

Provizio[®] SEM Scanner

User Manual

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This Provizio SEM Scanner User Manual is for devices of firmware 2.25 onwards.

1. Warnings and Safety Precautions

Improper use or handling 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. Keep these instructions in a safe place. Follow the instructions below to ensure safe and trouble-free operation of your system.

Rx ONLY

Federal (US) law restricts this device to sale by or on the order of a physician or other licensed health practitioner. The Provizio SEM Scanner has been designed and constructed in accordance with applicable European Medical Device Directives and United States (US) regulations and requirements, as well as U.S. and international standards for operation of electrical equipment, electromagnetic compatibility, and stipulated safety requirements.

1.1 Warnings

- **WARNING:** The standard of care should be followed for reducing the risk of developing pressure injuries. Readings from the Provizio SEM Scanner 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 injuries.
- **WARNING:** Do not use the Provizio SEM Scanner on broken or otherwise compromised skin.
- **WARNING:** Only use with Provizio SEM Scanner components.
- **WARNING:** To prevent the spread of infection, the Provizio SEM Scanner 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. A session can be defined as scanning the sacrum, left heel and right heel for the same patient.
- **WARNING:** To avoid damaging the sensor head it is important to train your healthcare practitioners correctly on how to install and remove the single-use sensor.

- **WARNING:** Undue force is not required to either install or remove the single-use sensor - the device has been designed to ensure a simple process but achieve a secure connection once installed.
- **WARNING:** To avoid potential damage to the sensor connector (sensor head on the device) ensure that healthcare practitioners are aware of the difference between the single-use sensor and the sensor connector.
- **WARNING:** Do not attempt to clean or disinfect a contaminated single-use sensor.
- **WARNING:** Should the device contact contaminated surfaces 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 can only be serviced by the manufacturer (Bruin Biometrics, LLC) or a Bruin Biometrics LLC Authorized Service Center. Please contact your 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, Provizio SEM Scanner should not be used in the presence of flammable anesthetic agents.
- **WARNING:** The Provizio SEM Scanner will not operate correctly without first installing a single-use sensor.
- **WARNING:** Ensure there is no foreign material in the Charging Hub slot before placing the scanner in the Charging Hub.

1.2 Safety Precautions

- **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 mains and the Provizio SEM Scanner is fully charged prior to use.
- **CAUTION:** Do not immerse the Provizio SEM Scanner. Immersion may damage the scanner and prevent it functioning normally.
- **CAUTION:** Ensure that the sensor connector is completely dry before attaching a single-use sensor to the device.

NOTE: If the user and/or patient experiences any serious incident in relation to the device, it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1.3 Correct Handling of the Device

- **CAUTION:** Ensure the Provizio SEM Scanner is re-placed in the Charging Hub after use.
- **CAUTION:** Avoid placing the Provizio SEM Scanner on surfaces that may allow the Scanner to slide and fall.
- **CAUTION:** Do not place the Provizio SEM Scanner in uniform pockets from which it might fall.
- **CAUTION:** Avoid placing the Provizio SEM Scanner on hospital beds where possible, if required, ensure it does not fall on the floor.

2. General

2.1 Nomenclature

Pressure injuries¹ are also called pressure ulcers, decubitus ulcers, bed sores or pressure sores. ICD-10-CM, L89 defines a stage 1 pressure ulcer as “pre-ulcer skin changes limited to persistent focal edema” and Deep Tissue Injuries as “Pressure-induced deep tissue damage”.^{2,3}

Sub-epidermal Moisture (“SEM”) is interstitial fluid beneath the skin’s surface, which is equally known in literature as persistent focal edema, or localized edema.^{3,4,5}

Biocapacitance is the electrical capacitance of tissue which varies with changes in Sub-epidermal Moisture.^{3,5}

1 National wound care organizations in the United States including the National Pressure Injury Advisory Panel (NPIAP) have adopted the internationally preferred term -- “pressure injury”, in place of pressure ulcer. In 2019, the National Pressure Ulcer Advisory Panel (NPUAP) changed their name to the National Pressure Injury Advisory Panel (NPIAP) reflecting their commitment to a more accurate clinical description for pressure ulcers and injuries. Bruin Biometrics, LLC aligns with this up-to-date terminology. For the sake of clarity and completeness, we will refer to ‘pressure injuries’ in place of pressure ulcers throughout this document.

2 World Health Organization. International statistical classification of diseases and related health problems (10th ed). 2016. <https://icd.who.int/browse10/2016/en> (accessed 14 April 2020).

3 EPUAP/NPIAP/PPPIA 2019. European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. EPUAP/NPIAP/PPPIA.

4 Gefen, A. The SEM Scanner for early pressure ulcer detection: a 360-degree review of the technology. Wounds International. 2020; 11(4):22-30.

5 Gefen, A., et al. (2020). Update to device-related pressure ulcers: SECURE prevention. COVID-19, face masks and skin damage. (Journal of Wound Care Vol 29, NO 5, May 2020. Figure reprinted by permission of MA Healthcare Ltd.)

2.2 Indications for Use

Provizio SEM Scanners 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 injuries.

2.3 Device Description

The Provizio SEM Scanner (Figure 1) 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 ("SEM Δ "). The Provizio SEM Scanner is pre-calibrated and is provided with a Charging Hub and power supply for recharging the scanner.

The Provizio SEM Scanner provides measurements of biocapacitance as a "SEM value" when applied on the patient's skin. A comparison of multiple SEM measures across the anatomy will identify the maximum difference in SEM values, displayed as a "SEM Delta (Δ)". The greater the SEM Delta (Δ), the greater the localized edema at the specific anatomy.

A SEM Delta (Δ) greater than or equal to 0.6 (SEM Delta (Δ) \geq 0.6) indicates localized edema following the inflammatory process resulting from deformation, and an increased risk of developing more severe broken skin pressure injuries or deep tissue injuries in all population type and care settings.

The device displays a SEM Delta (Δ) value after taking a minimum of three (3) SEM Value readings. The reported SEM Delta (Δ) 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 injuries.




Figure 1 Provizio SEM Scanner and Charging Hub

The Provizio SEM Scanner can transmit collected SEM Values and SEM Delta (Δ), when associated with a valid patient identification number to a centralized, in-institution, data server for later review. Refer to the Gateway User's Manual for more information.

2.4 Provizio SEM Scanner

The Provizio SEM Scanner (Figure 2) has both manual patient ID entry and scanning patient ID barcodes. To be used it is separately supplied with single-use, non-sterile sensors.

 The Provizio SEM Scanner will not operate correctly without first installing a single-use sensor to the sensor connector.


 Ensure that the sensor connector is completely dry before attaching a single use sensor to the device.



Figure 2 Provizio SEM Scanner

2.5 Additional Provizio SEM Scanner Components

The Provizio SEM Scanner is packaged with a Charging Hub, a 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 scanner is placed in the Charging Hub. See Section 3.2 for charging instructions.

2.6 OEM Parts Kit

In the event of misplacing or losing the components provided with the Provizio SEM Scanner, an OEM Parts Kit is available for purchase to replace these items. The Kit includes a Charging Hub, power cord, plug adapter bag (with 5 regional adapters) and Instructions for Use (IFU) in cardboard packaging. Contact your Customer Service provider for more information.

2.7 Contraindications

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

2.8 Intended User Profile

The system is intended for use by healthcare professionals.

2.9 Adverse Effects

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

2.10 Warranty

This manual is intended to provide instructions on the proper use of the Provizio SEM Scanner. It should be used in conjunction with the appropriate training.

To request repair or replacement under warranty, purchasers should contact their local Customer Service provider. Warranty conditions may differ in some countries. Contact your Customer Service provider for warranty terms.

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

Warranty does not extend to any Warranted Products or parts thereof: (a) that 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 LLC User Manual, (d) on which the serial number has been removed or made illegible, (e) that have been modified by anyone other than Bruin Biometrics LLC or its authorized service center, unless authorized prior to such service by Bruin Biometrics LLC, (f) that are equipment sold as used, or (g) that are exposed to agents listed in Table 1, below. Table 1 is not an exhaustive list of agents which may compromise the integrity of the Provizio SEM Scanner.

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






















Severe Effect – NOT Recommended			
Benzene	Cyclohexane	Kerosene	Nitric Acid – 70%
Carbon tetrachloride	Ethyl Chloride	Trichloroethylene	Perchloroethylene
Chlorobenzene	Freon	Lacquer	Toluene
Chloroform	Gasoline, unleaded	Naphtha	Xylene

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

The contents of this User Manual do not constitute a warranty.

2.11 Table of Symbols

Table 2 Labelling Symbols

Symbol	Meaning
	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
	Medical Device
	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-60601-1
	Keep away from sunlight
	Keep dry

3. Provizio SEM Scanner 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 3 shows the packaged Provizio SEM Scanner.



Figure 3 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 Hub slot before placing the scanner in the Charging Hub.

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

Charge the Provizio 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 adapter (Figure 4). The adapter is



provided with several regional pin configurations. Select the configuration suitable for your institution, insert into the face of the adapter 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 adapter.
3. Insert the cylindrical connector of the adapter 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.

Place the scanner into the Charging Hub (Figure 5).

6. 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.
7. When positioning the Charging Hub, ensure the hub is placed in a manner so that will make it difficult to disconnect the Provizio SEM Scanner.
8. While the scanner is in the Charging Hub, the touchscreen is disabled. The display shows the status of the data upload and the battery charge level (Figure 6).

NOTE: When the Charging Hub is disconnected from mains power, the indicator light may remain on for a short time. This is normal behavior.

Refer to Section 6.3 for more information regarding the upload of patient data.

3.3 Connecting Device to Institution Wireless Networks

Figure 4 AC/DC Wall Adapter



Figure 5 Correct Positioning of Provizio SEM Scanner in the Charging Hub



Figure 6 Display During Charging

Please refer to your institutions Information Technology Department and the Bruin Biometrics LLC Technical Manual for instructions on connecting the Provizio SEM Scanner to your network.

4. Provizio SEM Scanner Operation

The Provizio SEM Scanner has both manual patient ID entry and scanning patient ID barcodes. To be used it is separately supplied with single-use, non-sterile sensors.

An overview of the key features of the Provizio SEM Scanner can be found in Figure 7.

⚠️ The Provizio SEM Scanner will not operate correctly without first installing a single-use sensor to the sensor connector.

See Section 7 for cleaning and disinfection procedures.

4.1 Key Features

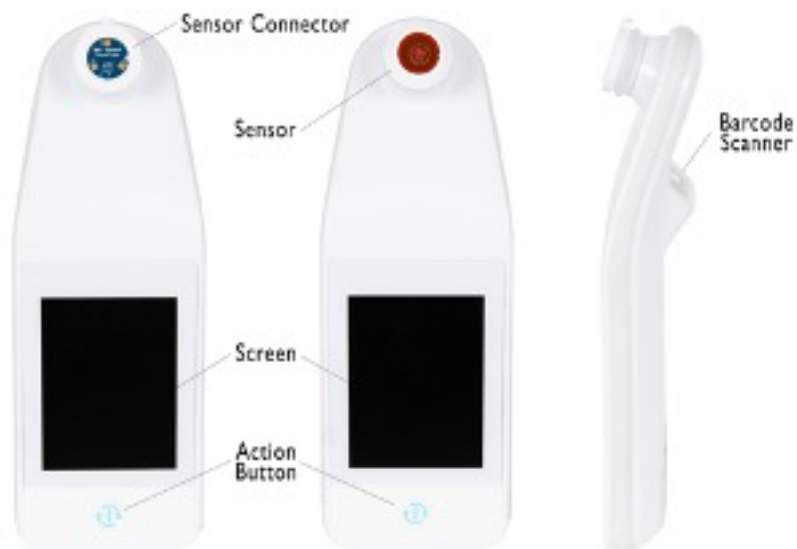


Figure 7 Key Features of Provizio SEM Scanner

4.2 Key Controls and Icons

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

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 Selection	Enters training & research mode
	Training QR Code	Enters training website when scanned by mobile device
	Training Mode	Enters training 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

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 setup
	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 failure	Scanner self-calibration has failed

4.3 Turning the Provizio SEM Scanner ON

⚠️ To prevent the spread of infection, the Provizio SEM Scanner 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. A session is defined as scanning the sacrum, left heel and the right heel for the same patient.

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

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

1. 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.
2. If the scanner is not in the Charging Hub, press and hold the Action button (ⓘ) until the screen illuminates.
3. Verify the scanner has no visible damage or sharp edges.

NOTE: DO NOT USE if the scanner is broken or any damage or sharp edges are found.

4. If required, clean and/or disinfect the unit per Section 7.

4.3.1 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. A session is defined as scanning the sacrum, left heel and the right heel for the same patient.

⚠️❑ 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 the sensor on the Provizio SEM Scanner connector (Figure 8). There is a notch in the sensor and a corresponding tab on the scanner connector to aid the alignment of the sensor. Firmly grip the scanner in one hand and using your finger and thumb using a hinge like maneuver install the sensor. You will hear and feel a click when the sensor sits correctly on the connector. Undue force is not required to either install or remove the single use sensor, the device has been designed to ensure a simple process but achieve a secure connection once installed.

To remove the sensor using the same hinge-like maneuver, firmly grip the scanner in one hand and using your finger and thumb gently pull the sensor away from the connector.

CAUTION: Ensure you only take hold of the sensor not the entire sensor head during the process.

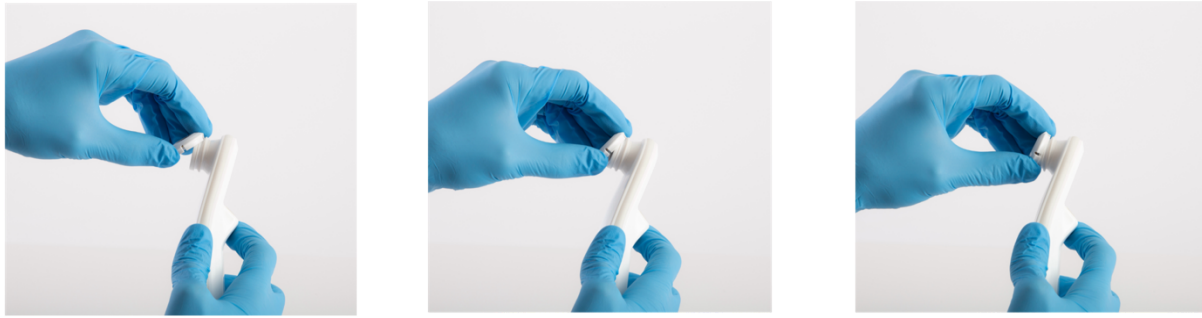


Figure 8 Installation of the Single-Use Sensor

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

The sensor installation screen (Figure 9) will be displayed, prompting the installation of the single-use sensor.

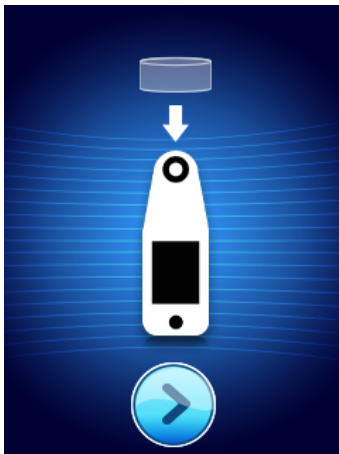


Figure 9 Install Sensor Screen

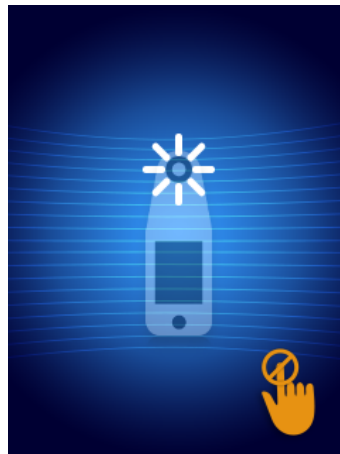


Figure 10 Sensor Calibrating Screen

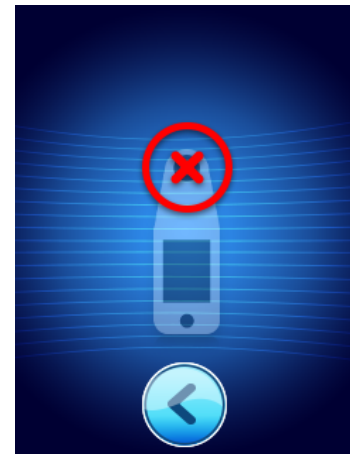


Figure 11 Failed Calibration Screen

After you have installed the sensor (Section 4.3.1), press the Next Screen (➡). The scanner will then re-calibrate to the installed sensor (Figure 10). If the scanner fails calibration (Figure 11), remove the sensor and discard. Attempt calibration again by installing a new sensor.

If the scanner continues failing calibration, please contact Customer Service. After the scanner is successfully calibrated the Provizio SEM Scanner splash screen will be displayed (Figure 12, below).

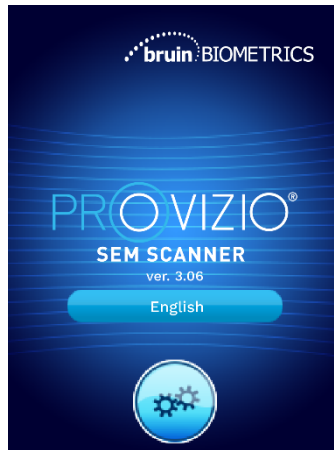


Figure 12 Provizio SEM Scanner Splash Screen

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

Touching the Language button (English) will allow you to Change Language. After a few 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 Select Mode of Operation

After successful calibration, the Provizio SEM Scanner offers two possible modes (Figure 13):

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.



Figure 13 Mode Selection

In each of these modes, touching the Home icon (🏠) will return you to the Install Sensor Screen and a new patient session will begin.

4.5.1 Data Upload Mode

Upon entering Data Upload Mode the display will show the barcode scanning screen(s) (Figure 14). The barcode reader will accept both 1-D and 2-D barcodes.

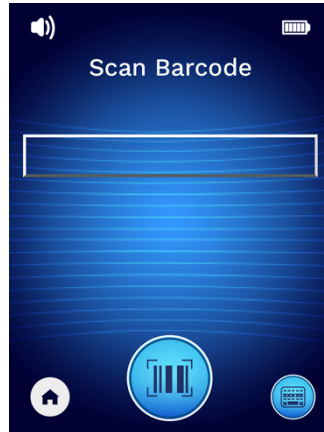


Figure 14 Barcode Scanning Screen

Press the Barcode button (📊) to activate the scanner. Use the green light to aim the reader at the barcode (Figure 15).



Figure 15 Scanning a Patient ID

Once the scanner has identified the barcode, the Body Selection Screen will be displayed (Section 4.6).

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 4.5.4).

Following the entry of the patient ID, the system will move to the Select Body Location Screen.

4.5.2 Manual Charting Mode

Upon entering Manual Charting Mode, the Body Selection Screen will be displayed (Section 4.6).

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 Values and SEM Delta (Δ) should be noted in the patient's physical or electronic medical record per your institutions policies and procedures.

4.5.3 Training

Pressing the Training button (🎓) in the lower left corner of the Mode Selection screen (Figure 13, page 18) will implement a practice mode for training and learning (Figure 16):

1. The screen will allow you to launch a training website by scanning the top QR code using a camera on your mobile device.
2. Clicking on the Training Mode button (🎓) will launch a practice scanning session on the device.



Figure 16 Training Screen

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 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.

4.5.4 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 bracelet barcode ID 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**).

4.6 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 Delta (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 Delta (Δ) value for that area (Δ0.2). The SEM Delta (Δ) value for each body area may be deleted by touching the Delete (x) icon next to the SEM Delta (Δ) value.



Figure 19 Body Location Selection Screen

Touching the Home icon (🏠) will return you to the Install Sensor Screen, and a new patient session will begin.

NOTE: If you accidentally touch the Home icon (🏠) before scanning the 3 body areas, a prompt (Figure 20) will be displayed to allow you to either complete the session or leave the session.

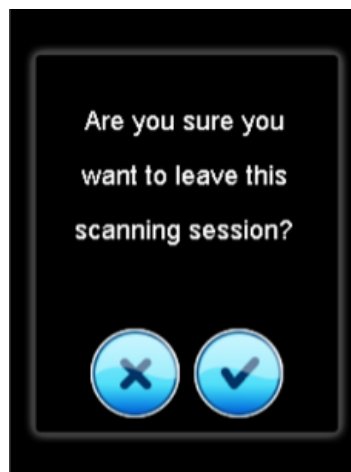


Figure 20 Leaving Scanning Session

5. Taking Measurements

5.1 General

⚠️ Do not use the Provizio SEM Scanner on broken or otherwise compromised skin.

⚠️ To prevent the spread of infection, the Provizio SEM Scanner 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.

Remove the sensor from the pouch and place the sensor on the Provizio SEM Scanner connector (Figure 8). There is a notch in the sensor and a corresponding tab on the scanner connector to aid the alignment of the sensor. Firmly grip the scanner in one hand and using your finger and thumb using a hinge like maneuver install the sensor. You will hear and feel a click when the sensor sits correctly on the connector. Undue force is not required to either install or remove the single use sensor, the device has been designed to ensure a simple process but achieve a secure connection once installed.

To remove the sensor using the same hinge-like maneuver, firmly grip the scanner in one hand and using your finger and thumb gently pull the sensor away from the connector.

A SEM Delta (Δ) equal to or greater than 0.6 (≥ 0.6) at an anatomical site suggests the increased risk of pressure injuries.

The general layout of the measurement screen is shown in Figure 21.

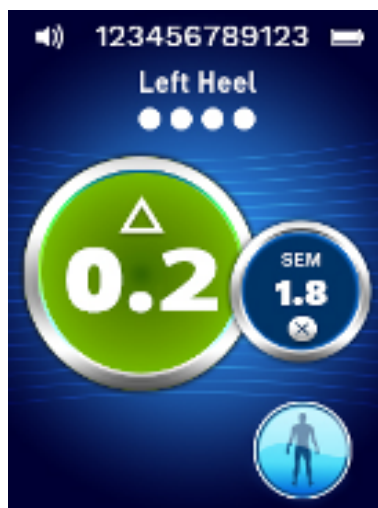



Figure 21 Measurement Screen (Left Heel)

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, indicating that more than nine measurements have been completed.

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

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

The smaller circle on the right image () displays the current SEM value measurement. This measurement may be deleted by touching the Delete icon (). 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, press the Refresh Icon () to clear current data and commence a new scan.

5.2 Taking 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. Ensure to lift the device directly and smoothly off the skin surface, do not drag the device along the skin surface.

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 22).

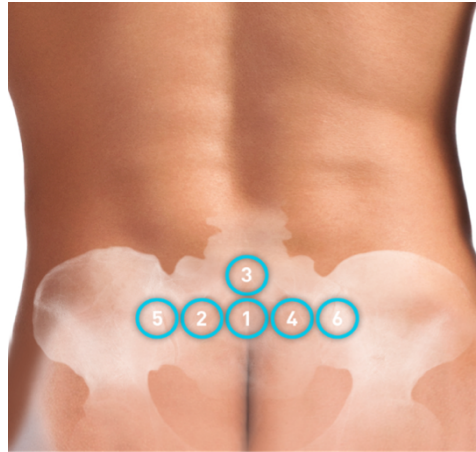


Figure 22 Recommended Sacral Measurement Locations

1. As a starting point, #1 is just above the gluteal cleft of the sacrum, around S3 of the sacral bone.
2. #2, #4, #5 and #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 Taking 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 23).



#1: Back of the heel around the calcaneus. Avoid placing the Provizio SEM Scanner on the achilles tendon.



#2: Lateral side of the heel. Lateral side is the same side as the little toe (fifth toe). Avoid placement of the Provizio SEM Scanner on the lateral malleolus



#3: Medial side of the heel. Medial side is the same side as the big toe (first toe). Avoid placement of the Provizio SEM Scanner on the medial malleolus.



#4: Heel pad (sole of the heel) from the back edge of the heel.

Figure 23 Recommended Heel Measurement Locations

1. #1 begins at the back of the heel.
2. #2 and #3 are positioned on the side of the heel, near the base of the heel.
3. #4 is on the heel pad, near the back of the foot.
4. If one of the measurement locations is calloused, it is advised not to take a reading. The heel scanning session can be finished with only 3 readings.

5.4 Out of Range Readings

A smart 3-step detection workflow is implemented to keep track of scans and detect out of range readings or even detect a scanner needing servicing.

The clinical range of SEM readings (individual SEM reading, not a SEM Delta (Δ) value) is between 1.1 and 4.5, any reading outside of those is classed as out of range.

Out of Range Warning: If the scanned reading is determined to be out of range, the Scanner will warn you by asking you to delete and rescan (Figure 24a).

Replace Sensor Warning: If an out of range reading is detected twice in a row, the Scanner will ask you to change the sensor and rescan (Figure 24b).

Call Customer Service: If an out of range reading is detected even after the sensor change and for the third time in a row, the Scanner will ask you to call Customer Service as the Scanner is likely to require service (Figure 24c).

When any of the out of range reading warning occurs, the healthcare practitioner scanning must acknowledge the warning by clicking the blue tick icon. Scanning cannot be continued until this action has been completed. Once the blue tick is clicked the out of range reading will be automatically deleted by the scanner.

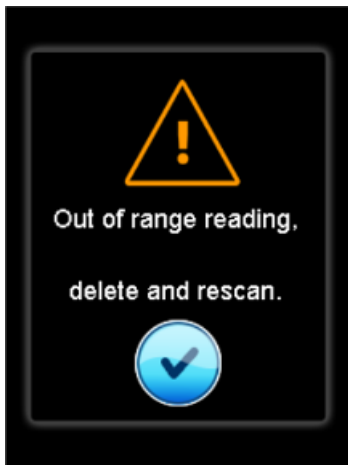


Figure 24a Warning Screen

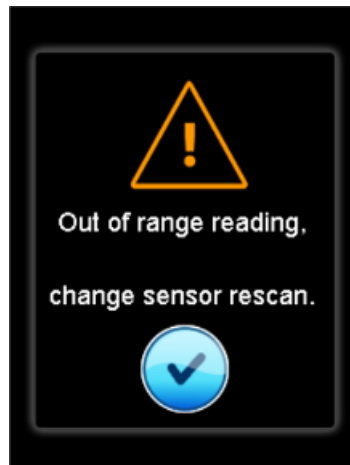


Figure 24b Warning Screen

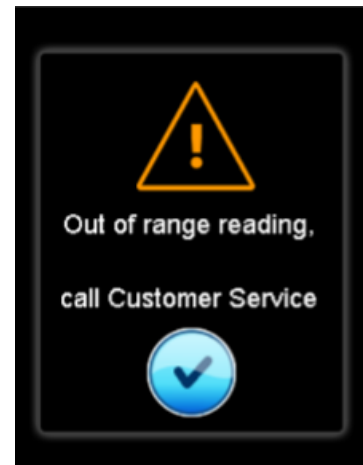


Figure 24c Warning Screen

6. Finishing the Session

6.1 Remove the Single-Use 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. A session is defined as scanning the sacrum, left heel and the right heel for one patient.

The sensor is removed in the reverse manner of the installation. To remove the sensor using the same hinge-like maneuver, firmly grip the scanner in one hand and using your finger and thumb gently pull the sensor away from the connector.

CAUTION: Ensure you only take hold of the sensor not the entire sensor head during the process (Figure 25).

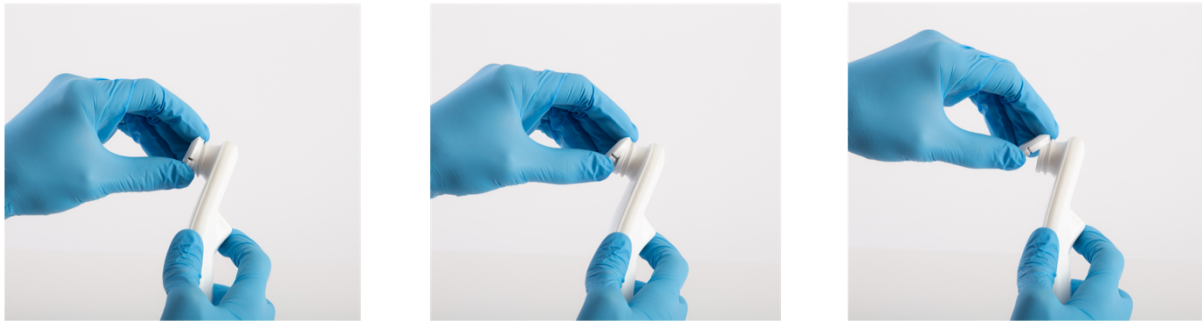


Figure 25 Removing the single-use sensor

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 Scanner 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 (scanning the sacrum, left heel and the right heel for one patient).

⚠️ 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 Hub slot before placing the Provizio SEM Scanner in the Charging Hub.

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 Provizio SEM Scanner. Should a red cloud with a white X appear (Table 8) this means the data is not automatically uploading, this is usually because the Facility WIFI has not initiated: in which case:

- Try simply removing and replacing the device into the Charging Hub – if the issue persists;

- Ensure there are no known WIFI issues ongoing in Facility – if none;
- Refer the issue to your Facility IT support – they have access to a Guide to decode the error and find a resolution.

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 Scanner should be properly cleaned and disinfected according to the instructions provided in this User Manual 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 (scanning the sacrum, left heel and the right heel for one patient).

⚠️ Should the device come in contact with contaminated surfaces 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

Bruin Biometrics LLC recommends manual cleaning and disinfecting the Provizio SEM Scanner 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.

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, Bruin Biometrics LLC tested the use of wipes designed to perform both processes: a cleaner and chemical disinfectant in one wipe form.

The entire body of the scanner is capable of being safely cleaned and disinfected, including the sensor connector.

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

Remove any cleaning or disinfection product as per the manufacturer’s instructions.

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

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 26a and Figure 26b. Continue wiping for the entire 45 seconds even if there is no visible dirt and debris. Do not reuse the wipes.



Figure 26a Clean the Sides and Back of the Scanner



Figure 26b Clean the Front of the 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. 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 Provizio SEM Scanner with the wipe, you are applying the cleaning and disinfecting agent onto the scanner.

Before starting the disinfection, first clean the scanner 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 scanner for 45 seconds to remove dirt and debris from the scanner as shown in Figure 27 and Figure 28. Continue wiping for the entire 45 seconds even if there is no visible dirt and debris. Do not reuse the wipes.



Figure 27 Clean the Sides and Back of the Scanner



Figure 28 Clean the Front of the 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 scanner surface should be fully coated with the wipe solution. Do not reuse the wipes.

4. 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:

5. After completing Steps 1 – 5 for cleaning, repeat these steps to perform disinfection.
6. Place the cleaned scanner on an aseptic or disinfected surface after wiping for at least 2 minutes to properly disinfect the scanner before returning it to the Charging Hub or using on another patient.
 - **NOTE:** Do not place the scanner 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 scanner with a fresh wipe. Do not reuse wipes.
7. Allow the 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 the clean and disinfected Provizio SEM Scanner 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. Guidance and Manufacturer’s Declaration

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

The Provizio SEM Scanner is intended for use in the electromagnetic environment specified in Table 10. Users should ensure that the Provizio SEM Scanners are used in such an environment.

The Provizio SEM Scanner includes wireless charging which involves RF emissions. The strength and frequency of the emission are as follows: 100kHz and 1V_{rms}

8.1 Electromagnetic Environment

Table 10 Electromagnetic Environment


Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR11	Group 1	The Provizio SEM Scanner 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 A	The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential ENVIRONMENT (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

8.2 Electromagnetic Immunity

Table 11 Electromagnetic Immunity - Part 1

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air	± 8 kV contact ± 2, 4, 8, 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	AC power ports, ±2 kV	AC power ports, ±2 kV	Mains power quality should be that of a typical commercial or institution environment.
Surge IEC 61000-4-5	AC power ports, kV, ± 1 kV line(s) to line(s)	AC power ports, kV, ± 1 kV line(s) to line(s)	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	Dips 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° Interrupts 0 % UT; 250/300 cycles	Dips 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° Interrupts 0 % UT; 250/300 cycles	Mains power quality should be that of a typical commercial or institution environment. If the user of the Provizio SEM Scanner Charging Hub requires continued operation during power mains interrupts, it is recommended that the Charging Hub be powered from an uninterruptible power supply or a battery.

Table 12 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 _{rms} /m, 50 & 60 Hz	30 A _{rms} /m, 50 & 60 Hz	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	Immunity to Conducted Disturbances, Induced by RF Fields: AC power ports, 0.15 – 80 MHz, 3 V _{rms} , 80% AM at 1kHz	3 Immunity to Conducted Disturbances, Induced by RF Fields: AC power ports, 0.15 – 80 MHz, 3 V _{rms} , 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Provizio SEM Scanner 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	Radiated, RF, EMF Immunity: Radiated Immunity, 3 V/m, 80 – 2700 MHz, 80% AM at 1 kHz	Radiated, RF, EMF Immunity: Radiated Immunity, 3 V/m, 80 – 2700 MHz, 80% AM at 1 kHz	Recommended separation distance: $d = 1.2 \cdot \sqrt{P}$ 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  symbol:

8.3 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 no closer than 30cm (12 inches) to any part, including cables included by the manufacturer.

9. Specifications

Table 13 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	1.0 to 4.5 SEM Value units
SEM Value Repeatability ⁶	+/- 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 Hub AC Mains Voltage	100-240 V
Charging Hub Mains Current	0.5 A

10. Disposal

10.1 Packaging

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

⁶ 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.

10.2 Single-Use Sensor

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

10.3 Provizio SEM Scanner

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

11. Troubleshooting

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

Table 14 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 Customer Service.
The charging indicator (green light) does not illuminate when the Scanner is positioned on the Charging Hub.	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 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 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 Provizio SEM Scanner is turned on. Ensure the scanner is on the measurement screen for the selected mode. Ensure a single-use sensor is correctly positioned.
The single-use sensor will not attach to the sensor connector	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.

Pat. <https://sem-scanner.com/product/bbi-intellectual-property/>

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OTH-SEM250-0781-US Provizio SEM Scanner E250 User Manual Rev 00 (DOC-1093) Ver. 0

Approved By:

[\(CO-247\) User Manual Documentation](#)

Description

This change will complete the following: Publication of OTH-SEM250-0781-US and OTH-SEM250-0781-OUS. Content based on the original OTH-0359 Manuals with the following changes: OTH-SEM250-0781-OUS: UK language updates throughout Removal of US specific warning in Section 1.1 'Warnings' Addition of section 1.3 'Correct handling of device' More context added to section 5.4 'Out of range readings' for new range of 1.1-4.5 OTH-SEM250-0781-US: Update to section 5.4 'Out of range readings' for new range of 1.1-4.5 Additionally, OTH-SEM300-0005 will be updated with the following: Update to section 5.4 'Out of range readings' for new range of 1.1-4.5

Justification

Firmware updates have resulted in a change of readings considered in range for the "Out of range workflow" and require an update. OTH-SEM250-0781-US/OUS are being created as a new manual separate from legacy and to alleviate translation update issues.

Assigned To:	Initiated By:	Priority:	Impact:
Callum Housley	Tyler Steely	High	Minor

Version History:

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