

# **SEM SCANNER POINT OF CARE 200 SERIES**

## **INSTRUCTIONS FOR USE**

## Table of Contents

1. Warnings and Safety Precautions .....	3
2. General.....	4
2.1 Device Description.....	4
2.1.1 SEM Scanner Device.....	4
2.1.2 SEM Scanner Display.....	5
2.2 SEM Scanner Accessories.....	6
2.3 Indications for Use.....	6
2.4 Contraindications .....	6
2.5 Intended User Profile.....	6
2.6 Adverse Events .....	6
2.7 Warranty.....	6
2.8 Table of Symbols .....	7
3. Operating Instructions .....	7
3.1. Unpacking and Inspection .....	7
3.2. Charging the Device .....	8
3.3. Use of Device.....	9
3.4. Acquiring a Single Reading.....	11
3.5. Acquiring Multiple Readings .....	12
3.6. Displaying Average and Maximum Values in an Assessment.....	13
3.7. Resetting the SEM Scanner.....	13
3.8. Ending SEM Scanner Operation.....	14
3.9. Summary of Action Button Functions .....	14
4. Cleaning and Disinfection.....	15
4.1. Cleaning and Disinfection Overview .....	15
4.2. Scanner Cleaning and Disinfection Instructions.....	15
5. Troubleshooting .....	17
6. Guidance and Manufacturer’s Declaration – Electromagnetic Emissions .....	18
6.1. Electromagnetic Environment.....	18
6.2. Electromagnetic Immunity.....	19
6.3. Separation Distance.....	21
7. Specifications.....	22

## 1. Warnings and Safety Precautions

The SEM Scanner Point of Care 200 Series (SEM Scanner) has been constructed in accordance with the European Medical Device Directives as well as international regulations and 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 SEM Scanner system. Keep these instructions in a safe place. Follow the instructions below to ensure safe and trouble-free operation of your system.



- **WARNING:** To prevent the spread of infection, the SEM Scanner should be properly cleaned and disinfected with Metrex CaviWipe™ Low Alcohol (17.20% Isopropanol Alcohol) Surface Disinfectants after it is used on a patient.
- **WARNING:** Should the device come in contact with non-sterile 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 SEM Scanner as this can result in unintended hazards. SEM Scanners cannot be serviced or repaired. Please contact 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, do not use the SEM Scanner in the presence of flammable anesthetics.
- **CAUTION:** Examine the SEM Scanner for damage or sharp edges prior to each use. If any damage or sharp edges are found do not use the device

## 2. General

### 2.1 Device Description

The SEM Scanner enables trained medical personnel to scan relative surface tissue for detection of localized tissue damage. The system includes the Scanner and a charging station as an accessory.

The SEM Scanner detects relative tissue surface electrical capacitance through application of low amplitude signals from an electrode structure placed on the patient's skin. The surface electrical capacitance value can be used to indicate the presence of sub-epidermal moisture, a biophysical measure associated with localized tissue edema. The SEM Scanner is indicated to be used as an adjunct to the current standard of practice and visual assessment (e.g., pitting edema).

The SEM Scanner assesses changes in surface electrical capacitance and expresses the result in a SEM Value that ranges from 0.5 to 7.0. The SEM Value is directly correlated to changes from "electrode in air" to "electrode on skin."

The SEM Scanner has been tested to have a useful life of at least one year.

#### 2.1.1 SEM Scanner Device

**Action button**  
(turns device on and off and resets readings)



**Figure 1. SEM Scanner Top View Showing Display and Action Button**

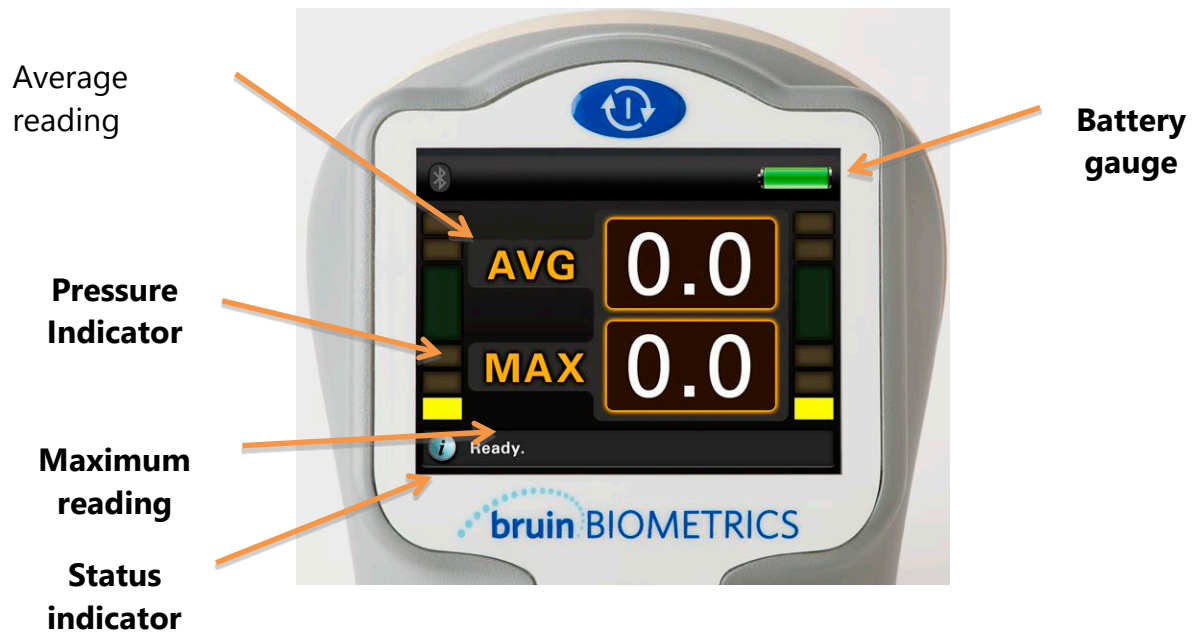


**Figure 2. The electrode on the bottom of the SEM Scanner**



**Figure 3. SEM Scanner Side View**

### 2.1.2 SEM Scanner Display



**Figure 4. SEM Scanner Display**

Item	Function
Battery Gauge	Battery icon indicating current battery state of charge
AVG	Average value of acquired readings
Pressure Indicator	Bars indicating increased applied pressure change color from yellow to green to yellow as applied pressure increases.
Status Indicator	Number of acquired readings, status indicator, or error messages

**Table 1. Legend for Figure 4**

## **2.2 SEM Scanner Accessories**

The SEM Scanner ships with an Inductive Charging Mat and medical device approved wall-mount power supply that is used when charging the device.



**Figure 5. Inductive Charging Mat**

## **2.3 Indications for Use**

The SEM Scanner is a device intended to provide information that a physician or health care professional can utilize as an adjunct to the current standard of care for the detection of pressure induced tissue damage.

## **2.4 Contraindications**

Do not use on broken skin.

## **2.5 Intended User Profile**

The system is intended for use by trained physicians, nurses or technicians.















## **2.6 Adverse Events**

No known adverse events.

## **2.7 Warranty**

BBI warrants that the defects in materials and workmanship for one year from the date of purchase.

## 2.8 Table of Symbols

Symbol	Meaning
	Manufacturer's Catalog designation or number
	Contact/European Representative of manufacturer
	Dispose of this equipment according to local regulations for electrical and electronic waste disposal
	Instruction are included and must be followed
	Serial number
<b>IPX1</b>	Water ingress protection
	Caution or warning
	Symbol designated that product meets European standards for safety
	Manufactured By
	Type BF Applied Part
<b>Rx ONLY</b>	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician
	
	
	
	
	

**Table 2. Table of Symbols**

## 3. Operating Instructions

### 3.1. Unpacking and Inspection

After the SEM Scanner is unpacked verify that the scanner has no signs of damage.

### 3.2. Charging the Device


The device must be charged before using it for the first time.

The device also needs to be charged if the SEM Scanner screen displays a red, low battery icon (Figure 6).



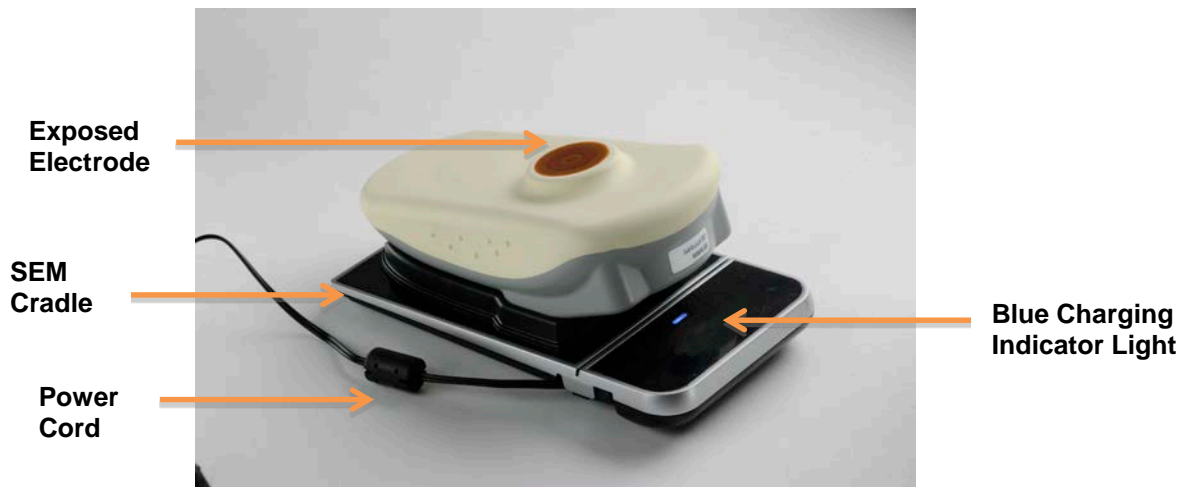
**Figure 6. The battery gauge is in the upper right corner of the SEM Scanner Display**

Follow the steps below to charge the device:

1. Connect the charging mat power adaptor to the power outlet.
2. Ensure that the SEM Scanner is OFF by pressing and holding the Action Button  for 6 seconds until the display screen is blank.
3. Turn the SEM Scanner upside down (so the electrode is on top) and press it firmly into the cradle on the charging mat (Figure 7).
4. A blue charging mat indicator light indicates that it is charging the SEM Scanner. If the blue light is not illuminated then the SEM Scanner may not be positioned securely in the cradle. Do not press the Action Button to turn the SEM Scanner on while it is on the charging mat.
5. Leave the device on the charging mat for at least 6 hours to completely charge the battery.

When fully charged, the battery provides for approximately three hours of SEM Scanner accumulated operation.






**Figure 7. Correct positioning of the SEM Scanner on the charging mat**

### **3.3. Use of Device**

The SEM Scanner should be properly cleaned and disinfected after it is used on a patient. See Section 4 of this User Manual for detailed cleaning instructions.

Follow the steps below to start a session:

1. Remove the SEM Scanner from the charging mat.
2. Verify the scanner has no visible damages or sharp edges and that the electrode is sealed against the base. Do not use the device if the electrode seal is broken or any damage or sharp edges are found.
3. Turn the SEM Scanner on by pressing the Action Button  for approximately one second (Figure 8).



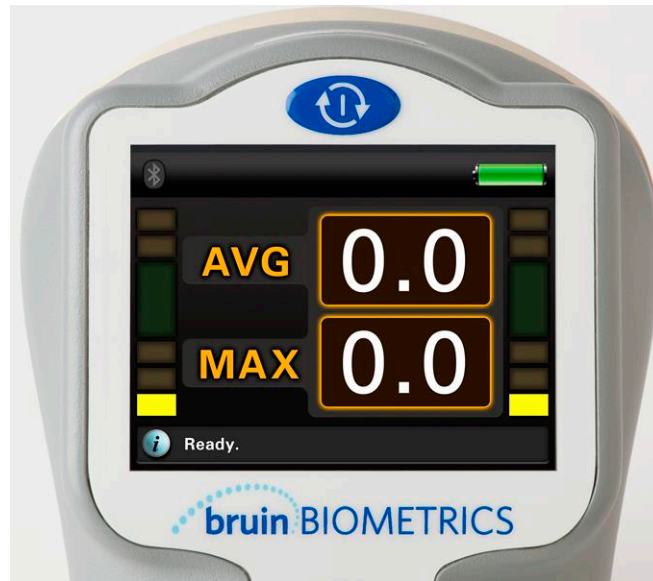
**Figure 8. Starting a Session**

After turning on the SEM Scanner, an audio tone will sound and the initialization screen will be displayed (Figure 9). It will take approximately 45 seconds for the device to initialize and be ready for use.



**Figure 9. SEM Scanner Initialization Screen**

It is important that the SEM Scanner's electrode remains untouched during initialization. If the electrode is touched during initialization, turn off the device and re-initialize. Once initialization is complete, the Status Indicator will display "Ready" (Figure 10).



**Figure 10. SEM Scanner is fully charged, initialized and ready for use**

### ***3.4. Acquiring a Single Reading***

The SEM Scanner automatically obtains readings when the electrode is applied with appropriate pressure to an anatomical location (Figure 11).

Follow the steps below to acquire a single reading:

1. Ensure that any surface moisture or matter is removed from the area on the skin being assessed.
2. Apply the electrode to the desired anatomical site with sufficient pressure for approximately one second as indicated with the green bars. The electrode must be in complete contact with the skin to acquire a proper reading.
3. Confirm a reading has been taken by listening for the SEM Scanner to emit a short audio tone.
4. Perform cleaning and disinfection procedure between each location on a patient. See Section 4 for Cleaning and Disinfection Instructions.



**Figure 11. SEM Scanner Acquiring Heel Reading**

Upon acquiring a reading, the Status Indicator on the SEM Scanner Display will read, "1 Reading Taken."

### **3.5. Acquiring Multiple Readings**

Follow the steps below to acquire multiple readings:

1. Ensure that any surface moisture or matter is removed from the area on the skin being assessed.
2. Apply the electrode to the desired anatomical site with sufficient pressure for approximately one second. The electrode must be in complete contact with the skin to acquire a proper reading.
3. Confirm a reading has been taken by listening for the SEM Scanner to emit a short audio tone.
4. Lift the SEM Scanner and then press down again at the same site to obtain an additional reading.
5. Repeat this process until the desired number of readings is taken. (This may be 3 or 4 readings per anatomical site.)

The number of readings used for the AVG and MAX calculations will be displayed in the status bar (Figure 12).

6. Perform the cleaning and disinfection procedure between each location on a patient. See Section 4 for Cleaning and Disinfection Instructions.




**Figure 12. The SEM Scanner Display Showing 3 Readings Taken**

### **3.6. *Displaying Average and Maximum Values in an Assessment***

The SEM Scanner records values in sample sets according to the number of readings taken during an assessment. The Average and Maximum values in a sample set are both displayed on the SEM Scanner display. Each time a new reading is taken these values will be updated and displayed by the SEM Scanner.

The average of 3 SEM Scanner patient measurement readings should be recorded.


### **3.7. *Resetting the SEM Scanner***

To clear the sample set and start recording readings for a new sample set, select and hold the Action Button  for one second (Figure 13).



**Figure 13. Resetting the SEM Scanner**

### 3.8. Ending SEM Scanner Operation

To end SEM Scanner operation, press and hold the Action Button  for approximately 6 seconds until the SEM Scanner screen becomes blank. The SEM Scanner operation is now ended and power is off.

### 3.9. Summary of Action Button Functions

Desired SEM Scanner Action	Approximate Time to Hold Action Button	Result
Start Operation	1 second	Turns the power on. SEM Scanner will begin initialization when the button is released.
Stop Operation	6 seconds	Turns the power off. SEM Scanner screen will be blank.
Clear Results	1 second	Resets the AVG and MAX values displayed on the screen.

**Table 3. Summary of Action Button Functions**

## 4. Cleaning and Disinfection

### 4.1. Cleaning and Disinfection Overview

The SEM Scanner should only be cleaned and disinfected with Metrex CaviWipe™, Low Alcohol Surface Disinfectant. No other cleaning and disinfection methods have been approved or validated, using cleaning and disinfection procedures other than the method recommended in this manual will void the warranty.

### 4.2. Scanner Cleaning and Disinfection Instructions

To properly clean and disinfect the SEM Scanner, wipe it for at least 1 minute and 45 seconds and allow it to dry for at least 2 minutes.

Follow the steps below to clean and disinfect the SEM Scanner:

1. Obtain 3 Metrex CaviWipes, Low Alcohol (17.20% isopropanol) Surface Disinfectant. Use the first wipe for 45 seconds to clean the scanner. Wipe all surfaces of the SEM Scanner, making sure to clean the crevices on the sides of the device as well (Figure 14-16).



**Figure 14. Cleaning the Bottom of the SEM Scanner**



**Figure 15. Cleaning the top of the SEM Scanner**



**Figure 16. Cleaning the sides of the SEM Scanner**

2. Use the second wipe to completely clean the scanner again for 30 seconds.
3. Use the third wipe to perform another 30 second overall final wiping of the device. The device surface should be fully coated with the wipe solution after the cleaning
4. Allow the device to sit for at least 2 minutes to properly disinfect the device before returning it to storage or using on another patient.
5. The charging mat is typically used in a clean office environment with clean and disinfected scanners. The charging matt should be cleaned only as needed to maintain a good appearance and proper functionality. More extensive cleaning may be required if the system is accidentally soiled or contaminated. Follow the cleaning and disinfection recommendations above



## 5. Troubleshooting

Problem	Resolution
The device does not turn on.	Charge the SEM Scanner per Section 3.2 of this User Manual.
The device shuts off prior to recording a reading.	Charge the SEM Scanner per Section 3.2 of this User Manual.
No display is visible when the Action Button is pressed and the unit has been actively charged for 6 hours.	Contact your product distributors Customer Service.
The number of pressure bars illuminated does not change when the sensor is pressed.	Contact your product distributors Customer Service.
The charging indicator (blue light) does not illuminate when the SEM Scanner unit is positioned on the charger.	<p>Ensure the charging mat is connected to a power source and all cables are securely connected.</p> <p>Ensure the SEM Scanner is positioned securely in the charging mat cradle.</p> <p>If the charging mat continues to not charge contact your product distributor's customer service.</p>
The display is corrupted.	Do not continue to use the device. Try turning the device off and then back on. If this does not resolve the problem, contact your product distributor's customer service.
There are visible cracks anywhere on the device.	Do not continue to use the device. Contact your product distributor's 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 distributor's customer service.

**Table 4. Troubleshooting**

## 6. Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

### 6.1. Electromagnetic Environment

This data is included pursuant to IEC 60601 labelling requirements.


The SEM Scanner is intended for use in the electromagnetic environment specified in Table 5. The user of the SEM Scanner should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR11	Group 1	The 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.  The SEM Scanner 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.
RF emissions CISPR11	Class A	
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

**Table 5. Electromagnetic Environment**

## 6.2. Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 hospital 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 hospital 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 hospital environment. If the user of the SEM Scanner charging system requires continued operation during power mains interrupts, it is recommended that the SEM Scanner system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be a levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the 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	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>Recommended separation distance:</p> $d = 1.2 \cdot \sqrt{P} \quad 150\text{kHz to } 80 \text{ MHz}$ $d = 1.2 \cdot \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \cdot \sqrt{P} \quad 800\text{MHz to } 2.5 \text{ GHz}$ <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</p> <div style="text-align: right;">  </div> <p>the following symbol:</p>

**Table 6. Electromagnetic Immunity**

### 6.3. Separation Distance

The SEM Scanner is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SEM Scanner can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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 SEM Scanner is listed in Table 7.

Separation distance according to frequency of transmitter (meters)			
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \cdot \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

**Table 7. Separation Distance**

## 7. Specifications

Item	Specifications
Applied Part	Type BF
Battery Life	3 hours (typical)
Method of Cleaning and Disinfection	Clean the device as defined in Section 4 using Metrex CaviWipe™, Low Alcohol (17.20% isopropanol) Surface Disinfectant
Water ingress protection	IPX1
Duty Cycle	Continuous operation
Power Source	Internally powered equipment
SEM Value Range	0.5 to 7.0 SEM Value units
SEM Value Accuracy	+/- 0.4 SEM Value units
Storage	The 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 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	0.35 A

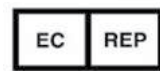
**Table 8. Specifications**

©2014 Bruin Biometrics LLC or its affiliates. All rights reserved.



 **Bruin Biometrics, LLC.**

10960 Wilshire Blvd, Suite 950  
 Los Angeles, CA 90024  
 Phone: (310) 268-9494  
 E-mail: [info@bruinbiometrics.com](mailto:info@bruinbiometrics.com)  
 Website: [www.bruinbiometrics.com](http://www.bruinbiometrics.com)



**Emergo Group**

Molenstraat 15  
 2513 BH The Hague  
 The Netherlands  
 Tel.: 31-0-70345-8570  
 Fax: 31-0-70346-7299