and disposal of packaging.

II.2 *Single Use Sensor*

Single-use sensors should be disposed of following institutional policies and procedures for patient contacting materials.

II.3 *Scanner*

Cleaned and disinfected scanners should be disposed of according to local regulations for electrical and electronic waste disposal.



I 2 Troubleshooting

If any situation cannot be resolved, please contact your Product Specialist or BBI Customer Service.

Table I 7. Troubleshooting

Problem	Resolution
The scanner does not turn on	Ensure Provizio SEM Scanner is fully charged per Section 3.2.
The scanner shuts off prior to recording a reading	Ensure Provizio SEM Scanner is fully charged per Section 3.2.
No display is visible when the Action Button is pressed, and the unit has been actively charged for 6 hours.	Contact your Product Specialist or BBI Customer Service.
The charging indicator (green light) does not illuminate when the Scanner is positioned on the charger.	Ensure the Charging Hub is connected to a power source and all cables are securely connected. Ensure the Provizio SEM Scanner is positioned securely in the Charging Hub. Ensure that mains power is turned on.
The display is corrupted.	Do not continue to use the device. Try turning the device off and then back on.
There are visible cracks or damage anywhere on the device.	Do not continue to use the device. Contact your Product Specialist or BBI Customer Service.
The thin covering over an electrode is peeling off, or an electrode is separating from the flexible membrane.	Do not continue to use the device. Contact your Product Specialist or BBI Customer Service.



Problem	Resolution
There is no indication of an SEM measurement during a session by visual flash, sound or change on the screen	Ensure the scanner is turned on. Ensure the scanner is on the measurement screen for the selected mode. Ensure a single-use sensor is correctly positioned (Provizio SEM Scanner S only).
The single-use sensor will not attach to the sensor connector	Ensure you have a Provizio SEM Scanner S version scanner. Ensure the single-use sensor is correctly aligned.
Patient data is not uploaded	Ensure the scanner is correctly configured to connect to the Gateway Server. Consult your Information Technology Department.



ENGLISH

Pat. <https://sem-scanner.com/patents/>

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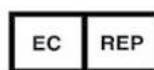
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