

User Guide

Sunlight MiniOmni™ Ultrasound Bone Sonometer

For Adults and Pediatrics



GENERAL

Software Version 4.2

Text Revised: May, 2020 © BeamMed Ltd.

Document Number DUM-0090 Revision 04

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TABLE OF CONTENTS

GENERAL	2
CONTACT INFORMATION	2
TABLE OF CONTENTS	3
1. ABOUT THIS MANUAL	7
1.1. GLOSSARY	7
2. ESSENTIAL PRESCRIBING INFORMATION	8
2.1. DEVICE DESCRIPTION	8
2.1.1. Probes	8
2.1.2. MiniOmni models	9
2.2. INTENDED USE	9
2.3. CONTRAINDICATIONS	9
2.4. WARNINGS AND PRECAUTIONS	10
2.5. GENERAL SAFETY INSTRUCTIONS	10
2.6. ADVERSE EVENTS	12
3. SYSTEM COMPONENTS	14
3.1. IDENTIFYING SYSTEM COMPONENTS	14
3.1.1. Standard Components	14
3.1.2. Optional Accessories	16
4. DETAILED DESCRIPTION OF COMPONENTS	17
4.1. MINIOMNI MAIN UNIT	17
5. SOFTWARE SETUP	18
5.1. PRIOR TO INSTALLATION	18
5.2. SETUP DISK	18
5.3. MICROSOFT .NET FRAMEWORK	19
5.3.1. Microsoft Visual Studio	19
5.4. MINIOMNI SOFTWARE INSTALLATION	20
5.5. RUN MINIOMNI	21
6. HARDWARE SETUP	22
6.1. STEP 1 – CONNECTOR CABLES, POWER SUPPLY AND FOOT PEDAL (OPTIONAL)	22
6.1.1. MiniOmni USB Data Connector	22
6.1.2. Power Supply	23
6.1.3. Foot Pedal	23
6.2. STEP 2 – CONNECTING THE PROBE	23
6.2.1. Connecting the Probe	23
6.3. STEP 3 – VERIFY APPLICATION – DEVICE COMMUNICATION	24
7. STARTING THE SYSTEM	25
7.1. WELCOME AND LOGIN	25
7.1.1. A Note on User Names in MiniOmni	25
7.2. FIRST-TIME PC REGISTRATION	26
7.3. AUTOMATIC SQV OPTION ON FIRST LOGIN EACH DAY	26
7.4. OVERVIEW OF THE MINIOMNI SCREEN	27

8. SYSTEM QUALITY VERIFICATION (SQV)	30
8.1. WHAT IS SQV?	30
8.2. PERFORMING SYSTEM QUALITY VERIFICATION	31
8.2.1. Finding the SQV Screen	31
8.2.2. Using the SQV Screen	32
8.2.3. Prepare probe	33
8.2.4. Position the phantom and probe	33
8.2.5. Check for acoustic coupling	33
8.2.6. Execute the measurement	33
8.2.7. Determine the Expected SOS Value for the Phantom SQV Test	34
8.2.8. Enter the Expected SOS Value	35
8.2.9. Check the result	36
8.2.10. Print Result	36
9. CHOOSING THE AGE GROUP AND PATIENT	37
9.1. CHOOSE AGE GROUP	37
9.2. PATIENT SELECTION AND OPTIONS	38
10. PATIENT MAINTENANCE	39
10.1. NEW PATIENT – GENERAL	39
10.2. NEW PATIENT CLINICAL INFO	40
10.3. CHOOSING A PATIENT FROM THE EXISTING PATIENT LIST	41
10.4. DELETING A PATIENT	42
11. PERFORMING THE PATIENT MEASUREMENT	43
11.1. PREPARING FOR THE SOS MEASUREMENT	ERROR! BOOKMARK NOT DEFINED.
11.2. LOCATING THE MEASUREMENT SITE FOR THE DISTAL 1/3 RADIUS	43
11.2.1. Position the patient and the limb	43
11.2.2. Identify the Region to be measured	43
11.2.3. Mark the exact half point	44
11.3. UNDERSTANDING THE MINIOMNI MEASUREMENT SCREEN	44
11.3.1. Terms and Definitions	44
11.4. MEASUREMENT SCREEN FORMATS	45
11.4.1. Measuring SOS at the Radius	46
11.4.2. Completing the Measurement	46
12. MEASUREMENT RESULTS	49
12.1. MEASUREMENT RESULTS SCREEN	49
12.1.1. Printing/Saving the report	50
12.2. BONE DENSITY MEASUREMENT REPORT	51
12.3. GUIDELINES TO EVALUATING THE SOS MEASUREMENT	52
12.3.1. SOS Value, T-score and Z-score	52
12.3.2. Measurement Comments	53
12.4. MEASUREMENT HISTORY	54
12.5. DELETING A MEASUREMENT RESULT	55
13. MULTI-SITE MEASUREMENTS	56
13.1. OPERATING THE MINIOMNI MULTI-SITE MEASUREMENT FEATURE	57
14. MEASUREMENT AT PLX, TIB AND MTR	65
14.1. PROXIMAL PHALANX OF THE THIRD FINGER SITE	65

14.1.1. <i>Position the patient</i>	65
14.1.2. <i>Identify the Region to be measured</i>	65
14.2. MID-SHAFT TIBIA SITE	68
14.2.1. <i>Position the patient</i>	68
14.2.2. <i>Identify the Region to be Measured</i>	68
14.3. MEASURING SOS AT THE TIBIA	69
14.4. METATARSAL V SITE	71
14.4.1. <i>Positioning the patient</i>	71
14.4.2. <i>Determining the area to be scanned</i>	71
14.4.3. <i>Measuring SOS at the Metatarsal V</i>	72
15. CLOSING THE MINIOMNI APPLICATION	75
16. PEDIATRIC APPLICATION OF MINIOMNI.....	76
16.1. NEW PATIENT – PEDIATRIC – GENERAL.....	76
16.2. NEW PATIENT – PEDIATRIC – GIRL – CLINICAL INFO	77
16.3. NEW PATIENT – PEDIATRIC – BOY – CLINICAL INFO.....	78
16.4. MEASUREMENT SCREEN – PEDIATRIC	79
16.5. PEDIATRIC MEASUREMENT RESULTS.....	80
16.5.1. <i>SOS Value, Percentile and Z-Score For Pediatric Measurements</i>	81
16.6. BONE DENSITY MEASUREMENT -- PEDIATRIC	82
16.7. GROWTH REFERENCE REPORT – PEDIATRIC	83
17. CLEANING AND DISINFECTING	84
17.1. GENERAL INSTRUCTIONS	84
17.2. THE MINIOMNI DEVICE	84
17.2.1. <i>Cleaning the MiniOmni Device</i>	84
17.3. THE ULTRASONIC PROBE.....	84
17.3.1. <i>Cleaning Precautionary Notes for the Ultrasonic Probe</i>	84
17.3.2. <i>Cleaning the Ultrasonic Probe</i>	84
17.3.3. <i>Disinfection Precautionary Notes for the Ultrasonic Probe</i>	85
17.3.4. <i>Disinfection for the Ultrasonic Probe</i>	85
18. OPTIONS SCREEN	86
18.1. PRACTICE MODE	87
18.1.1. <i>Resetting your CV scores</i>	88
18.2. OPTIONS – ABOUT.....	88
18.3. OPTIONS – HELP	89
18.4. OPTIONS – SETTINGS – DEFAULT VALUES.....	90
18.5. OPTIONS – SETTINGS – SETUP.....	91
18.6. OPTIONS – SETTINGS – REPORT OPTIONS	92
18.7. OPTIONS – ADMINISTRATION – IMPORT/EXPORT	93
18.7.1. <i>Exporting patient data from MiniOmni:</i>	94
18.7.2. <i>Options – Administration – EXPORT HIS</i>	95
18.7.3. <i>The CSV file structure</i>	96
18.7.4. <i>Options – Administration – Delete Patients' Data</i>	97
18.8. OPTIONS – ADMINISTRATION – BACKUP/RESTORE.....	99
18.9. OPTIONS – ADMINISTRATION – PRINT SETUP.....	100
18.9.1. <i>Options – Administration – Users</i>	101
18.10. OPTIONS – ADMINISTRATION – LICENSE	102
19. TROUBLESHOOTING.....	103

20. OPERATING AND STORAGE CONDITIONS	105
20.1. CONFORMANCE TO STANDARDS	105
21. MINIOMNI TECHNICAL SPECIFICATIONS	106
22. PC SPECIFICATIONS	107
23. MANUFACTURER DECLARATION	108
23.1. GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC EMISSIONS	108
23.2. GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC IMMUNITY	108
23.3. GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC IMMUNITY	109
23.4. GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC EMISSIONS	109
23.5. RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE [ME EQUIPMENT OR ME SYSTEM]	110
24. SOFTWARE LICENSE AND WARRANTY	111
25. CLINICAL STUDIES	113
26. TANNER STAGES OF PUBERTY	114
26.1. TANNER STAGES OF MALE PUBERTY	114
26.2. TANNER STAGES OF FEMALE PUBERTY	115
27. LABELS AND SYMBOLS	116
27.1. LABELS	116
27.2. SYMBOLS	116
27.3. ELECTRONIC DISPOSAL	116

1. ABOUT THIS MANUAL

This manual provides the information necessary to operate the Sunlight MiniOmni system in a safe and efficient manner. Please read and thoroughly understand the manual before operating the system. If any part of this manual is not clear, contact customer support for clarification.

1.1. GLOSSARY

CM probe: Probe for measurement of SOS at the radius and tibia (Tibia requires Multi site feature license).

CR probe: Probe for measurement of SOS at the metatarsal (requires Multi site feature license).

CS probe: Probe for measurement of SOS at the phalanx (requires Multi site feature license).

Measurement cycle: Several scan movements repeated continuously until MiniOmni indicates that it has recorded an SOS value.

MiniOmni, MiniOmni Bone Sonometer, and MiniOmni system: Equivalent terms that refer to the Sunlight MiniOmni product.

Model P: Model designed for SOS measurement in children (pediatric use).

Model S: Model designed for SOS measurement in adults.

Phantom: Plastic block ("phantom limb") used to perform System Quality Verification (SQV) on the device.

QUS: Quantitative Ultrasound, an advanced method of using ultrasound for the assessment of bone status.

Scan: Application of a probe to a skeletal site, and movement of the probe over the site to acquire SOS signals.

SOS: The speed of sound, as recorded in bone tissue.

SOS Percentile: The percentile ranking to which the patient belongs with respect to his or her gender and age-matched peers.

SQV: System Quality Verification. The SQV test must be performed once each day, before performing the first SOS measurement.

Sunlight MiniOmni: A device manufactured by BeamMed Ltd. Device description is provided in section 2.1 below
T-Score: T-score value is the number of standard deviations by which the current patient's SOS value exceeds or falls below the mean of this young adult group.

Z-Score: The difference between the patient's SOS result and the average SOS of a population of the same age and gender in units of population standard deviation.

2. ESSENTIAL PRESCRIBING INFORMATION

2.1. DEVICE DESCRIPTION

The Sunlight MiniOmni Ultrasound Bone Sonometer is a non-invasive ultrasound device capable of measuring bone speed of sound (SOS) at one or more skeletal sites.

Sunlight MiniOmni Ultrasound Bone Sonometer is a modified version of the well-established Sunlight Omnisense system. Sunlight MiniOmni is based on the Sunlight Omnipath technology and Omnisense devices already approved by the CE.

It is comprised of a Main Unit hand held probes, each designed to measure SOS at one or more specific skeletal sites. The basic system is offered with one probe, capable of measuring SOS of the distal one-third radius.

Reference databases are provided for measurements at each of the skeletal sites.



MiniOmni measures SOS utilizing a technology based on well-established laws of physics applied to the transmission of signals along the bone. The measurements are performed while the subject and the operator are comfortably seated.

Results are expressed in meters per second (m/sec), reflecting the upper 95th percentile of the sorted SOS values. MiniOmni reports the bone SOS, together with the Z-score (units of standard deviations relative to age and gender matched population reference values), for adults also as a T-score values (units of standard deviations relative to population reference values of healthy young adults), computed using the patient's SOS value and a reference database. For any two measured skeletal sites, MiniOmni may report the Multi-Site, which combines the individual results into a single clinical index.

No calibration is required. Daily system verification is accomplished using the System Quality Verification (SQV) phantom supplied with the device.

2.1.1. PROBES

MiniOmni has multiple skeletal sites measuring capability using different probes. The probes designed to support measurement at the following areas:

- CM probe - used for bone strength assessment at the radius and tibia.
- CS probe - used for bone strength assessment at the phalanx.
- CR probe - used for bone strength assessment at the metatarsal.

The probes can be supplied with MiniOmni.

2.1.2. MINIOMNI MODELS

S- Adult application

P- Pediatric application

All MiniOmni models (S and P) are mechanically and electrically identical and differentiated only by the software solution available for the customer.

2.2. INTENDED USE

The Sunlight MiniOmni Ultrasound Bone Sonometer is a non-invasive device that is designed for the quantitative measurement of the velocity of ultrasound waves (“Speed of Sound” or “SOS” in m/sec) propagating along bones of adults and children. SOS provides a measure of skeletal fragility.

The output expressed as a Z-score, and for adults also as a T-score, and can be used in conjunction with other clinical risk factors as an aid to the physician in the diagnosis of osteoporosis and other medical conditions leading to reduced bone strength and, ultimately, in the determination of fracture risk.

The SOS measured by MiniOmni has a precision error low enough in comparison with the expected annual change in a patient’s measurement to make it suitable for monitoring bone changes which occur during the years of accelerated growth and in the early years following menopause (i.e.: age range approximately 50-65 years).

2.3. CONTRAINDICATIONS

None.

2.4. WARNINGS AND PRECAUTIONS

Three types of special messages appear in this User Manual:



A **warning** indicates the possibility of injury, death or other serious adverse reactions associated with the use or misuse of the device.



A **caution** indicates the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunctions, device failure, damage to the device or damage to other property.



A **note** provides other important information.

2.5. GENERAL SAFETY INSTRUCTIONS



Warning: Never attempt to operate the MiniOmni unit if it is plugged into an outlet that does not meet all electrical code requirements.



Warning: The system is not sterile. However, the probe must be cleaned and disinfected before each patient session. The proper cleaning and disinfection procedure is described in this User Guide, in [Chapter 17.2.1. Cleaning the MiniOmni Device](#).



Warning: Make sure that there is proper grounding in the wall outlet.



Warning: To prevent fire or electric shock, do not open or expose the unit to rain or moisture.



Warning: Changes or modifications not expressly approved by BeamMed Ltd. could affect the safety and effectiveness of the system and will void the system's warranty.



Warning: Do not use on subjects with breached skin or open sores on the skin area that comes with contact with the probe.



Warning: Use only indoors, in a clean, dry environment.



Warning: PC's, Monitors, printers and other interfacing accessories used with the MiniOmni Bone Sonometer must meet IEC 601-1, IEC 950, UL 2601 or equivalent safety standards.



Warning: Do not operate with a damaged cord or plug. If damaged, have the cord or plug replaced immediately by a qualified service technician.



Warning: Do not operate a probe that is physically damaged.



Warning: Do not use in the presence of a flammable anesthetic mixture containing air, oxygen or nitrous oxide.



Warning: The system contains no user-serviceable components. Do not open the system covers.



Warning: Medical device regulations restrict the operation of the BeamMed application to trained and qualified personnel.

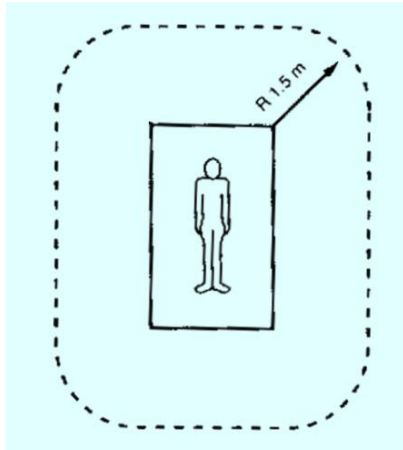


Warning: Use MiniOmni system only with the dedicated power supply.



Warning: Please note the following safeguards/notices for printer or other peripheral equipment installation:

1. All the equipment connected to Sunlight MiniOmni shall be certified according to standard IEC601-1, UL2601, IEC950 or other IEC/ISO standards, or equivalent, applicable to the equipment.
2. When Sunlight MiniOmni is used together with other equipment in the patient area, the equipment shall be either powered by an isolation transformer or connected via an additional protective earth terminal to system ground unless it is certified according to standard IEC601-1 or UL2601, or equivalent safety standard.



3. The leakage current could increase when connected to other equipment.



Caution: Immediately upon receipt of MiniOmni, check the external box for damages. If it was damaged, please note this condition on the bill of lading and call a BeamMed representative.



Caution: The information contained in this Manual is intended for the sole and exclusive use of the Company's customers with the BeamMed application. Any other unauthorized use of this Manual or any of the information it contains is prohibited.



Caution: Do not operate or store MiniOmni near a heat source or air conditioner and always store the System Quality Verification (SQV) Phantom near the MiniOmni unit.



Caution: MiniOmni provides no protection against the harmful ingress (entry) of liquids. Hence, when cleaning the unit, avoid applying liquid near probe connections and sockets.



Caution: SQV phantom and probes should not be immersed in liquid of any kind. Dry or pre-moistened wipes may be used to clean them.



Caution: Use BeamMed recommended and approved ultrasound coupling gels with the MiniOmni Sonometer to generate and maintain acoustical contact of the probe with the skin.



Caution: Ultrasound Gel is for external use only.



Caution: When applying ultrasound coupling gel, do not use a Q-tip, an examination glove treated with talc, or any other applicator that may introduce fibers or other foreign matter into the probe.



Caution: Do not expose the SQV phantom to direct sunlight.



Caution: When conducting the System Quality Verification procedure, avoid touching the temperature indication strip on the phantom with the fingers, as this affects the phantom temperature reading required for correct interpretation of the procedure results.



Caution: When conducting System Quality Verification, be sure that no air bubbles are trapped in the gel between the phantom and probe, as this affects the acoustic contact of the probe with the phantom.



Caution: Refer all service problems to qualified BeamMed representative only.



Caution: Verify the correct date setting of the computer prior to measuring the patient.



Caution: Never attempt to modify MiniOmni DB files outside the MiniOmni application. The files are write-protected and any attempt to externally modify or erase them could cause major damage to the MiniOmni SW.



Caution: SQV must be conducted with the phantom temperature between 15 and 30 degrees Centigrade (59-86 degrees Fahrenheit).



Caution: The System Quality Verification (SQV) procedure must be performed once per day, before measuring the SOS. For details, see [Section 8. System Quality Verification \(SQV\)](#).



Caution: Determining the exact location where the probe is to be applied is an important part of preparing for an SOS measurement. Measures of the speed of sound in bone depend strongly on the site being measured. To draw any statistically meaningful conclusions from an SOS result, the conditions of the measurement should be as close as possible to those used in building the baseline data. Therefore, the exact procedure given in this Guide must be followed for each site.



Caution: Deleted measurements are not recoverable (see [Section 10.4. Deleting a Patient](#)).



Caution: The user is responsible for protecting the PC and the network from malicious activities such as hacking and from the introduction of malicious software.



Caution: If the PC that is used to run the MiniOmni application is connected to a hospital/clinic network, it is the user's responsibility to ensure that the network is protected by a firewall SW as well as by anti-Virus and anti-malware programs



Caution: When closing down MiniOmni, do not simply plug off the power supply. This could cause permanent loss of data. Follow the prescribed exit procedure (see [Section 15. Closing the MiniOmni Application](#)).



Note: We recommend installing the MiniOmni on a new or recently formatted PC to ensure smooth operation.



Note: Measurement at the Radius is limited to patients with BMI lower than 35.

For patients with BMI higher than 35 it is recommended to measure other sites (Tibia), Or using different probes (CS for proximal Phalanx III or CR for the Metatarsal V)

2.6. ADVERSE EVENTS

Sunlight MiniOmni is based on the well-established Sunlight Omnipath technology and the predicated Sunlight Omnisense device, already CE marked. Sunlight MiniOmni is using the same probes, acoustic algorithms and reference databases as implemented in the Sunlight Omnisense. Due to the above, no clinical studies were conducted specially for the MiniOmni. No adverse events were reported in the course of the clinical studies performed for the Sunlight Omnisense, in which a total of approximately 4000

subjects underwent Omnisense measurement. There are no known potential adverse effects of Sunlight MiniOmni on health.

3. SYSTEM COMPONENTS

3.1. IDENTIFYING SYSTEM COMPONENTS

The figures which follow illustrate the components of your MiniOmni System. Review this material briefly to familiarize yourself with important controls, ports and connectors, as well the accessories used in patient measurement.



Caution: Immediately upon receipt of MiniOmni check the external box for damages. If it was damaged, please note this condition on the bill of lading and call a BeamMed representative.









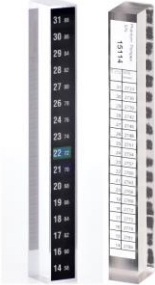





Note: Save the packing material in which MiniOmni was shipped, in case it must be moved to another location, or returned for service.

Please verify that the unit you received has connectors and features as described in [Section 3.1.1](#).

3.1.1. STANDARD COMPONENTS






The MiniOmni System includes the following standard components:

Standard Component		Notes
Windows PC (not included with System)		MiniOmni is designed to work with your existing PC. The specifications for the Windows PC are provided in Section 22. PC Specifications .
Stationary chair (not included with System)		All SOS measurements are conducted with the patient seated. The chair should be sturdy, comfortable and stationary.
Desk or table (not included with System)		Provide stable support for the arm during measurement and scanning.
MiniOmni Main Unit		Compact main unit which is the core of the MiniOmni system
CM ultrasound probe		Used for bone strength assessment at the radius and tibia Tibia requires Multi Site license

Standard Component		Notes
Radius/Tibia measurement gauge		Used to locate the scan site for the Radius or Tibia
Skin marker		Mark the scan location.
Ultrasonic gel		Provide acoustic contact between the probe and the site being measured.
System Quality Verification Phantom		The SQV Phantom is used to take SOS measurements during the System Quality Verification process.
Hand Rest		The hand rest supports the lateral edge of the outstretched palm when scanning the Radius.
Power supply and cable		MiniOmni power unit supplied with dedicated power cable (100-240 volt)
User Guide		Printed guide for system operation
USB connection cable		Dedicated USB cable for MiniOmni
Software Installation CD		Enables installation of the MiniOmni software

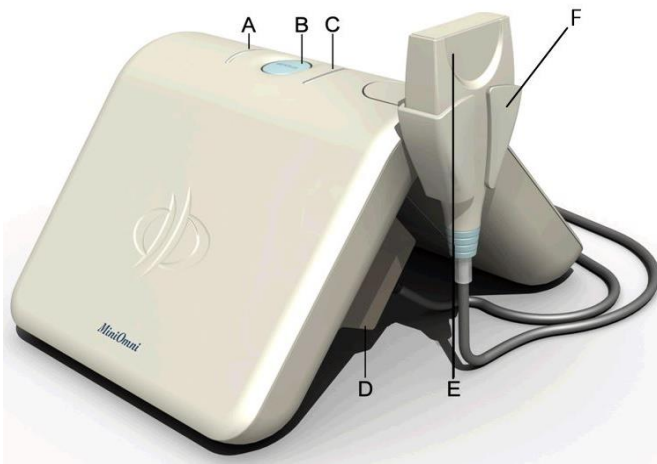
3.1.2. OPTIONAL ACCESSORIES

In addition, The MiniOmni System includes the following optional accessories:

Optional Accessory		Notes
CS ultrasound probe		Used for bone strength assessment at the phalanx . Requires Multi Site license
CR ultrasound probe		Used for bone strength assessment at the metatarsal . Requires Multi Site license
Proximal Phalanx and Metatarsal measurement gauge (L gauge)		Used to measure the limb in order to locate the scan site at the Proximal Phalanx and the Metatarsal
Foot Pedal		The foot pedal lets you begin hands-free measurement. It is attached to host PC USB port.
Carrying case		Mobile case for safe and comfortable carrying of the device

4. DETAILED DESCRIPTION OF COMPONENTS

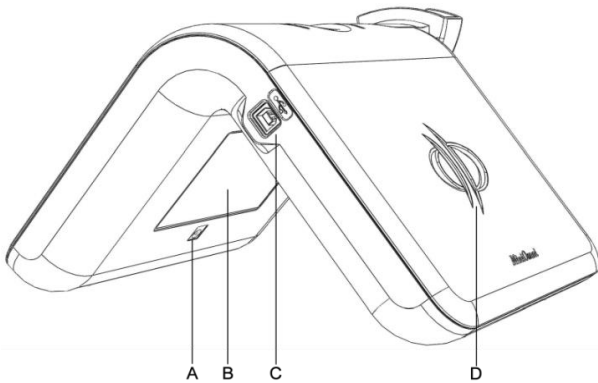
4.1. MINIOMNI MAIN UNIT



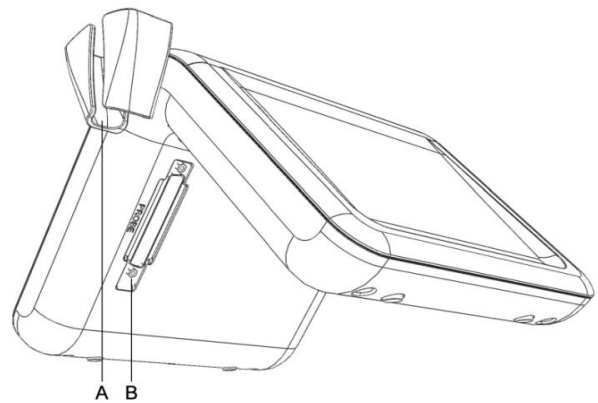
- MiniOmni Indicators and Ports:**
- A. Connection Indicator LED
 - B. Measurement button
 - C. Measurement Indicator LED
 - D. Probe connector
 - E. MiniOmni probe
 - F. Probe holder

MiniOmni, front view

All of the cables and connectors are connected to the sockets and ports located on the inner side of the device, except for the USB socket which is located on the side of the unit, opposite the side of the probe holder (see illustrations below).



- MiniOmni – side view :**
- A. Power Inlet (use only with a MiniOmni approved power supply)
 - B. MiniOmni label
 - C. USB socket
 - D. Logo



- MiniOmni – inner view:**
- A. Probe holder
 - B. Probe slot

5. SOFTWARE SETUP

5.1. PRIOR TO INSTALLATION

Ensure that the PC / laptop you intend to use with MiniOmni meets the minimal technical requirements specified in [Section 22. PC Specifications](#).



Note: We recommend installing the MiniOmni software on a new or recently formatted PC / laptop to ensure smooth operation.

Ensure that your user permission includes “administrator permissions”.

Ensure that the UAC (User Account Control) settings are set to the lowest level. The procedure is as follows:

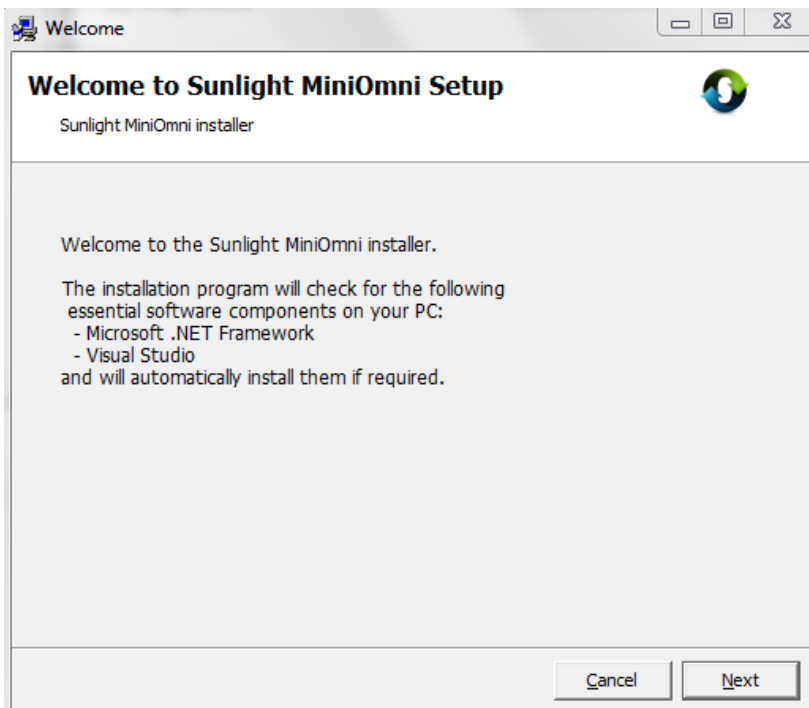
- Click the **Start** button on the bottom left of the Windows Screen.
- Type **UAC** into the start menu of Control Panel Search box.
- Slide the bar to ‘never notify’ - this will disable the UAC.
- Click **OK** and restart the computer.

Follow this guide from [Step 5.2 Setup Disk](#) to install the MiniOmni software.

5.2. SETUP DISK

Insert the Setup Disk supplied with your MiniOmni Package into the CD/DVD Tray on your PC or locate on your computer the latest MiniOmni installation file received from your dealer or downloaded from BeamMed’s web site.

Run the file "Sunlight MiniOmni" and follow the on-screen instructions, as detailed below.

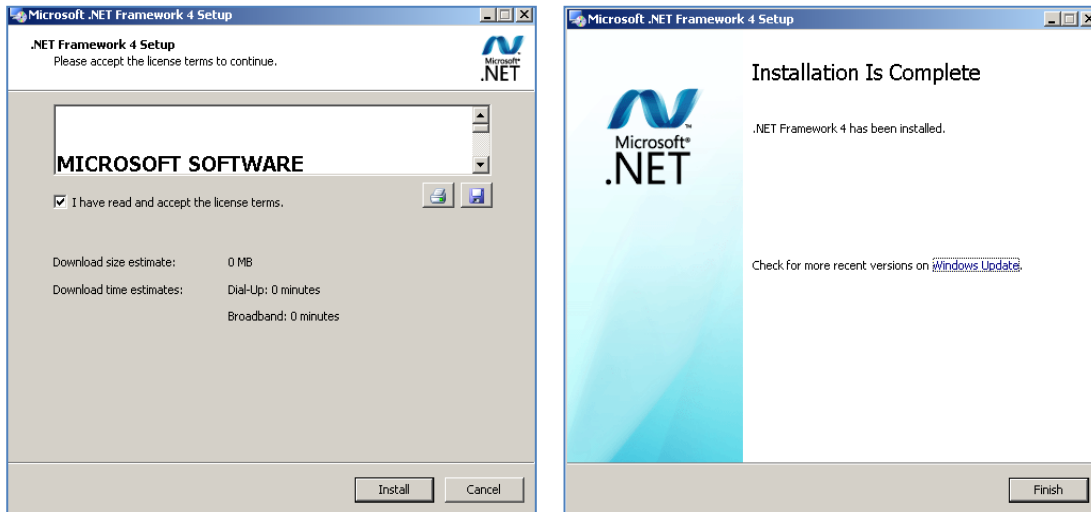


5.3. MICROSOFT .NET FRAMEWORK



Note: If your PC requires “.NET framework” environment, the setup will automatically detect it and start the installation. If your PC already has the proper “.NET” version, this step will be skipped automatically.

Follow the on-screen instructions to install the Microsoft .NET Framework.



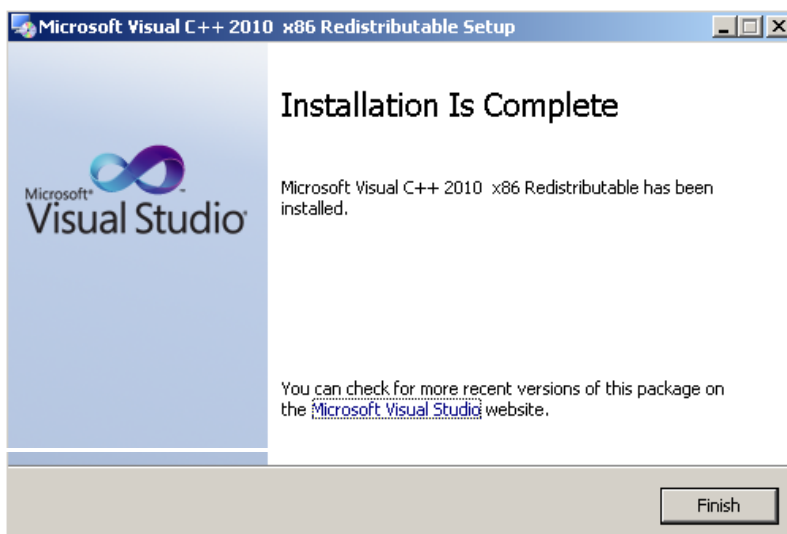
Example screens for installation of the Microsoft .NET Framework

5.3.1. MICROSOFT VISUAL STUDIO



Note: If your PC requires Microsoft Visual Studio environment, the setup will automatically detect it and start the installation. If your PC already has Visual Studio installed, this step will

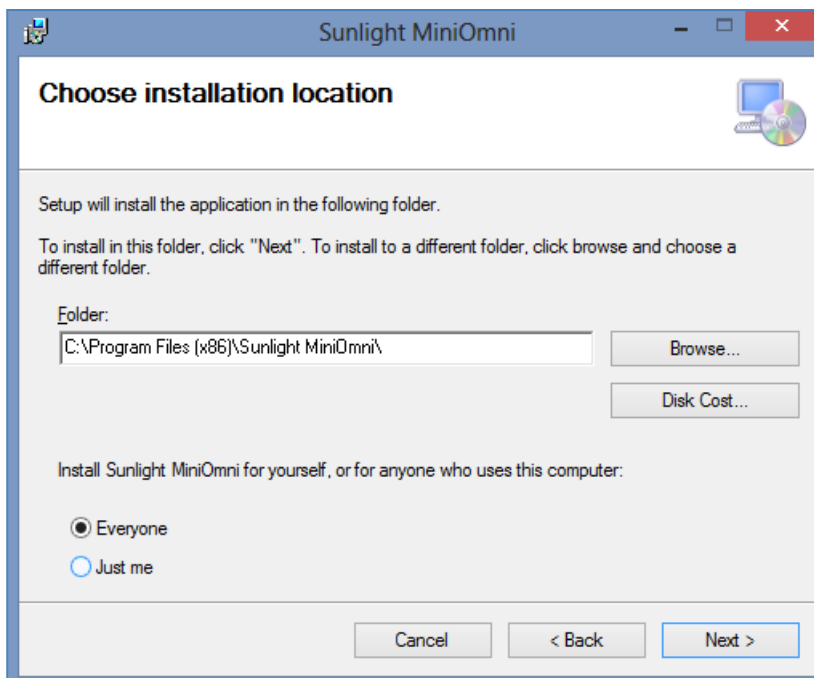
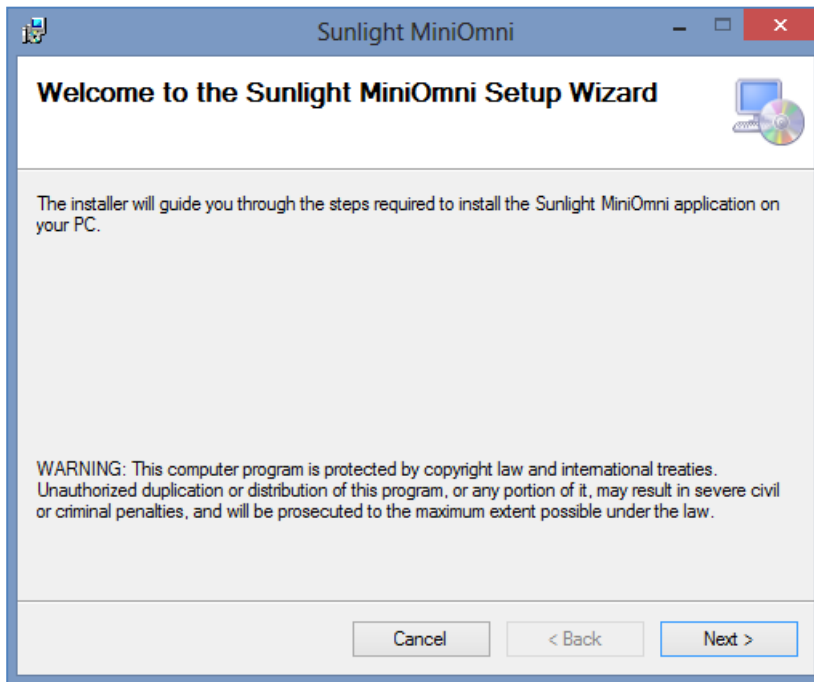
Follow the on-screen instructions for the Microsoft Visual Studio installation. When setup for Microsoft Visual Studio is complete, the following screen will display:



Example screen for installation of Microsoft Visual Studio

5.4. MINIOMNI SOFTWARE INSTALLATION

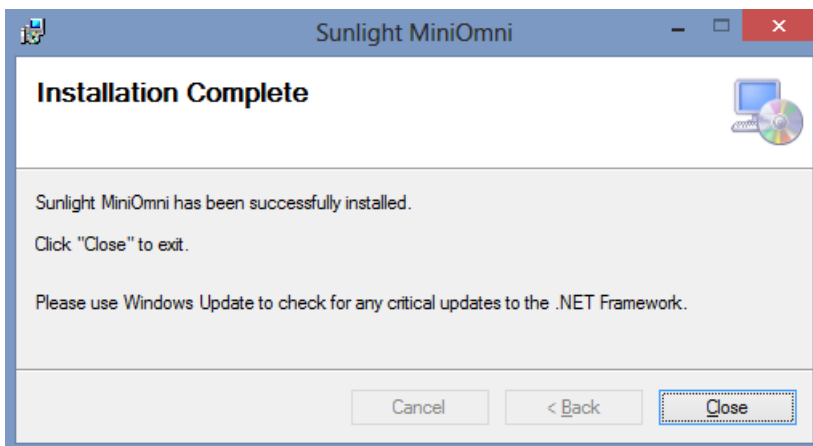
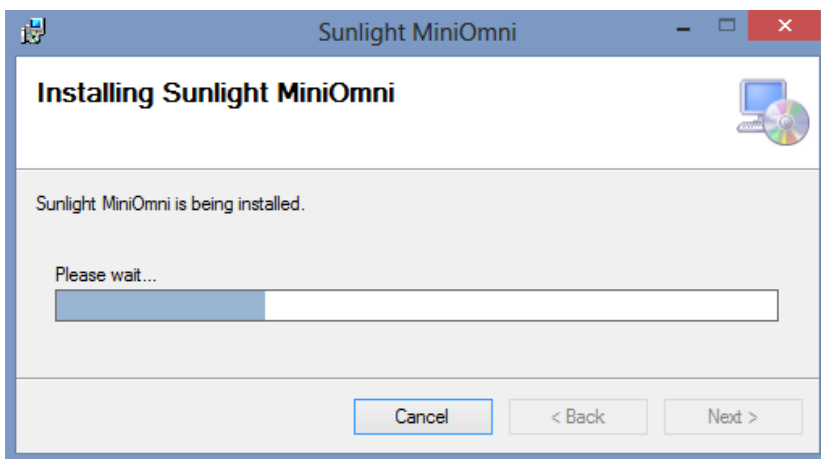
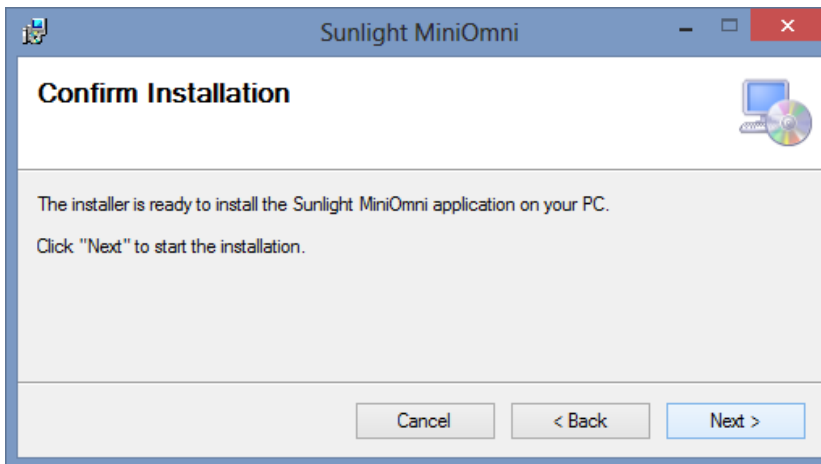
These screens will automatically display. Follow the on-screen instructions for the MiniOmni installation.



Follow on-screen instructions



Note: You may click on **Disk Cost...** to check whether there is sufficient disk space on the destination drive.



Follow the on-screen instructions

5.5. RUN MINIOMNI

To start the application and ensure that the installation procedure was completed successfully, click on the MiniOmni Icon created on your desktop or browse to Start menu>Programs>Sunlight MiniOmni>MiniOmni.Exe.



The user Login screen will display, as discussed in [Section 7.1. Welcome and Login.](#)

6. HARDWARE SETUP

When attaching cables and connectors, insert each component connector securely into the corresponding socket and tighten the screws if required.

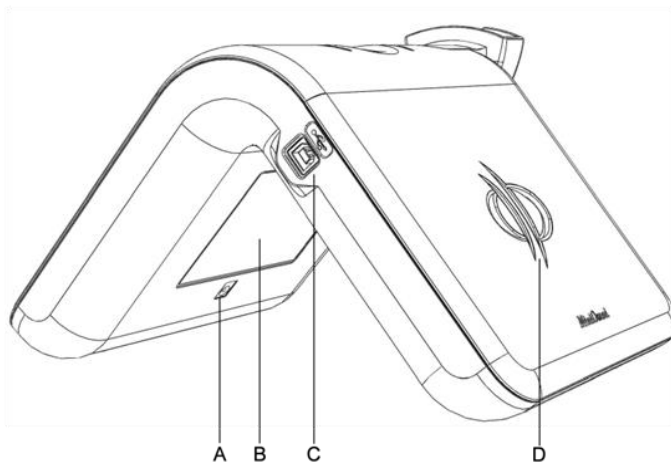
6.1. STEP 1 – CONNECTOR CABLES, POWER SUPPLY AND FOOT PEDAL (OPTIONAL)

6.1.1. MINIOMNI USB DATA CONNECTOR



USB connection cable

Insert one end of the USB Data cable connector into your PC USB socket and the other end into the MiniOmni USB Socket. The MiniOmni USB socket is shown as item C in the illustration below.



MiniOmni – USB view:

- A. Power Inlet (use only with a MiniOmni approved power supply)
- B. MiniOmni label
- C. USB socket
- D. Logo

6.1.2. POWER SUPPLY

Note carefully the power rating of your MiniOmni unit (230 or 110 V switching power adapter) and ensure that you are using an electrical outlet with the correct rating.

The Power Supply black cord is a standard 3-prong that you plug into a standard wall outlet.



Warning: Use MiniOmni system only with the dedicated power supply.

Attach the MiniOmni unit power cable (see below) to the MiniOmni power inlet. The MiniOmni power inlet is shown as item A in the illustration - [MiniOmni – USB View diagram](#). Plug the other end of the cable into a standard electrical outlet.



Power supply

6.1.3. FOOT PEDAL

If ordered, connect the foot pedal to the PC by inserting its USB connector into a USB socket in your PC (no installation required).



6.2. STEP 2 – CONNECTING THE PROBE

6.2.1. CONNECTING THE PROBE



Connector as seen from the probe side

Pins on a probe connector



Connector as seen from the MiniOmni side

Pins on Unit Probe socket

Probes should be attached to the MiniOmni unit during initial setup, and should remain connected during use. After the initial setup, probes are connected/disconnected only when replacing probes or transporting the MiniOmni.

Note carefully the arrangement of the pins on the probe connector. Ensure that you insert the connector into a probe socket so that corresponding pins are aligned. Press the connector firmly into its socket. Tighten the locking screws, as this ensures proper electrical ground.

6.3. STEP 3 – VERIFY APPLICATION – DEVICE COMMUNICATION

When MiniOmni is connected to the PC via the USB port (USB) and to the power supply, the power indication LED is turned on and the *Connection* icon is displayed (on the lower left side of the screen):



If the power supply or the USB cables are disconnected, the *No Connection* icon is displayed:



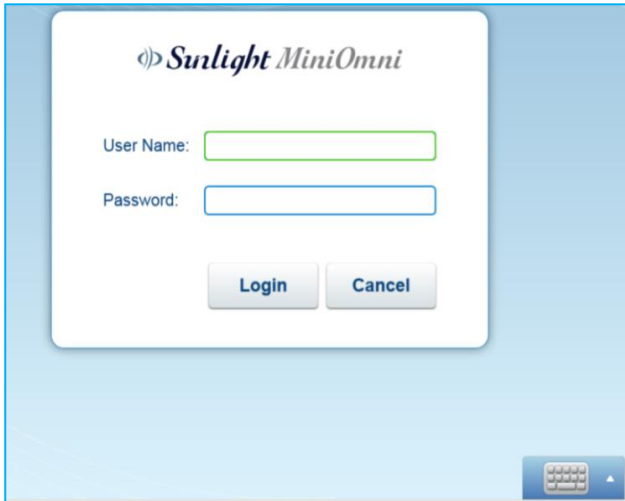
7. STARTING THE SYSTEM

Make sure that the MiniOmni Main unit is connected to the MiniOmni Power Supply and that the USB cable is connected on one side to the MiniOmni Main Unit and other side to the operating PC, as detailed in [Section 6. Hardware Setup](#).

Double click on the MiniOmni Desktop Icon to start the application.

7.1. WELCOME AND LOGIN

The user Login screen appears as follows:

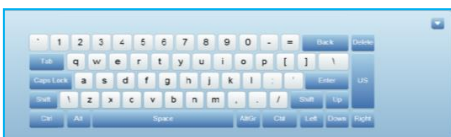


Note: For first time use, the default username is **sunlight (lower case)**. Default password is **omni** (lower case).



Note: If the application asks for a registration code, enter the code provided with the device.

Click on the **Keyboard** button to access the onscreen keyboard, or use your regular mouse and keyboard. Enter your user name and password, and click **Login** to continue.



7.1.1. A NOTE ON USER NAMES IN MINIOMNI

MiniOmni supports two types of users:

- System Administrator user – Has access to all system functions. The default name for the System Administrator is **sunlight** and the initial password is **omni**.
- Physician / Operator user – Has ability to limit the access to patients' information to himself only.



Caution: For a higher level of security, change the administrator's password after the first login.

For detailed instructions on how to view and change the list of users, see [Section 18.10. Options – Administration – Users](#)

7.2. FIRST-TIME PC REGISTRATION

The first time you use the MiniOmni, you will be asked whether you wish to register the device to the PC. The following dialog box will appear:



Press **Yes** to register the PC and approve the software license. For more information, see [Section 18.11. Options – Administration – License](#).

If you have not performed a System Quality Verification (SQV) test today, you will be automatically directed to perform an SQV test as shown in [Section 7.3. Automatic SQV Option on First Login Each Day](#). Otherwise go to [Section 9. Choosing the Age Group and Patient](#).

7.3. AUTOMATIC SQV OPTION ON FIRST LOGIN EACH DAY

The first login to MiniOmni each day, a message displays, with the option of performing an SQV (System Quality Verification) procedure:



You may press **OK** to perform an SQV procedure, [Section 8. System Quality Verification \(SQV\)](#), or **Ignore** to skip SQV.

7.4. OVERVIEW OF THE MINIOMNI SCREEN

Before looking at each MiniOmni screen in detail, please note the general layout of the screens:

Navigation button to move to the previous screen

Navigation button to move to the next screen

USB Indicates USB connected

USB Connected

USB not Connected

Probe Indicates whether the ultrasound probe is connected and the SQV status:

Probe is connected and SQV verified

Probe is connected and SQV required

Print Print Results

Delete Delete the data being viewed

Keyboard Show/Hide the onscreen keyboard

The screenshot shows a patient form for 'Michel Dan (223454)'. The form is divided into sections: General (Patient ID, Last Name, Middle Name, First Name, Birth date, Ethnicity, Gender, Measured Limb, Street & number, City, Country / State, Zip Code, Phone, Email, Mobile, Physician, Referring Physician, Allow only physician to view), Clinical Info, and Results. At the bottom of the form are buttons for 'Print' and 'Delete', and a keyboard icon. The status bar at the bottom left shows icons for USB and probe status.

The screenshot shows a patient data entry form for 'Michal Dan (223454)'. The form includes fields for Patient ID, Last Name, Middle Name, First Name, Birth date, Ethnicity, Measured Limb, Gender, Street & number, City, Country / State, Zip Code, Phone, Email, Mobile, Physician, and Referring Physician. There are also checkboxes for 'Allow only physician to view' and a 'Remarks' text area. At the bottom of the form are 'Print' and 'Delete' buttons. A 'Keyboard' button is located in the bottom right corner of the screen.

Navigation button to move to the previous screen (points to the left arrow button)

Navigation button to move to the next screen (points to the right arrow button)

USB
Indicates USB connected

USB Connected

USB not Connected

Print
Print Results

Delete
Delete the data being viewed

Keyboard
Show/Hide the onscreen keyboard

Probe
Indicates whether the ultrasound probe is connected and the SQV status:

Probe is connected and SQV verified

Probe is connected and SQV required

Layout of the MiniOmni screen

8. SYSTEM QUALITY VERIFICATION (SQV)

System Quality Verification (SQV) is performed once per day, before beginning the first Speed of Sound (SOS) measurement.

if you have already performed the SQV procedure today, you can proceed directly to the procedure for specifying the age group and patient, in [SECTION 9. CHOOSING THE AGE GROUP AND PATIENT](#).



Note: The phantom and the probe must be at room temperature when conducting System Quality Verification.



Caution: Do not expose the phantom to direct sunlight. The sun ultraviolet rays can permanently alter the characteristics of the phantom material.



Caution: Do not immerse the phantom in liquids. To clean the phantom, use a dry, soft tissue or pre-moistened cloth, followed by dry wipes to remove moisture.

8.1. WHAT IS SQV?

SQV checks if the system and the probes are working properly by examining the signals returned when the phantom, a Perspex (Lucite acrylic) block, is used as a substitute for bone.



Phantom limb used during SQV

SQV is performed separately for each probe.



Note: If you proceed with SOS measurements without SQV, the system will display a warning that no verification has been conducted:



If you press **Verify**, the SQV screen will display. If you press **Measure**, the normal measurement process will begin.

The MiniOmni screen will also display an exclamation mark:

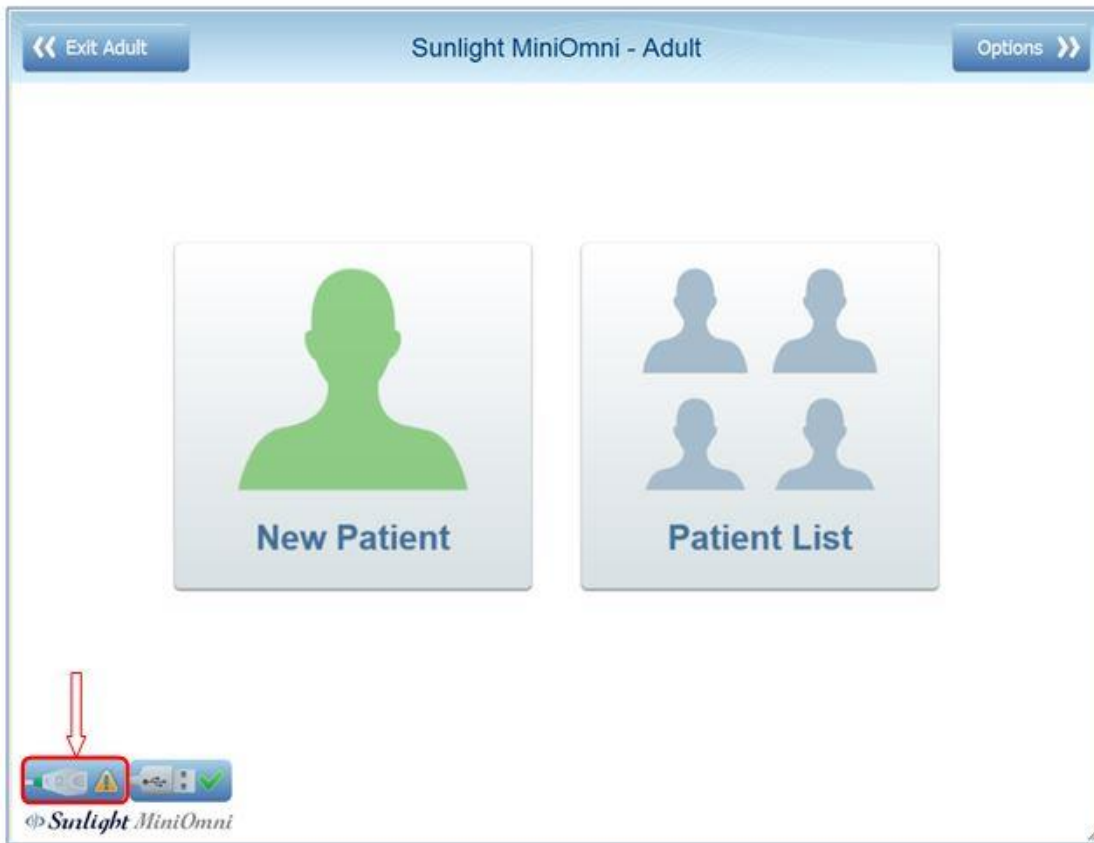


when SQV has not been performed.

8.2. PERFORMING SYSTEM QUALITY VERIFICATION

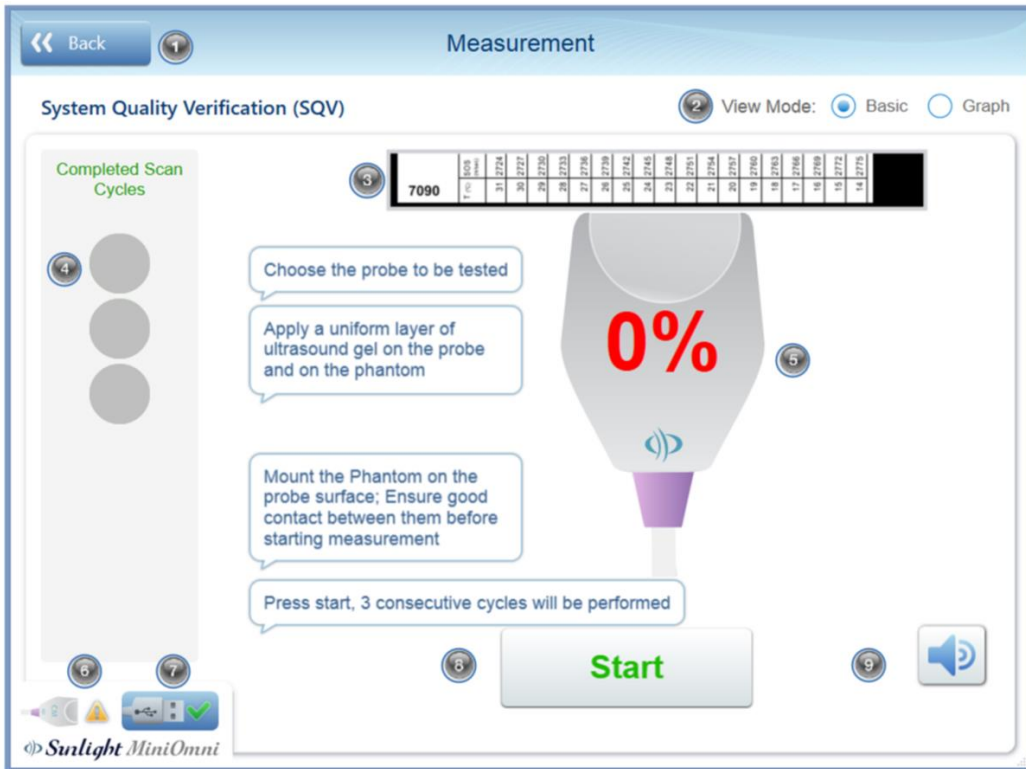
8.2.1. FINDING THE SQV SCREEN

The SQV screen can be accessed by clicking on the probe icon:




8.2.2. USING THE SQV SCREEN

After clicking **SQV**, the **Quality Verification** screen appears. For your reference, the Measurement screen is shown below. Details for performing SQV are provided in the next section.



Key to Screen			
1	Show previous screen	6	Status indicator for probe connection
2	View progress of SQV as progress bar or graph	7	Status of USB connectivity
3	Representation of Phantom	8	Start SQV
4	Number of completed scan cycles, this indication is not applicable when using the 1 cycle configuration	9	Audible alarm on/off
5	Progress bar		

 **Note:** A graph of the signal may be displayed instead of the probe image shown here. To activate the Graph display, click the Graph option in the View Mode selection:





Note: You may press on Item 8 (status indicator) at any time to review the SQV status:



Press – Cancel to return to the main screen

– **Verify** to perform a new SQV

8.2.3. PREPARE PROBE

Locate the probe and spread an even layer of ultrasound gel on its surface.

8.2.4. POSITION THE PHANTOM AND PROBE

Hold the probe in a vertical position, with the active surface facing upwards, and place the phantom directly on top of it, as seen in the figure below.



Positioning the phantom on the probe for SQV

The phantom rests on the probe; the probe is held steady, without moving, throughout the SOS measurement.

8.2.5. CHECK FOR ACOUSTIC COUPLING

To ensure effective coupling between the probe and phantom, it is important to remove any air bubbles which may be trapped between them. This is straightforward; the phantom is transparent and you can easily check for such bubbles by visual inspection. The figure below illustrates the orientation of the probe-phantom combination for the visual inspection.



Caution: Inspect the contact between probe and phantom visually, to ensure that no air bubble: are trapped there.

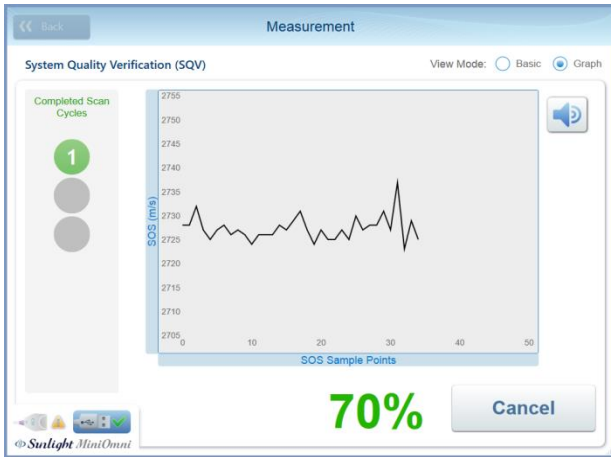
To remove air bubbles, simply press the phantom against the probe and move the phantom around in a short circular motion, without lifting it from the probe.

8.2.6. EXECUTE THE MEASUREMENT

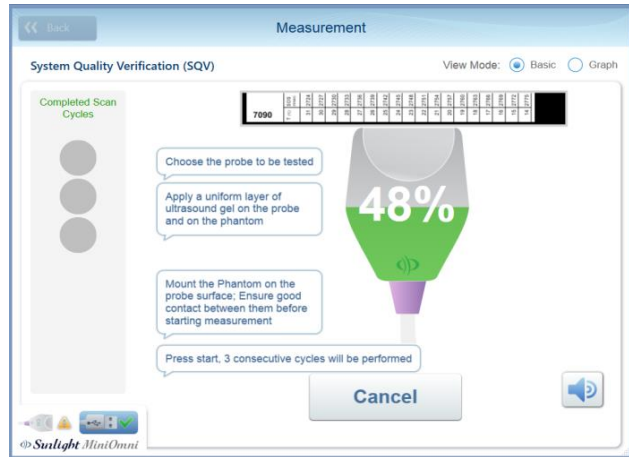
Press **Start** on the screen, or the **Measure** button on the MiniOmni device, to begin measuring SOS. An audible tone is heard during the measurement, indicating that a proper acoustic signal is being detected.

Hold the probe vertically, with the phantom set on top of it; do not touch the phantom throughout the measurement. Avoid any movement.

During measurement, an audible tone indicates correct acoustic contact. If no tone is heard, the *Measurement Sound* option has been set off or the PC speakers are off. To turn it on, Click on the sound On/Off symbol to the right of the graph/probe image.



Basic measurement mode (recommended)



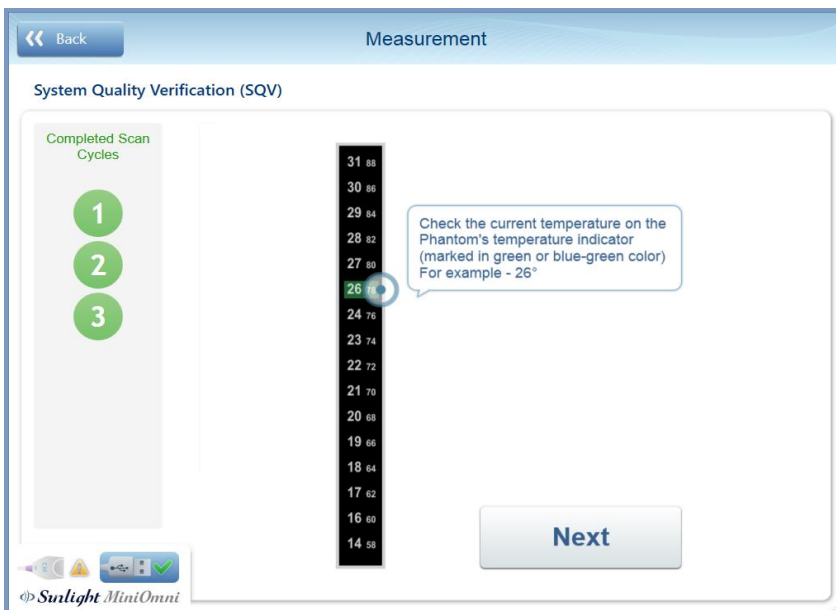
Graph measurement mode



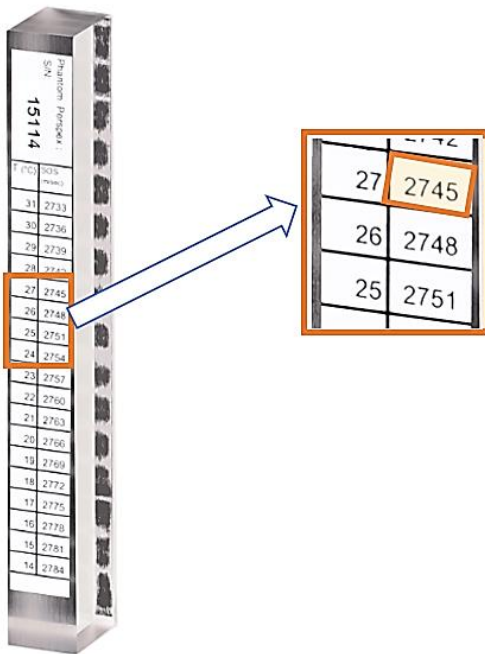
Caution: If the results of measurement cycles are not being accepted by MiniOmni, check that no air bubbles are being trapped between the probe and the phantom, and that sufficient ultrasound gel has been applied. If results are still not being accepted, your probe may be defective. Contact Your Local Dealer.

8.2.7. DETERMINE THE EXPECTED SOS VALUE FOR THE PHANTOM SQV TEST

In order to know whether the SQV was successful, MiniOmni must know the **expected SOS value**. This value depends on the physical properties of the Phantom, and the temperature. A list of temperatures and corresponding expected SOS values is printed on the side of each Phantom. An instructional screen displays:



This screen is asking you to look at the Phantom and note the expected SOS value for the current temperature. For example, the SOS value in the example phantom below for a temperature of **27°C** is **2745**.



Click on **Results** >> to see the next screen, where in this example you will type the SOS value **2745**.

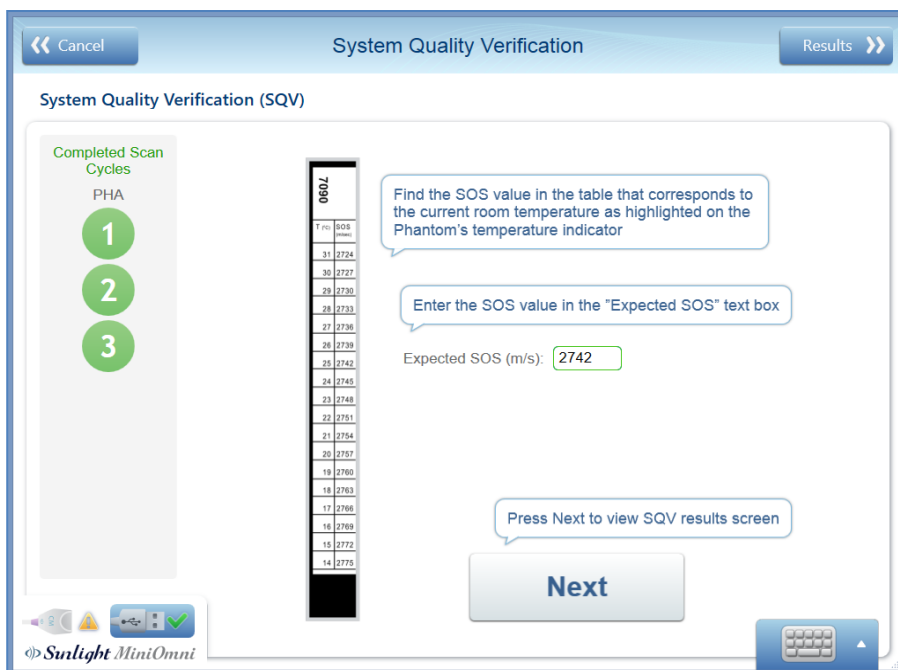


Caution: SQV must be conducted with the phantom temperature between 15 and 30 degrees Centigrade (59-86 degrees Fahrenheit).

The phantom material conducts heat slowly; therefore, it may take some time to stabilize to room temperature. Wait until a reading can be obtained before continuing with the SQV procedure.

8.2.8. ENTER THE EXPECTED SOS VALUE

Here you will enter the SOS value indicated on the side of the Phantom.

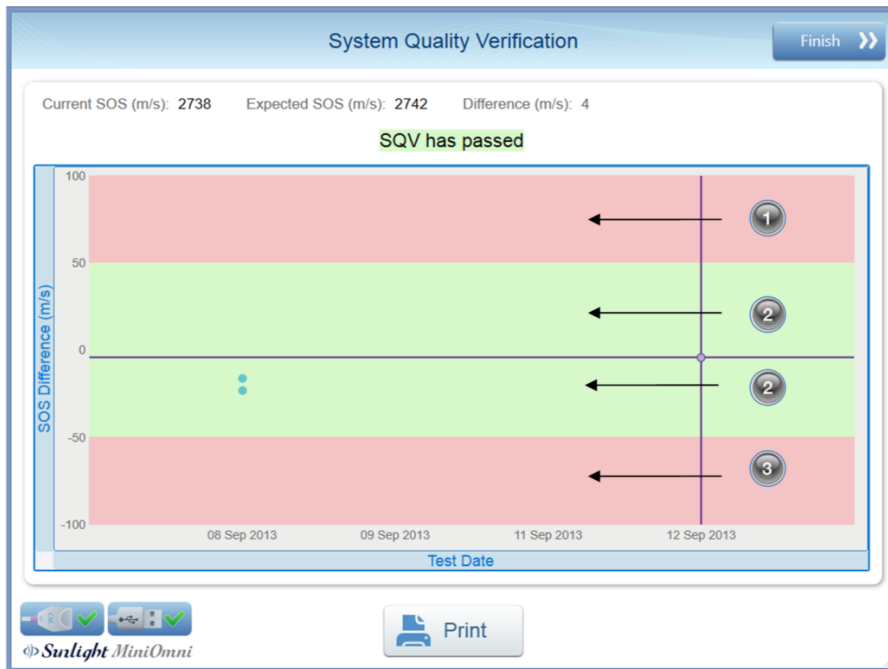


Entering the expected phantom SOS value

Type in the SOS value from the previous screen (in this example, **2742**) and press **Next**.

8.2.9. CHECK THE RESULT

The result is displayed graphically along with results from recent System Quality Verifications, as shown below.



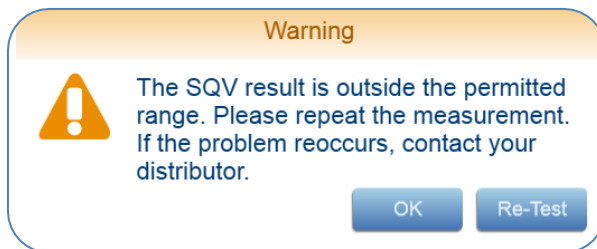
SQV result screen

An SQV result in range **1** or **3** is not acceptable. An SQV result in range **2** is acceptable.

Press **FINISH >>** to close the screen and return to the main menu.



Note: if SQV failed, the following message will appear:



Note: if SQV failed, the application will not allow performing patient measurement with this probe.

8.2.10. PRINT RESULT

If desired, the SQV result can be printed at this point, by pressing the Print button below the result graph:



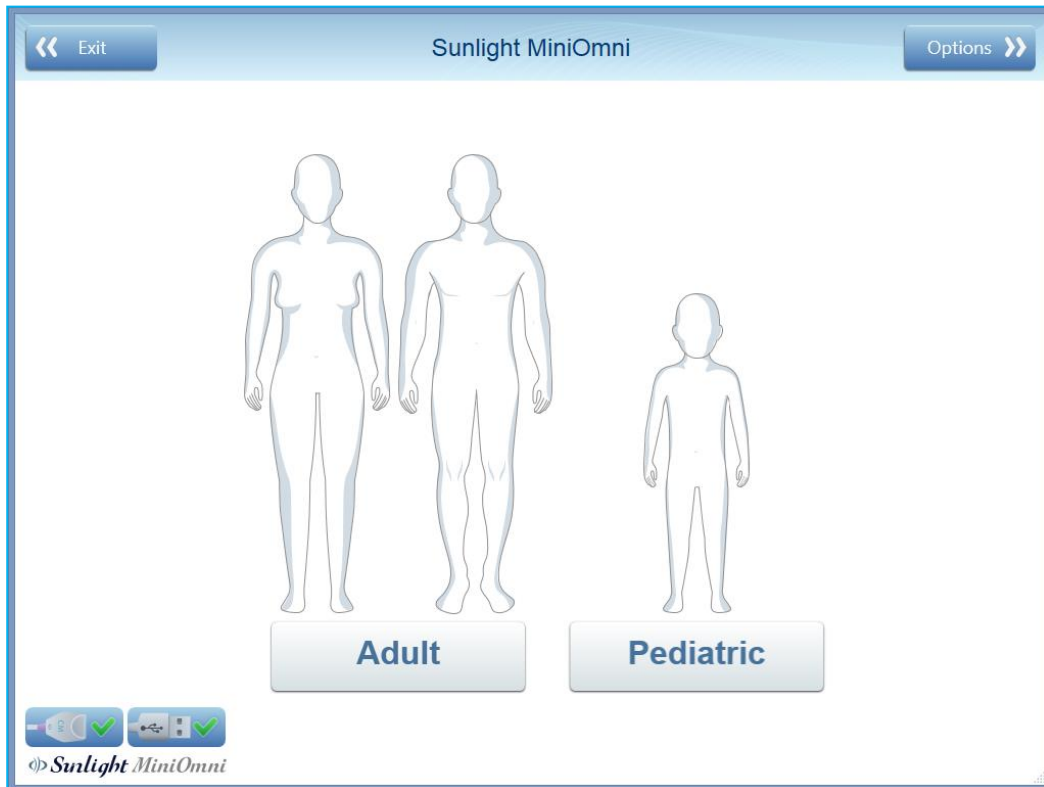
Click on **Finish >>** to return to the main menu screen.

9. CHOOSING THE AGE GROUP AND PATIENT

Before you can begin a measurement, MiniOmni requests the age category of the patient (adult or pediatric), and identification of the actual patient on whom you will perform the measurement.

9.1. CHOOSE AGE GROUP

This screen allows you to specify whether the patient is an adult (age 20 years and above) or pediatric.



Click on **Adult** or **Pediatric**.

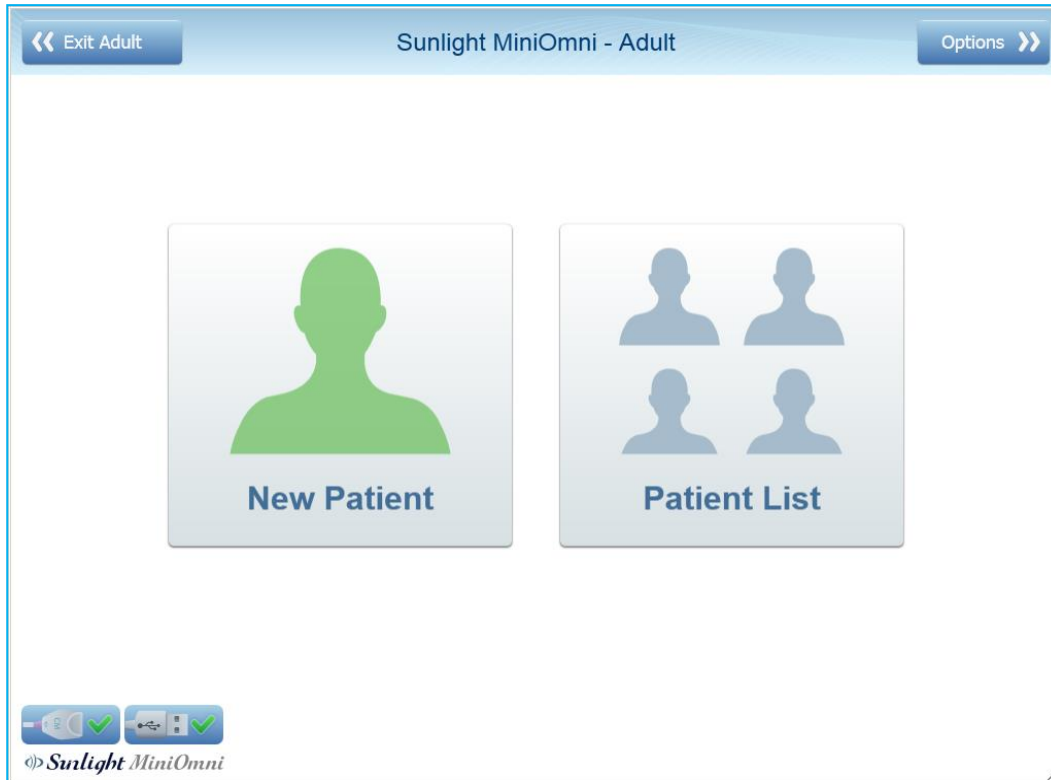


Note: The **Adult** or **Pediatric** buttons will be enabled (available for use), depending on which of these components are installed in your MiniOmni system. One or both components may be installed.



Note: Most the screens used in MiniOmni are the same for both the Adult and the Pediatric Applications. See [Section 16. Pediatric Application of MiniOmni](#) for details of those screens that are different for the Pediatric Application.

9.2. PATIENT SELECTION AND OPTIONS



This screen presents three choices: **Options**, **New Patient** or **Patient List**.

IF YOU HAVE NOT YET PERFORMED THE SYSTEM QUALITY VERIFICATION (SQV) TEST TODAY, refer to [Section 8. System Quality Verification \(SQV\)](#) for instructions on performing this test. SQV must be performed at least once each day.

IF YOU ARE WORKING WITH A PATIENT WHO IS NOT YET ENTERED INTO THE MINIOMNI SYSTEM, Click **New Patient**. The procedure for defining a new patient is described in [Section 10. Patient Maintenance](#).

IF YOU ARE WORKING WITH A PATIENT WHO IS ALREADY DEFINED IN THE MINIOMNI SYSTEM, click **Patient List** to select the patient from a list of patients in the system. The Patient List screen is described in [Section 10.3. Choosing a patient from the Existing Patient List](#).

IF YOU'RE NOT SURE IF THE PATIENT IS NEW, click **Patient List** to search for the patient. If you can't find the patient in the Patient List screen, you will still have the option of defining a new patient. A discussion of the **Options >>** screen is given in [Section 18. Options Screen](#).

10. PATIENT MAINTENANCE

This section describes the procedures for defining a new patient, accessing the list of existing patients, and deleting a patient.

10.1. NEW PATIENT – GENERAL

Key to Screen			
<< Back	Show previous screen	Measure >>	Starts the Radius site measurement; must be clicked after patient positioning.
Patient ID	Required. Can be automatically filled. See Section 15.5. Options – Settings – Setup.	Multi-Site	Allow selecting Tibia/Phalanx/Metatarsal sites (requires additional license)
Family Name	Required. Can be automatically filled. See Section 15.5. Options – Settings – Setup.	City/Street & Number	Patient address and contact details
Middle Name	Optional	Country/ State	
First Name	Required. Can be automatically filled. See Section 15.5. Options – Settings – Setup.	Zip Code	
Birth Date	Required. Ensure the correct age is entered.	Phone/ Mobile	
Ethnicity	Required. Can be automatically filled. See Section 15.5. Options – Settings – Setup.	Email	
Measured Limb	Optional – allow to repeat the same measurement next patient visit.	Physician	Select physician from the users list. The selected name will appear on the measurement report.
Gender	Required	Referring Physician	Type the referring physician. This information will appear on the measurement report.

Remarks	Any remark written here will be added to measurement report and will be saved.	Allow only physician to view	If clicked, only a physician user associated with this patient can see the patient's file.
----------------	--	-------------------------------------	--

Click on **Measure Radius\Multi Site >>** to begin the measurement, or click on the **Clinical Info** tab to add more information.

10.2. NEW PATIENT CLINICAL INFO

Key to Screen			
<< Back	Show previous screen	Measure Radius\Multi Site >>	Perform measurement
Height	Patient height, appears on report	Vitamin D	Related Clinical information
Weight	Patient weight, appears on report	Calcium	
BMI	Automatically shown. If Height and Weight entered, appears on report	Low calcium intake	
Left Handed	Repeatability	Low physical activity or none	
Family osteoporosis	Related Clinical information	High caffeine consumption	
Minor trauma		High alcohol consumption	

Indication	Data entered will be saved but will not show on the report	Current cigarette smoking	
Medications and diseases	Data entered will be saved but will not show on the report	Hip/Spine/Wrist/Other	

Note – to save new patients data, the operator should either proceed to the measure screen or go back and confirm the “would you like to save changes” message.

10.3. CHOOSING A PATIENT FROM THE EXISTING PATIENT LIST

The screenshot shows the 'Patient List' interface. At the top, there are navigation buttons: '<< Exit Adult' on the left and 'New Patient >>' on the right. Below these is a search bar labeled 'Search:' and a 'Customize Table' link. A horizontal menu of letters (A-Z) and an 'All' button is visible. The main area contains a table of patient records:

ID	First Name	Family Name	Gender	Date of Birth
♀ 22585258	Mary	Smith	Female	18/10/1972
♀ 223454	Michel	Dan	Female	14/06/1966
♀ 665857	Patricia	Johnson	Female	25/08/1949
♂ 55874152	James	Williams	Male	22/10/1970
♀ 875545	Linda	Jones	Female	10/12/1954
♀ 5547223	Barbara	Brown	Female	22/10/1932
♂ 5233696	Richard	Davis	Male	30/01/1955
♀ 2287548	Elizabeth	Miller	Female	05/05/1965
♀ 698741223	Jennifer	Taylor	Female	08/11/1974
♀ 142536987	Ruth	Edwards	Female	10/10/1944

At the bottom of the screen, there are icons for a keyboard and a mouse, and the Sunlight MiniOmni logo.

If the patient has already been defined in the system, you may choose the patient from the Patient List screen, shown above.

Type the first few characters of the patient's name to search for the patient. Double click on the patient's name to select the patient and go to the Measurement Startup screen.

If you cannot find the patient in the Patient List, click on **New Patient >>**. This allows you to enter the patient's information. These screens are shown in [Section 10. Patient Maintenance](#).

10.4. DELETING A PATIENT

Click on the Delete button on the Patient Information Screen. The following confirmation window appears:

The screenshot shows the Sunlight MiniOmni Patient Information Screen for Ruth Edwards (142536987). The screen has a header with a 'Back' button, the patient name and ID, and a 'Measure' button. Below the header is a form with fields for Patient ID, Family Name, Middle Name, First Name, Birth Date, Ethnicity, Gender, and Address. A 'Warning' dialog box is overlaid on the form, asking 'Are you sure you want to remove the current patient?' with 'Yes' and 'No' buttons. The bottom of the screen features a 'Print' button, a 'Delete' button, and a keyboard icon. The Sunlight MiniOmni logo is visible in the bottom left corner.

Press **Yes** to confirm the deletion. Press **No** to keep the patient record.

To delete more than one patient, see [Section 18.7.1. Options – Administration – Delete Patients' Data.](#)

11. PERFORMING THE PATIENT MEASUREMENT



Caution: The System Quality Verification (SQV) procedure must be performed once per day, before measuring the SOS. For details, see [Section 8. System Quality Verification \(SQV\)](#).

11.1. LOCATING THE MEASUREMENT SITE FOR THE DISTAL 1/3 RADIUS

11.1.1. POSITION THE PATIENT AND THE LIMB

SOS measurement at the Distal 1/3 Radius is at the point midway between the elbow and the end of the middle finger. It is important to locate the site precisely.



Caution: Determining the exact location where the probe is to be applied is an important part of preparing for an SOS measurement. Measures of the speed of sound in bone depend strongly on the site being measured. To draw any statistically meaningful conclusions from an SOS result, the conditions of the measurement should be as close as possible to those used in building the baseline data. Therefore, the exact procedure given in this Guide must be followed for each site.



Note: Always measure the patient's non-dominant side. In case of a disorder or impairment in the non-dominant limb, such as edema, a mass, a non-detachable ring, or IV line, use the contra-lateral side instead.

Seat the patient in a chair, opposite the operator and close to a standard desk.

11.1.2. IDENTIFY THE REGION TO BE MEASURED

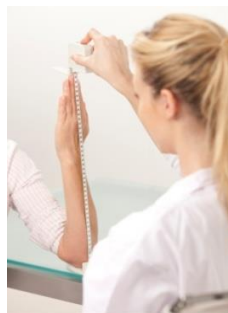


Note: The term “measurement” in this and the next step refers to the use of a gauge to find and mark the halfway point on the limb where an ultrasound scan will be applied. This is not to be confused with “SOS Measurement” which is the main function of MiniOmni.

Use the gauge supplied with the site kit to measure the Radius. The start and end points to be measured are not always the anatomical range of the bone. Measure from the gauge platform to the tip of the middle finger, as illustrated below:



Use of the gauge to measure the Radius.



Measure to the tip of the finger, not the tip of the nail.

Place the gauge on the desktop and set the patient's non-dominant elbow on a table with the forearm vertical and the palm open and extended vertically. All parts of the arm distal to the elbow should be aligned as straight as possible, but without noticeable muscular tension.

The examiner should verify that the arm is not slanted and that the platform is firmly seated on the desk surface. Ensure that the patient's fingers are not bent, particularly the third finger.

11.1.3. MARK THE EXACT HALF POINT

Note the measured length from the gauge platform to the tip of the middle finger. Do not include nail length in the measurement. Draw a line at exactly half the measured length with a skin marker. The line should be drawn on the radial surface perpendicular to the direction of the bone. Extend the line straight across the Radius to half the diameter of the arm.

11.1.3.1. MARKING THE RADIUS



Mark the exact half point of the measured length of the Radius.



Extend the mark straight across the Radius to half the diameter of the arm and apply a layer of US gel.

11.2. UNDERSTANDING THE MINIOMNI MEASUREMENT SCREEN

11.2.1. TERMS AND DEFINITIONS

A **scan** refers to the actual movement of the probe at the skeletal site. Scan movements are repeated continuously, typically 4-5 times, to complete a single measurement **cycle**.

A complete SOS site **measurement** consists of a minimum of three cycles, unless the MiniOmni 1 cycle configuration is used.

Measurement cycles are combined through a proprietary averaging formula into a single, final SOS value, called the measurement **result**.

11.3. MEASUREMENT SCREEN FORMATS



Note: If you are using the Pediatric Application, see information on the Pediatric Measurement Screen, in [Section 16.4. Measurement Screen – Pediatric](#).

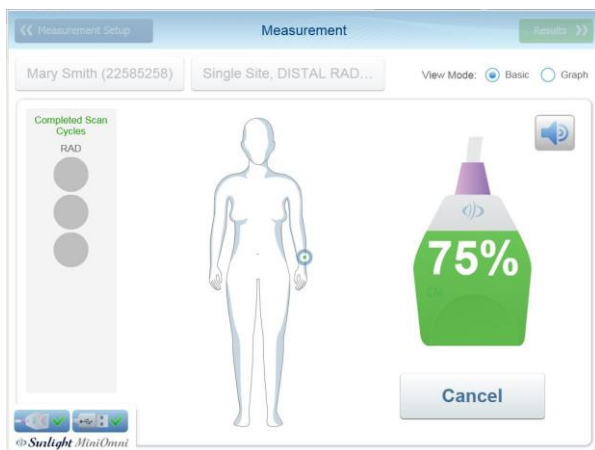
Depending on the definition of your system user ID and the patient type, you will be presented with one of the following two formats for the Measurement screen: Basic and Graph.



Basic (1 cycle configuration)



Graph (1 cycle configuration)



Basic (3 cycles configuration)



Graph (3 cycles configuration)

When using 3 cycles configuration -

- The current cycle number is displayed on the left side of the screen, out of a total of possible five.
- To ensure correct procedure, MiniOmni provides you with continuous feedback during the measurement. There are two feedback indicators on the screen:
 - Progress bar or graph bar advances normally with a good signal and is shown in green and white; a bad signal causes the color to change to red and stops the bar or graph from advancing.
 - Percentage numbers show as green and white when receiving a good signal, red if the signal is bad.
- In addition to the screen indicators, an audible tone is heard when both the acoustic contact and acoustic signal acquisition indicators are green.



Note: To insure accurate and reproducible results at the distal radius:

- The edge of the probe toward the palm side should follow the marked line on the skin at all times.
- Never hold the probe at an angle to the surface of the limb; maintain the surface of the probe perpendicular to the bone at all times.
- Do not hold the probe with only one hand.
- Do not use a circular motion. The probe movement should follow parallel to the marked line.
- The probe must be moved across the full range of 140 degrees, around the axis of the bone, while maintaining a position perpendicular to the bone. It is not sufficient to just tilt the probe around the marked line on the skin.
- Check to insure that a scan movement through 140 degrees takes about 4-5 seconds. Maintain the probe's surface in contact with the patient's skin throughout the scan. No part of the probe surface should be raised from the skin at any point during the scan.
- During the measurement cycle, concentrate on the site and the correct application of the probe. Avoid looking at the screen. Instead, use the audible signal to provide feedback and to guide you in correct execution of the scan.
- If the measurement is not going well, you can restart at any time during the cycle by pressing **Restart** (note that for the first cycle the button is labeled **Start**). The Foot Pedal is recommended to allow hands-free operation of MiniOmni during a measurement cycle. Pressing on the foot pedal is equivalent to clicking on the **Start/Restart** button. If MiniOmni is not receiving an appropriate signal — indicated by an intermittent sound or no sound — check that sufficient Ultrasound Gel is on the probe, as well as on the area being scanned.

11.3.1. MEASURING SOS AT THE RADIUS



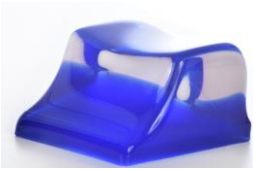
Note: If the probe is momentarily incorrectly positioned on the site, the audible tone will stop and the on-screen indicators may turn red. Some patients interpret this as a negative indication of bone status and may become alarmed. Explain to the patient before beginning the scan that these indicators are solely to guide the operator in appropriate positioning of the probe and have no bearing on bone status.

11.3.2. COMPLETING THE MEASUREMENT

Step 1. Disinfect the probe

Probes should be disinfected before each patient use. Disinfection must be done with pre-moistened towelettes/Alcohol wipes, not by immersion of any kind.

Step 2. Position the arm



Hand rest

To conduct the measurement, rest the patient's forearm on the desktop — the arm relaxed and the palm extended but still relaxed, and perpendicular to the desk surface when the palmar side is opposite the operator. Support the lateral edge of the palm with the hand rest supplied with MiniOmni.

As a precautionary measure, exam paper should be placed under the patient's hand, covering the table and the hand rest, to provide a physical barrier against possible soiling or contamination. Exam paper should be discarded after every single patient measurement. Do not place the palmar or dorsal surfaces of the hand on the rest; only the lateral surface is supported.



The hand rest is shown being used to position the patient.

Step 3. Apply Ultrasound Gel

Apply a thin, uniform layer of Ultrasound Gel to the CM probe and on the area to be scanned. The scan area is a rectangular region which has the skin mark as its distal side and width equal to the width of the probe.



Applying Ultrasound Gel

Cover the region to be scanned. This region extends the length of the mark and toward the elbow for a distance equal to the width of the probe.

Step 4. Position the probe

(See picture [Applying Ultrasound Gel](#)). Position the probe from the skin mark proximally and toward the elbow, parallel to the bone axis. The side of the probe that is marked with a small "T" (at the bottom) should be near the skin mark.

Hold the probe with both hands. Fingers 1-3 of both hands grasp the probe near the base (the surface applied to the scan area) while fingers 4-5 palpate the limb during the scan and aid in guiding the movement of the probe correctly. Press gently when applying the probe to the scan area.

Step 5. Execute the measurement cycle

Press the measure Button/foot-pedal to begin the measurement. Pressing the foot-pedal is equivalent to clicking on the *Start* button but allows you to concentrate on the site without requiring other hand actions. When the probe is in proper contact with the area to be scanned, an audible signal is heard from MiniOmni.

Move the probe about 70 degrees first to the lateral side, and then the same amount to the medial side, so that the probe executes an arc of about 140 degrees. One full probe movement, i.e. a distance of 140 degrees in one direction, should take 4-5 seconds.



Scanning the Radius

Scan begins with probe vertical to the positioned arm. Scan by moving first to the lateral direction, about 70 degrees. Continue the scan by returning the probe to the starting point.

Then scan in the opposite (medial) direction, about 70 degrees, and finally return again to start point. Repeat until measurement cycle is complete.

Step 6. Complete three measurement cycles

When using 3 cycles configuration -

When you complete a measurement cycle, an audible beep is heard and the **Cancel** button changes to **Start**. Repeat the procedure for a measurement cycle at least three times or until the Result button at the top right of the screen becomes active. Each completed cycle will be indicated by an advance of the Cycle indicator at the left side of the screen. If you have completed five cycles and the Result button is still grayed out, this means that the results of your measurement cycles have too much variability. An error message will appear and you will have to restart the measurement. If the methodology is being followed correctly, this will rarely happen.

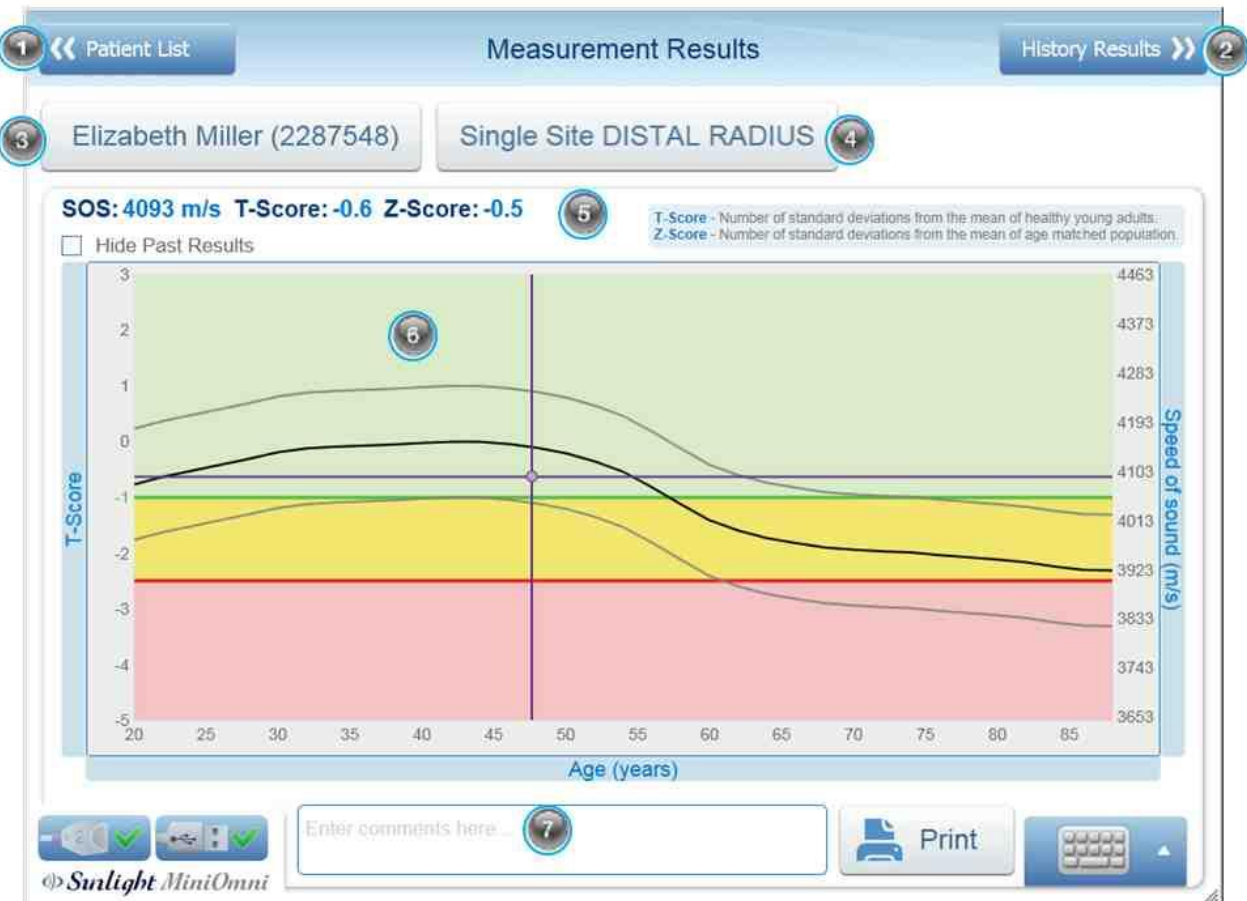
When three consistent cycles have been completed, you can click on the **Result** button to view the results of the measurement.

12. MEASUREMENT RESULTS

12.1. MEASUREMENT RESULTS SCREEN



Note: If you are using the Pediatric Application, see information on Pediatric Measurement Results, in [Section 16.5. Pediatric Measurement Results](#).



Key to Screen		
1	Back to the main patient list	5 The measurement result values (SOS, T & Z-scores)
2	Go to the patient history tab in patient file	6 Result graph current measurement is purple dot, if this site measured before the previous results will be blue dots)
3	Go to patient file	7 Comments that will appear on the measurement report and will not be saved in patient file
4	Go to measurement setup screen	

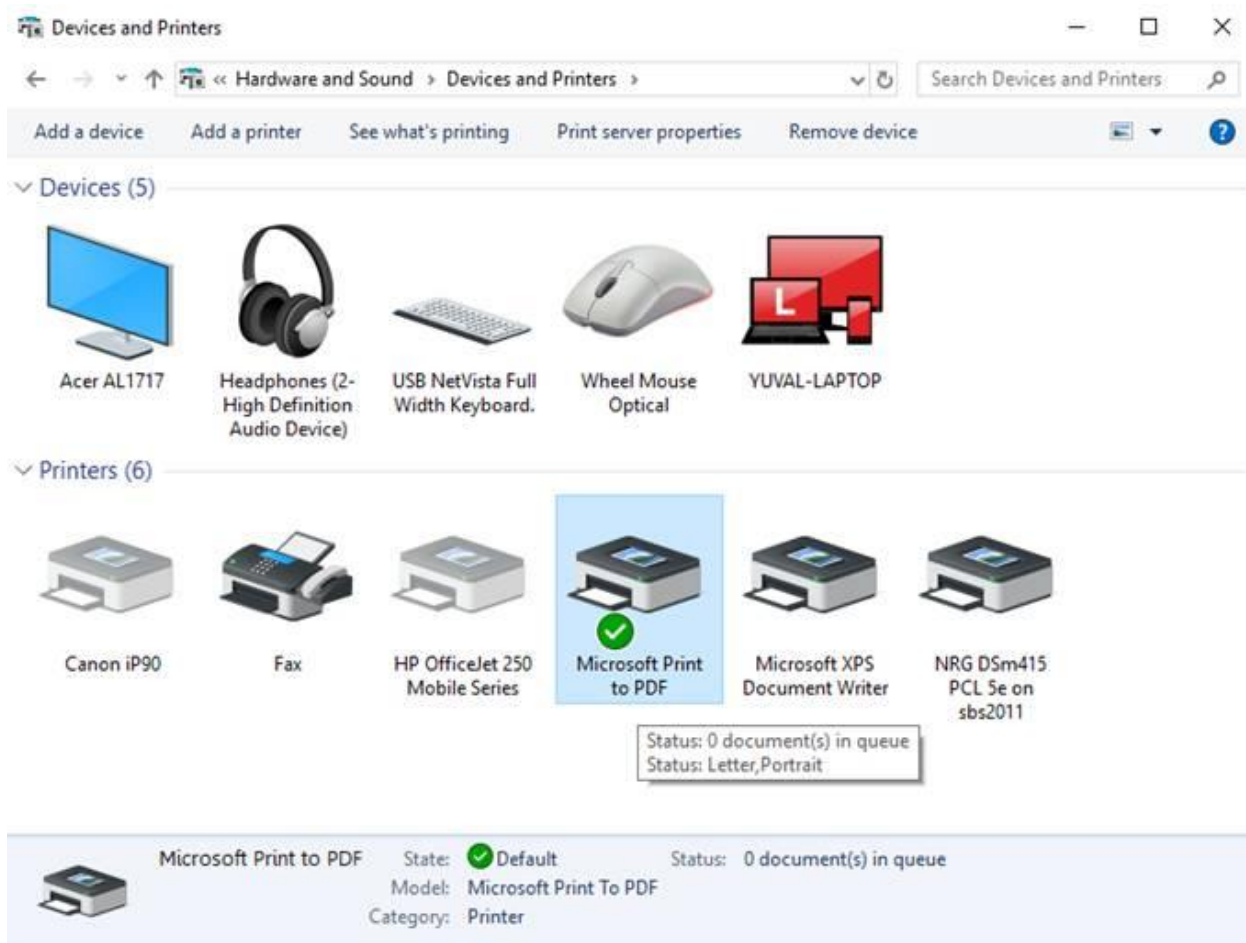
12.1.1. PRINTING/SAVING THE REPORT

When you click Results, and Print. When you press the PRINT button, you should see your own Printers. Your laptop or PC should have "PDF printer". You may need to define it on the Printers Setup (on Windows Control Panel) as the default. It can be easily added ask your IT team to do it.

(Other - You may also define the MICROSOFT XPS DOCUMENT WRITER. It will also save the report as image.)

*See [Section 12.2. RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE \[ME EQUIPMENT OR ME SYSTEM\]](#) to Setup if needed. Show it to your I/T person.

Your own normal Printer options should appear, click "Save As" the PDF or choose your own Printer as you normally do.



12.2. BONE DENSITY MEASUREMENT REPORT

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 Tel: 972-3-9236869 Fax: 972-3-9236867
 Email: Support@beammed.com

BeamMed - Focused On
 Bone Health

Test Date:
11/06/2019

Measurement Report

Patient ID: 2287548 Name: **Elizabeth Miller** 1

Gender: **Female** Referring Physician: **Dr. Smith**
 Age: **55.3** Reporting Physician: **BeamMed**
 Weight: **62.0** Operator: **sunlight**
 Height: **170.0**
 BMI: **21**

Measurement Results (Site: DISTAL RADIUS)

SOS Results: 4116 (m/s)
T-score: -0.4 (Number of standard deviations from the mean of healthy young adults)
Z-score: 0.3 (Number of standard deviations from the mean of age-matched population)

Summary

Comments: Operator remarks will be shown here 5

Physician Remarks: Physician Remarks here

4 Signature: _____

Device Details: System SN: 10 119923, Probe SN: 795, SW: 4.05, Print Date: 11 Sep 2013, RDB: American
Disclaimer: Here your disclaimer will be shown

6

BeamMed
 Sunlight MiniOmni

Key to Screen			
1	Patient details	4	Physician remarks
2	Result graph current measurement is purple dot (if this site was measured before, the previous results will be blue dots)	5	Measurement comments
3	The current measurement result values (SOS, T and Z-scores)	6	Device details and editable disclaimer

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Page 51 of 116

12.3. GUIDELINES TO EVALUATING THE SOS MEASUREMENT

12.3.1. SOS VALUE, T-SCORE AND Z-SCORE

The absolute value of an SOS measurement has no significance. Results are meaningful in relation to a reference database of SOS values taken from a large representative population.

A graph of reference SOS values for the current patient's gender is displayed. Speed of Sound (SOS) is plotted as a function of age. The thin lines above and below the bold reference curve represent one standard deviation above and below average, respectively. The SOS value obtained for the current measurement is shown as a purple round dot on the graph with dotted lines extended to show the corresponding points on the horizontal and vertical axes.

In the example, the patient has a T-score result of -0.4, equivalent to a Z-score of 0.3. That is, the result falls 0.4 standard deviations below the mean SOS value for normal young adults and falls 0.3 standard deviations above the line of the mean SOS value for his/her age. If previous measurements were performed on this patient, they will be displayed in the graph as gray round dots.

Displayed at the left of the screen below patient information are two types of statistical information derived from the basic SOS value. The following table explains these statistical values.

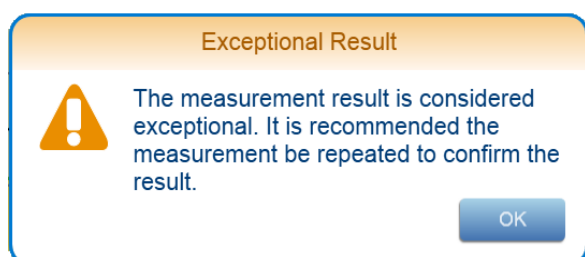
Measure	Meaning
T-score	This measure is most directly applicable to patient risk assessment. The T-score relates an SOS value to the scores obtained for young, healthy adults. The T-score value is the number of standard deviations by which the current patient's SOS value exceeds or falls below the mean of this young adult group.
Z-score	The Z-score is the difference between the patient's SOS result and the average SOS of a population of the same age and gender in units of population standard deviation.

Under certain conditions, the Z-score value of a measurement can be outside the range of ± 2.5 . For example: when carrying out a measurement in a patient's distal radius in a place where a bone fracture occurred in the past, the Z-score obtained will probably be lower than -2.5.

In the case above, as well as whenever a Z-score result falls outside the ± 3.25 range (i.e.: has a Z-value greater than +3.25 or smaller than -3.25), a re-measure is suggested.

In such a case, a pop-up box will appear, reading: "The measurement result is considered exceptional. It is recommended to repeat the measurement to certify the result."

Click **OK** to close the pop-up box, and then decide whether to proceed to measure the same bone in the contra-lateral limb, or carry out a new measurement of the same site.



"Suggest to re-measure" pop-up box

12.3.2. MEASUREMENT COMMENTS

Comments regarding the measurement for a particular patient may be added by adding comment to the *Measurements Comments* on the measurement screen. Up to 256 characters of the text entered will appear in the measurement report. After performing a further measurement, previous comments will not appear.

To enter comments to History results or as default to each printout for the same patient enter the comments from the Patient file at General Tab – "Remarks"

The Measurement Comments dialog box appears below.

 Print

The Patient>General Remarks dialog box appears below

Remarks:

Measurement Comments dialog box



Note: Use the Print icon to print a hard copy of the result for your patient, your own records, or for a referring physician.

12.4. MEASUREMENT HISTORY

MiniOmni includes a facility for reviewing the measurement history of a given patient, providing a convenient method for assessing changes over time.

To open the Measurement History screen, click on the **Results** tab. Each measurement result is displayed in a separate row. If the list is long, use the scroll bar to navigate up and down through the data. A patient file must be open to access that patient’s measurement history.



Key to Screen			
1	Back to the main patient list	4	Details of the selected site history results
2	Go to the measurement setup screen	5	The measurement result currently shown will be printed
3	Show the selected site history results	6	The measurement result currently shown will be deleted

Measurement results are displayed in a table format. The results of all measurements conducted for the current patient are displayed. Each measurement result is on a separate row. If the list is long, use the scroll bar to move through the data.

The graph plots Speed of Sound result data on the vertical axis against the dates of specific measurements on the horizontal axis. The resulting curve is indicative of changes over time. The thin lines below and above the reference curve represent a range of one standard deviation above and below the age matched reference curve for the current patient’s gender and ethnic group. The bands in this graph have the same meaning as the colored bands in the Result screen.

12.5. DELETING A MEASUREMENT RESULT

In certain situations, you may want to delete a particular measurement result for a patient. In this case, you may delete a measurement result by clicking on the measurement in the table below the results graph. Click **Delete** and press **Yes** to confirm. The selected measurement is now deleted from the system.



Caution: Deleted measurements are not recoverable.

13. MULTI-SITE MEASUREMENTS



Note: The Multi-Site Measurement feature is available only if pre-ordered with the system.

MiniOmni provides a unique capability among quantitative ultrasound systems in that it supports measurements at multiple skeletal sites. A key advantage of this feature is the improved accuracy of results which you can obtain from SOS measurements. The reason is straightforward: if the result of a measurement can be confirmed by measurements at additional sites, your assessment is far less subject to error.

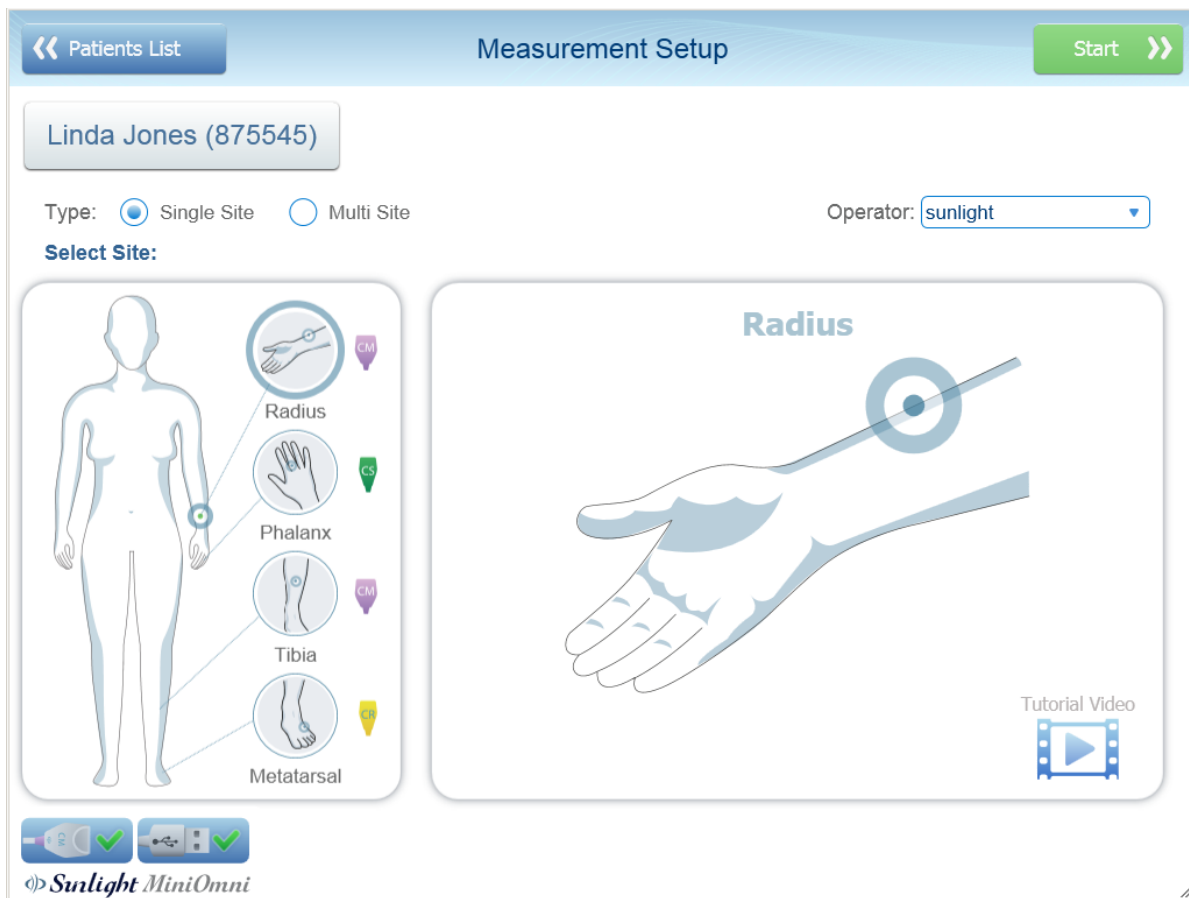
The MiniOmni Multi-Site capability is operated as follows: The *Measurement Setup* window includes a *Multi-Site* option which is user-selectable. Selecting the *Multi-Site* option will cause the right hand-side of the screen to change its appearance, showing two site images boxes. The Multi Site option includes all possible pairs of measuring sites: **RAD** (1/3 Distal Radius), **TIB** (Midshaft Tibia), **MTR** (Metatarsal V) and **PLX** (Proximal Phalanx III). Details of the physical procedures required for each measurement site can be found as shown in the following table:

For details on using this measurement site	See Section
RAD (1/3 Distal Radius)	11.2. Locating the Measurement Site for the Distal 1/3 Radius
TIB (Midshaft Tibia)	14.2. Mid-shaft Tibia site
MTR (Metatarsal V)	14.4. Metatarsal V Site
PLX (Proximal Phalanx III)	14.1. Proximal Phalanx of the Third Finger Site

Selecting a pair displays the Multi-Site Reference Database, together with the patient's results, including all available history. The patient's T-scores and Z-scores are also shown in the left hand side results table. When printing, the printed output shows the Multi-Site measurement curve and its results, including history, and the numerical results of the sites measured.

13.1. OPERATING THE MINIOMNI MULTI-SITE MEASUREMENT FEATURE

After clicking on the Measure Multi Site button from patient file page, the measurement setup screen appears:



Choose the Type of measurement: Single Site or Multi Site. Then choose the desired site: Radius, Phalanx, Tibia, or Metatarsal. If you choose a site for which the appropriate probe is not connected, the system will issue a warning: **"To Measure [name of site] you should connect [type of probe]"**.



Note: Multi Site is available for female patients only, Multi Site requires additional license.



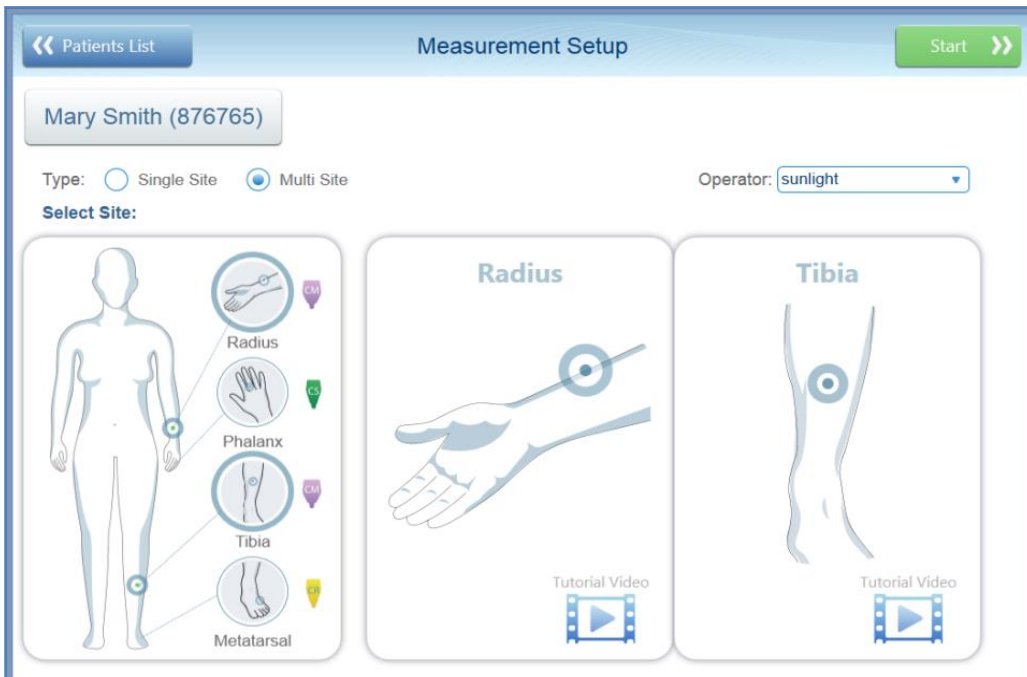
Note: If the symbol of a **clock** appears next to a site, it means that the site was already measured today:



Note: You may press on the patient's name – **"Linda Jones (875545)"** in the illustration – to view or change patient details, as shown in [Section 10. Patient Maintenance](#).

In this example of a multi-site measurement, we will measure the **distal radius** as the first site, and the **tibia** as the second site.

1. Open the file of the patient to be measured:



2. Select “Multi-Site” in the Measurement Type on the Measurement Setup screen.

3. Select a pair of sites to be measured. You may choose any pair-combination of the four sites.

4. Click **START >>**. The Site Listing screen appears, listing the two sites selected for measurement. Select the first site to be measured, in this example the radius.



Click on the top right button (**Measure Radius** in this example) to measure one of the sites. Alternatively, you may click on the button for the site you wish to measure first, in this example **Radius** or **Tibia**.



Note: If one or both of the sites has already been measured, the “clock” symbol will appear next to the site icon.



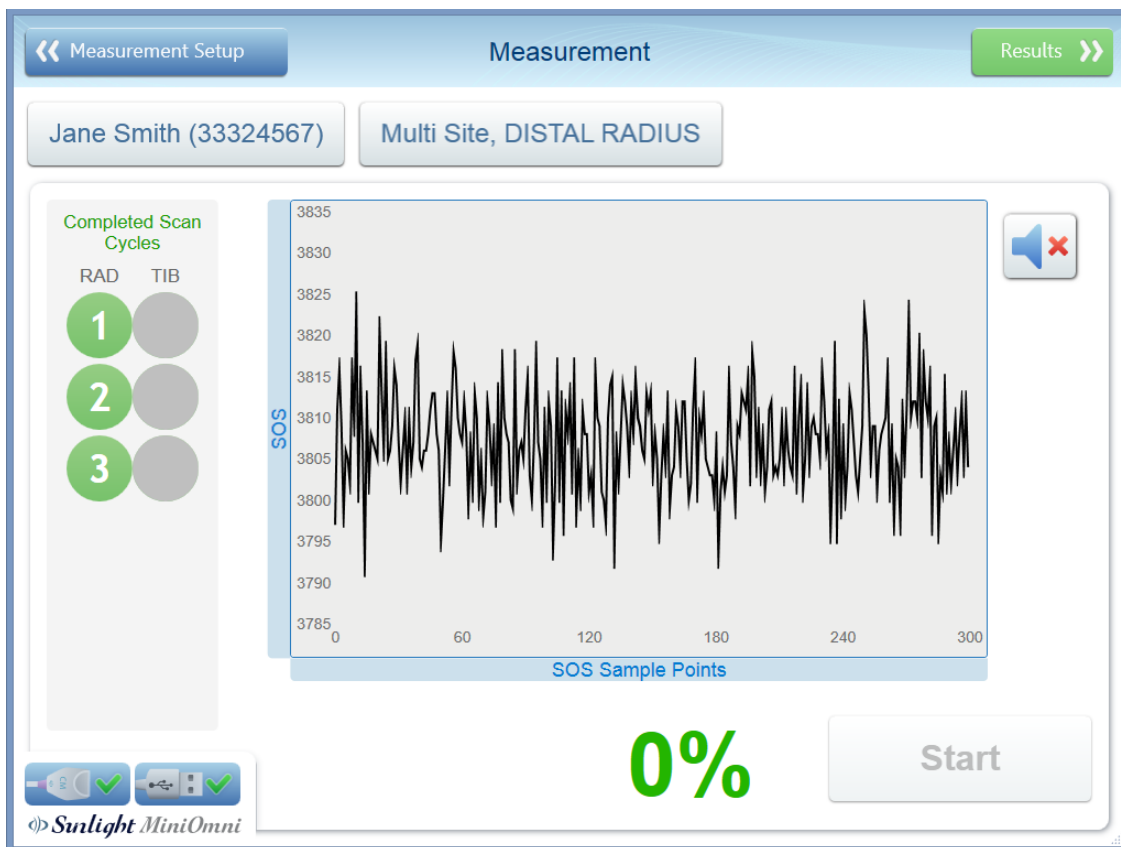
Press **Measure Radius >>** (or other site name) to measure the other site. If both sites have already been measured, **View Results >>** will display the Measurement Results screen.

"Clock" symbol (top right), indicating that the Radius site has been measured

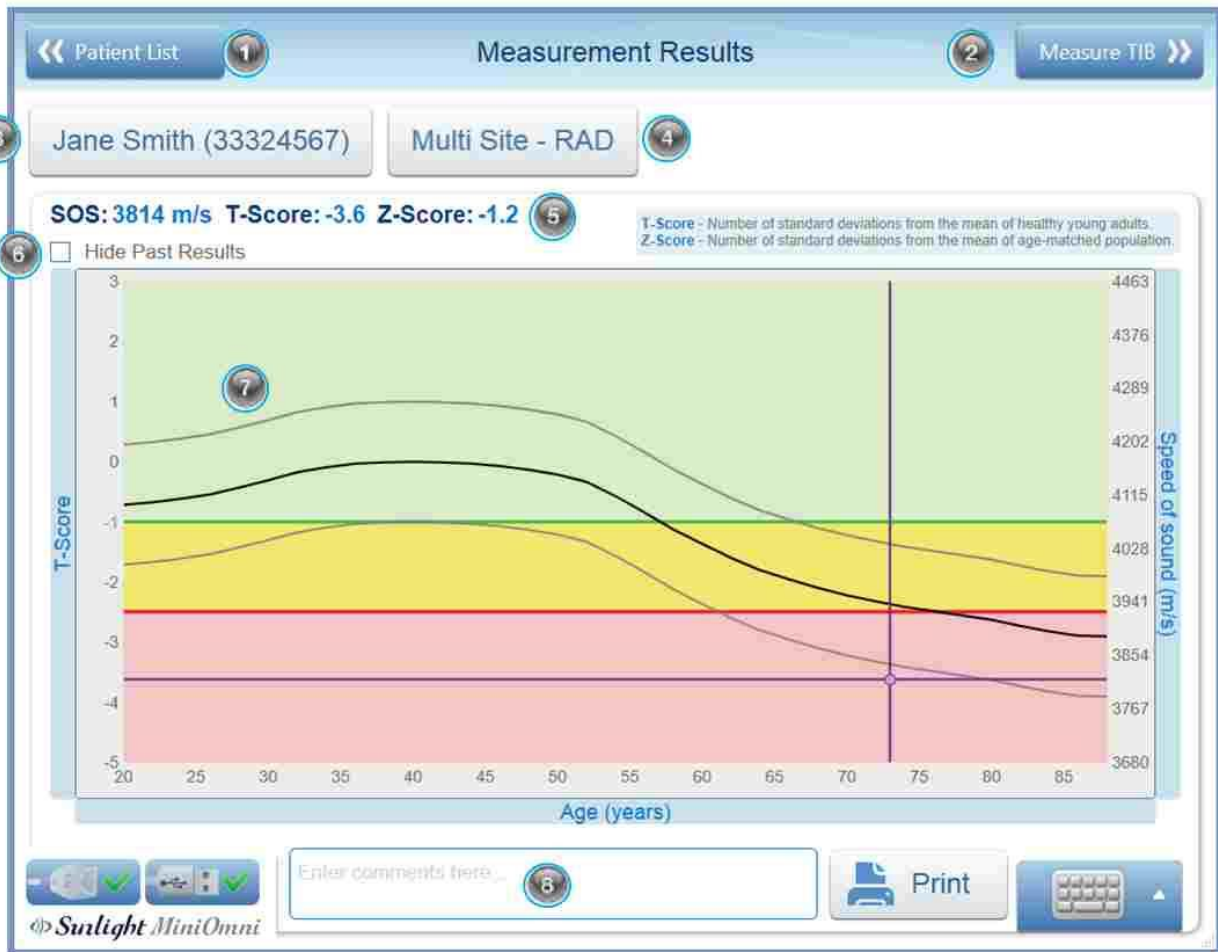
5. The measurement screen will display for the first site.

Click **Start** to begin measuring the first site. The measuring operation is carried out in the same manner as in a single site measurement ([Section 8.2.6. Execute the measurement](#)).

When the measurement is complete, the Measurement screen is displayed. In this example, the distal radius measurement screen is shown:

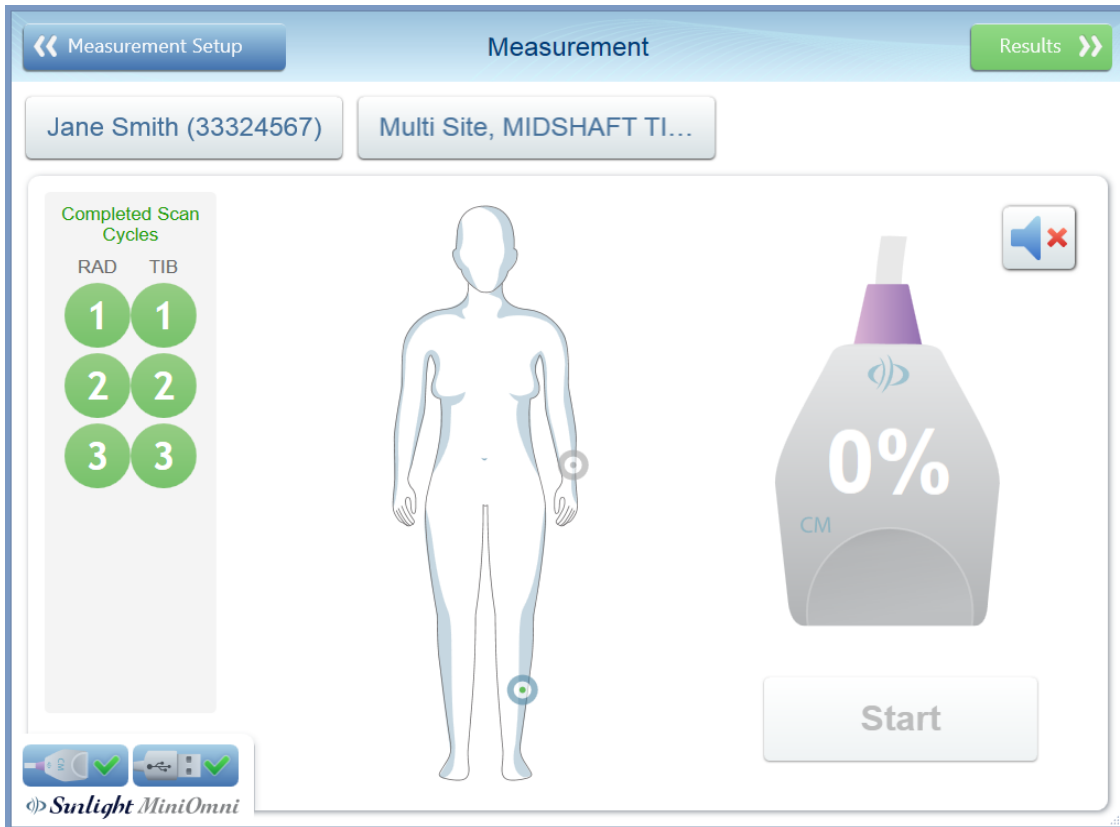


6. Click on **Results >>** to show the Measurement Results screen for the first site:



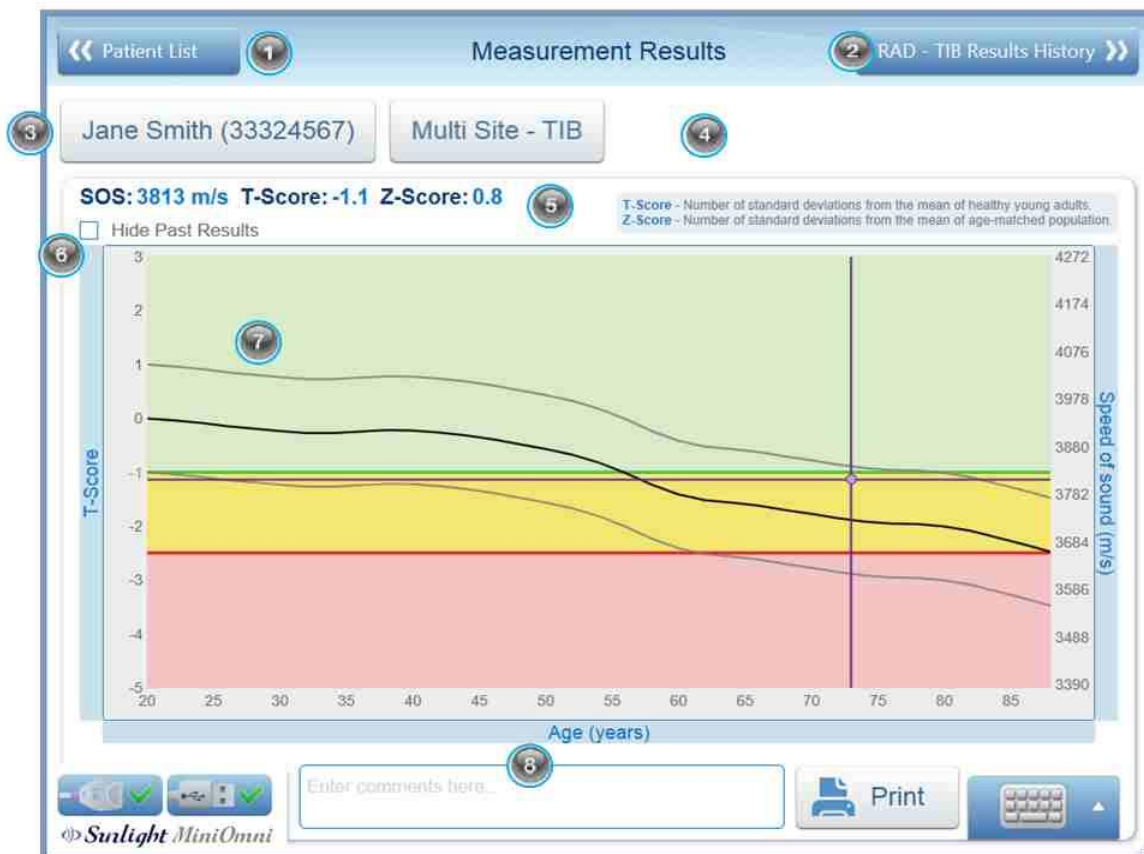
Key to Screen			
1	Back to the main patient list	5	The measurement result values (SOS, T & Z-scores)
2	Go to 2nd site measurement screen	6	If checked, previous results will not be presented
3	Go to patient file	7	Result graph current measurement is purple dot. If this site was measured before, the previous results will be blue dots
4	Go to measurement setup screen	8	Comments that will appear on the measurement report and will not be saved in patient file

7. Click on the button on the top right (**Measure TIB >>** in this example) to measure the second site.



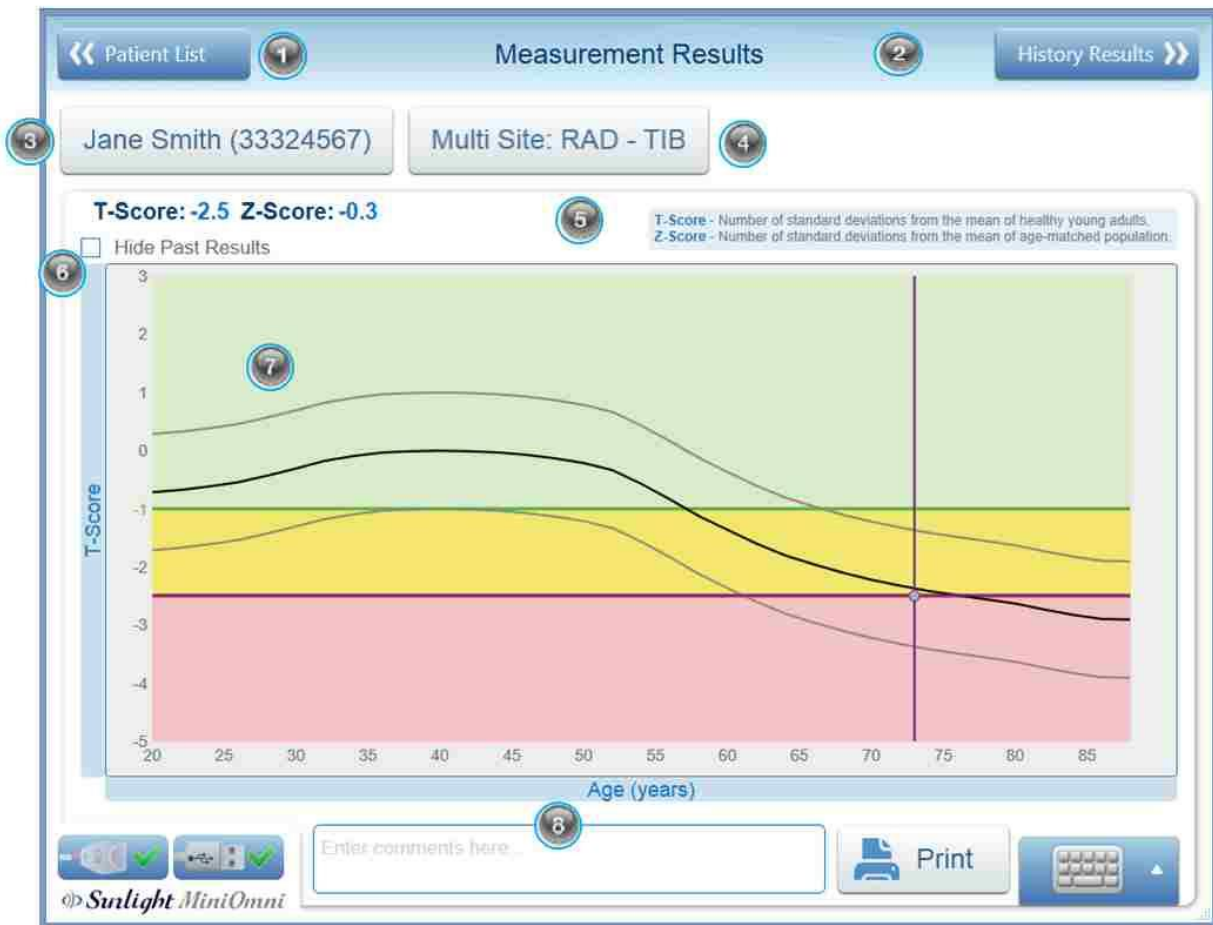
8. Click **Start** to begin measuring the second site. The measuring operation is carried out in the same manner as in a single site measurement.

9. Click on **Results>>** to see the measurement results for the second site.



Key to Screen			
1	Back to the main patient list	5	The measurement result values (SOS, T and Z-scores)
2	View final multi-site results	6	If checked, previous results will not be presented
3	Go to patient file	7	Result graph current measurement is purple dot. If this site was measured before, the previous results will be blue dots
4	Go to measurement setup screen	8	Comments that will appear on the measurement report and will not be saved in patient file

10. Click on the button on the top right (**RAD - TIB Results History >>** in this example) to view the final multi-site measurement results.



Key to Screen			
1	Back to the main patient list	5	The measurement result values (T and Z-scores)
2	View History results	6	If checked, previous results will not be presented
3	Go to patient file	7	Result graph current measurement is purple dot. If this site was measured before, the previous results will be blue dots
4	Go to measurement setup screen	8	Comments that will appear on the measurement report and will not be saved in patient file

This screen shows the final results for a multi-site measurement.

11. At this stage you may choose to print the Multi-site results obtained. An example of a Multi-Site Report printout is shown below.

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 Email: Support@beammed.com

BeamMed - Focused On
 Bone Health

Measurement Report

Test Date:
11/06/2019

Patient ID: 33324567 Name: Jane Smith

Gender: **Female**
 Age: **73.0**
 Weight: **62.0**
 Height: **156.0**
 BMI: **25**

Referring Physician: **Dr. Smith**
 Reporting Physician: **BeamMed**
 Operator: **sunlight**

Measurement Results (Site: DISTAL RADIUS - MIDSHAFT TIBIA)

The graph plots T-Score (y-axis, -5 to 3) against Age in years (x-axis, 20 to 85). A purple dot at age 73.0 indicates the current measurement with a T-score of -2.5. Other colored dots represent previous measurements.

3 SOS Results: **3844 (m/s)**
 RAD. SOS Result: **3814 (m/s)**
 TIB. SOS Result: **3813 (m/s)**
 T-score: **-2.5** (Number of standard deviations from the mean of healthy young adults)
 Z-score: **-0.3** (Number of standard deviations from the mean of age-matched population)

Summary

4 **Comments:**Comments entered from "Measurement Results" screen will appear here.
Physician Remarks:Remarks entered from "Patient File" will appear here.

Signature: _____

Device Details: System S/N: 10 11 99 23, Probe S/N: , SW: 4.0.0, Print Date: 12 Sep 2013, RDB: Curassian
 Disclaimer: Here your disclaimer will be shown

Key to Report	
<p>1 Patient details</p>	<p>3 The current measurement result values (SOS, T and Z-scores). Note that it is possible to see each site results and to combine multisite results.</p>
<p>2 Result graph current measurement is purple dot. If this site was measured before, the previous results will be blue dots.</p>	<p>4 Comments/Remarks entered by Physician/Operator</p>

Note: If you wish to calculate Multi-site results after measuring a patient at two sites with Single Site measurement: Simply save and close the second single-site measurement, indicate Multi-Site for the Measurement Type, and ensure that the sites already measured appear in the Measurement setup screen. Click "Start" and "Go to results".

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Page 64 of 116

14. MEASUREMENT AT PLX, TIB AND MTR



Note: Multiple site measurements are available in a multi-site license only.

In addition to the 1/3 Distal Radius site, three other sites are available for measurement using the MiniOmni:

- PLX (Proximal Phalanx III)
- TIB (Midshaft Tibia)
- MTR (Metatarsal V).

Details of each of these measurement sites are provided below.

14.1. PROXIMAL PHALANX OF THE THIRD FINGER SITE

14.1.1. POSITION THE PATIENT

The patient should be seated comfortably, opposite the operator and adjacent to a standard desk or table. The arm and hand are placed on the desk, close to the operator.



Note: Always measure the patient's non-dominant side. In case of a disorder or impairment in the non-dominant limb, such as edema, a mass, a non-detachable ring, or IV line, use the contra-lateral side instead.

14.1.2. IDENTIFY THE REGION TO BE MEASURED

Determining the area to be scanned:

1. To find the correct scanning area, first use the right angled L-gauge supplied with MiniOmni to measure the phalanx, as described below. The gauge is illustrated below.

The L-gauge has two sections — the scale on the shorter “leg” of the gauge is fitted to the proximal phalanx; the scale on the longer “leg” of the gauge applies to the medial phalanx.



L-gauge for measuring the phalanx

Bend the patient's third finger so that the medial phalanx is at right angles to the proximal phalanx. Fit the gauge to the patient's finger so that the right angle of the gauge fits over the right angle made by the medial and proximal phalanges. The shorter “leg” of the gauge should hold to the proximal phalanx while the longer “leg” of the gauge is against the medial phalanx. The correct gauge position is illustrated below.



The shorter part of the L gauge should hold to the proximal phalanx while the longer section is against the medial phalanx.

2. Note the length of the medial phalanx on the scale on the longer “leg” of the gauge. Find the same unit of length on the proximal phalanx using the scale on the shorter “leg” of the gauge and mark the point with a skin marker. Ensure that the proximal phalanx joint is behind the mark. Continue drawing the mark around the finger, to one half the circumference of the phalanx, i.e. the entire dorsal side.



Marking the scan position – Illustration of mark on proximal phalanx

3. Position the patient’s hand face down on the desk, i.e. the palmer side is to the desk surface. The fingers should be relaxed and not stretched or rigid.

Measuring SOS at the Phalanx:

- a. Select the CS probe for measuring at the proximal phalanx III.
- b. Disinfect the probe.

Probes should be disinfected before each patient use. Disinfection must be done with pre-moistened towelettes/Alcohol wipes, not by immersion of any kind. Apply ultrasound gel to the probe surface.

3. Apply a uniform layer of ultrasound gel to the CS probe and on the entire dorsal surface of the proximal phalanx of the third finger.



Applying ultrasound gel to the scan area

4. Use your non-dominant hand to grasp the third finger by the distal and medial parts and raise it slightly from the desk surface. Ensure that the patient is not experiencing any discomfort.



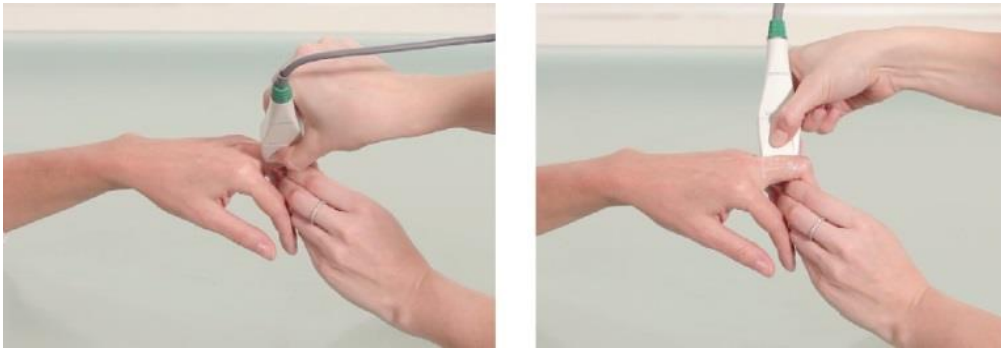
Grasping the patient’s finger – correct position of the proximal phalanx for scanning is maintained by the operator’s grasp.

5. Hold the probe with your dominant hand so that fingers 1-3 are grasping it near the base (the surface applied to the scan area) and apply it to the proximal phalanx. The side of the probe that is marked with a small “T” (at the bottom) lies at the marked point on the skin, and the remainder of the probe’s surface

extends distally toward the medial phalanx. Use the fingers 4-5 to palpate the limb during the scan and aid in guiding the movement of the probe correctly.

6. Press the foot-pedal or Measure button to begin the measurement cycle. When the probe is in proper contact with the area to be scanned, an audible signal is heard.

7. The scan is executed by moving the probe around the proximal phalanx, from its dorsomedial to its dorsolateral part, in an arc of about 180 degrees but no wider. During the scan movement, the probe is held perpendicular to the bone at all times, never at an angle. The movement is repeated until the measurement cycle is complete. A single scan movement through 180 degrees should take 4-5 seconds.



The range of probe movement during the scan

To scan, move the probe first in the medial direction, about 90 degrees, then back to the start point and further in the lateral direction, again 90 degrees, and return to start.



Note: To ensure accurate and reproducible results at the phalanx:

- One end of the probe surface should follow the marked point on the skin at all times.
- Never hold the probe at an angle to the surface of the limb.
- The probe should be held so that the short dimension of its surface is tangent to the bone while its long dimension is parallel to the bone axis.
- Do not use a circular motion. The probe movement should follow parallel to the marked line.
- Scan approximately 180 degrees but no further.
- Check to ensure that a scan movement through 180 degrees takes about 4-5 seconds. A faster or slower scan may generate an inaccurate result.
- Maintain the probe's surface in contact with the patient's skin throughout the scan. No part of the probe surface should be raised from the skin at any point during the scan.
- Avoid climbing with the probe over the small bulge found at the proximal/medial end of the Proximal Phalanx III.
- Do not press hard. Additional pressure does not contribute any improvement in acoustic contact.
- During the measurement cycle, concentrate on the site and the correct application of the probe. Avoid looking at the screen.

Instead, use the audible signal to provide feedback and to guide you in correct execution of the scan.

When using 3 cycles configuration - Repeat the entire procedure of the measurement cycle three times, or until the **Result** button becomes active.

14.2. MID-SHAFT TIBIA SITE

14.2.1. POSITION THE PATIENT

The patient is seated in a chair. The leg should be bent 90 degrees at the knee. The leg may be bent slightly more than this amount, but not less; the leg should not be stretched forward. The patient's heel should be placed firmly on the floor.



Note: Always measure the patient's non-dominant side. In case of a disorder or impairment in the non-dominant limb, such as edema, or a mass, use the contra-lateral side instead.

14.2.2. IDENTIFY THE REGION TO BE MEASURED

1. The length of the leg is measured, starting from the plantar surface of the heel and ending at the tip of the knee (knee height). The measurement should be conducted using the gauge supplied with the skeletal site kit. The picture shows the gauge to be used.



Sunlight gauge for measuring the tibia (also used in measuring the radius).

At left the gauge is closed; at right, extended for measurement.

2. The patient's foot holds the gauge platform firmly on the floor. Measure to the tip of the knee (knee-height). Find the exact halfway point to the distance measured and use a skin marker to draw a line on the dorsoanterior surface of the leg, perpendicular to the direction of the bone. The line should be extended straight across the dorsoanterior surface of the Tibia. The figure below illustrates the correct measurement procedure.



Use of the gauge to measure the tibia

3. **Raise** the patient's leg and position the ankle on a leg rest. The height of the leg rest should be the same as the height of the chair. The patient's leg should rest comfortably; if necessary, the knee may be bent slightly to avoid discomfort from overstretching the leg. *Do not* use the leg rest to support any part of the leg above the ankle. Correct leg positioning is shown in the illustration.



Patient with limb to be scanned in leg rest. Note position of leg for measuring at the tibia.

14.3. MEASURING SOS AT THE TIBIA

1. Use the CM probe for measuring at the mid-shaft tibia.
2. Disinfect the probe.

Probes should be disinfected before each patient use. Disinfection must be done with especially pre-moistened towelettes/Alcohol wipes, not by immersion of any kind. Apply ultrasound gel to the probe surface.

3. Refer to the sequence of photos in [Section 14.2.2. Identify the Region to be Measured](#). Apply a uniform layer of ultrasound gel to the CM probe and on the area to be scanned. The area to be scanned is a rectangular region which has the skin mark as a center line and width equal to the width of the probe.
4. The probe has markers at its center point on either side. Position the probe so that the center markers are aligned with the skin mark on the patient's leg and the long dimension of the probe is parallel to the bone axis. The short edge of the probe that is marked with a "T" (at the bottom) should be closer to the foot.
5. Hold the probe with both hands. Fingers 1-3 of both hands grasp the probe near the base (the surface applied to the scan area) while fingers 4-5 palpate the limb during the scan and aid in guiding the movement of the probe correctly. Press gently when applying the probe to the scan area.
6. Press: Enter/Foot Pedal/ measurement button to begin the measurement cycle. When the probe is in proper contact with the area to be scanned, an audible signal is heard.
7. The scan movement begins 3 to 4 centimeters medial to the tibial crest and ends at the crest about 70 degrees of rotation. Move first towards the crest and then back to the starting position, repeating continuously until the measurement cycle completes. Do not move the probe lateral to the crest. One cycle of movement to the tibial crest and back again to the starting point should take 5-6 seconds.



Correct scan procedure for the mid-shaft tibia: The skin mark is used to guide the scan. Begin 3-4 centimeters medial to the tibial crest. scan toward the crest and then back again, until the measurement cycle completes.



Note: To ensure accurate and reproducible results at the tibia:

- The center mark on the probe should follow the marked line on the skin at all times.
- Never hold the probe at an angle to the surface of the limb.
- The probe should be held so that the short dimension of its surface is tangent to the bone, and its long dimension is parallel to the bone axis.
- Hold the probe with both hands as described. Do not hold the probe with only one hand.
- Do not use a circular motion. The probe movement should follow perpendicular to the marked line.
- Probe movement should extend at least 3 centimeters but not more than 4 centimeters from the crest.
- Do not continue the scan laterally from the crest.
- Check to insure that a scan movement to the crest and back takes about 5-6 seconds. A faster or slower scan may generate an inaccurate result.
- Maintain the probe's surface in contact with the patient's skin throughout the scan. No part of the probe surface should be raised from the skin at any point during the scan.
- Do not press hard. Additional pressure does not contribute any improvement in acoustic contact.
- During the measurement cycle, concentrate on the site and the correct application of the probe. Avoid looking at the screen.
Instead, use the audible signal to provide feedback and to guide you in correct execution of the scan.

If the measurement is not going well, you can restart at any time during the cycle by pressing Restart (note that for the first cycle the button is labeled Start).

The Foot Pedal is recommended to allow hands free operation of MiniOmni during a measurement cycle. Pressing on the foot pedal is equivalent to clicking on the Start/Restart button.

If MiniOmni is not receiving an appropriate signal — indicated by an intermittent sound or no sound — check that sufficient Ultrasound Gel is on the probe as well as on the area being scanned.

14.4. METATARSAL V SITE



Note: Always measure the patient's non-dominant side. In case of a disorder or impairment in the non-dominant limb such as an edema or mass, use the contra-lateral side instead.

14.4.1. POSITIONING THE PATIENT

The patient is seated in a chair opposite the operator. The leg is extended and placed on a leg rest; the foot as close to the operator as possible, as shown below.

Initial patient position for the metatarsal V:



14.4.2. DETERMINING THE AREA TO BE SCANNED

1. To locate the region of interest, instruct the patient to “make a fist” with their toes, i.e. flex them downward and together so that the distal part of the metatarsal V is prominent. The figure below illustrates the correct attitude of the foot.

Patient position prior to marking the ROI:



The toes are flexed downward and together by the patient, to make the distal part of the metatarsal V prominent.

Marking the distal end of metatarsal V:



Place a single dot at the distal prominence of the metatarsal.

2. With a skin marker place a dot just proximal to the prominence. The dot coincides with the distal end of the metatarsal shaft.

3. The L-gauge supplied with the metatarsal site kit is illustrated below. Note that the same L-gauge is used with the proximal phalanx.

L-Gauge for use with metatarsal V:

The L-gauge is used for marking of the Region of Interest at the metatarsal. (The same gauge that is used for the phalanx).

Position the L-gauge on the foot so that the inside corner is at the dot marked previously, the long part is parallel to the bone extending to the lower part of the lateral malleolus, and the short part is parallel to the toes. Mark two perpendicular lines, coinciding with the inside shape of the L-gauge; the lines meet at the marked dot. Ensure that the gauge is fixed to the malleolus, and that the gauge's internal corner remains aligned with the dot marked earlier. The two lines drawn will be referred to as the "long mark" and the "short mark." The figure below illustrates the marking procedure.

Marking the scan region with the L-gauge:



Draw two perpendicular lines inside the L-gauge. The distal prominence of the metatarsal V is the meeting point of the two lines.

14.4.3. MEASURING SOS AT THE METATARSAL V

1. Adjust the patient's position so that the Achilles ligament is supported by the leg rest, as close to the operator as possible.

2. Use the CR probe for measuring at the metatarsal V.

3. Disinfect the probe

Probes should be disinfected before each patient use.

Disinfection must be done with specially pre-moistened towelettes/Alcohol wipes, not by immersion of any kind.

Apply ultrasound gel to the probe surface.

4. Apply a uniform layer of ultrasound gel to the CR probe and on the area to be scanned. The area to be scanned is a rectangular region whose length follows the long mark and whose width extends one to two centimeters in the dorsal direction.

5. Place the probe parallel to the bone; the probe's long axis is aligned and centered with the long mark and its short edge is parallel to and proximal along the short mark. The short end that is marked with a small "T" should be closer to the short skin mark.

6. Hold the probe with one hand. Use the thumb and fingers 2-3 to grasp the probe around the two narrow sides of its neck and near its base; fingers 4-5 palpate the bone during the scan to stabilize the hand. Press gently with the probe when scanning.

7. Press the foot-pedal to begin the measurement cycle. When the probe is in proper contact with the area to be scanned, an audible signal is heard.

8. Scan by moving the probe in a direction perpendicular to the long mark for a distance of one to two centimeters in the dorsal direction, and then back again to the starting point. Repeat this movement continuously until the scan cycle completes. Do not move the probe quickly.

Scanning the metatarsal V



Hold the probe against the flat surface of the bone, and move it in a range of one to two centimeters toward the dorsal side and back, repeating until the scan completes.



Note: To ensure accurate and reproducible results at the metatarsal:

- The probe should be maintained parallel to the metatarsal bone, never diagonal to it.
- Never hold the probe at an angle to the surface of the limb. The probe should be held so that the short dimension of its surface is tangent to the bone while its long dimension is parallel to the bone axis.
- Do not use a circular motion. The probe movement should follow parallel to the marked line.
- Probe movement should extend at least 1 centimeter but not more than 2 centimeters dorsal to the long marked line.
- Maintain the probe's surface in contact with the patient's skin throughout the scan. No part of the probe surface should be raised from the skin at any point during the scan.
- Do not press hard. Additional pressure does not contribute any improvement in acoustic contact.
- During the measurement cycle, concentrate on the site and the correct application of the probe. Avoid looking at the screen. Instead, use the audible signal to provide feedback and to guide you in correct execution of the scan.

If the measurement is not going well, you can restart at any time during the cycle by pressing **Restart** (note that for the first cycle the button is labeled **Start**).

The Foot Pedal is Recommended to allow hands free operation of MiniOmni during a measurement cycle. Pressing on the foot pedal is equivalent to clicking on the **Start/Restart** button.

If MiniOmni is not receiving an appropriate signal — indicated by an intermittent sound or no sound — check that sufficient Ultrasound Gel is on the probe as well as on the area being scanned.

15. CLOSING THE MINIOMNI APPLICATION

From any Application screen click on the Back button on the top left of the screen until you get to the following screen – than click on the << **Exit** button at the top left of the screen.

Caution: When closing down MiniOmni, do not simply shut off the power supply. This could cause permanent loss of data. Follow the prescribed exit procedure.



16. PEDIATRIC APPLICATION OF MINIOMNI

Most of the features and screens of the Pediatric Application of MiniOmni are identical to the standard Adult system. This section provides details for screens and procedures that differ in the Pediatric Application.

16.1. NEW PATIENT – PEDIATRIC – GENERAL

Key to Screen			
<< Back	Show previous screen	Measure >>	Perform measurement
Patient ID	Required. Can be automatically filled. See Section 18.5. Options – Settings – Setup	Street & Number	Patient address and contact details
Family Name	Required. Can be automatically filled. See Section 18.5. Options – Settings – Setup	City	
Middle Name	Optional	Country/ State	
First Name	Required. Can be automatically filled. See Section 18.5. Options – Settings – Setup	Zip Code	
Birth Date	Required. Ensure the correct age is entered	Phone	
Ethnicity	Required. Can be automatically filled. See Section 18.5. Options – Settings – Setup	Email	
Measured Limb	Optional – allow to repeat the same measurement next patient visit	Mobile	
Gender	Required	Physician	Choose physician name from the application user list. This information will appear on the measurement report.
Growth reference	Required. Relevant to Anthropometric History	Referring Physician	Type the referring physician. This information will appear on the measurement report.
Remarks	Any remark written here will be added to measurement report and will be saved	Allow only physician to view	If clicked only Physician user associated with this patient can see the patient file

Depending on the **Gender** chosen here, the appropriate screen appears when you click on **Clinical Info**: Choose **Female** to see the **New Patient-Pediatric-Girl-Clinical Info** screen, as shown in [Section 16.2. New Patient – Pediatric – Girl – Clinical Info](#).

Choose **Male** to see the **New Patient-Pediatric-Boy-Clinical Info** screen, as shown in [Section 16.3. New Patient – Pediatric – Boy – Clinical Info](#).

16.2. NEW PATIENT – PEDIATRIC – GIRL – CLINICAL INFO

New patient

General

Growth information

Current Age: 0.0 Years Current Height (cm): 0.0

Current Weight (kg): 0.0 BMI: BMI Percentile: 0

Clinical Info

Anthropometric

Results

Pediatric Bone Health Data

Prenatal and Delivery History

Gestational age: 0

Birth Weight (kg): 0.0

Born small for gestational age (SGA)

Born at very low birth weight

Tanner stage

Pubic hair: 1

Breast: 1

Precautious puberty

Menarchial age: 0

Lifestyle and Risk Factors

Insufficient calcium intake

Repeated dieting over the last year

Low or no physical activity

Over weight / Obesity

Previous fractures

Number of previous fractures: 0

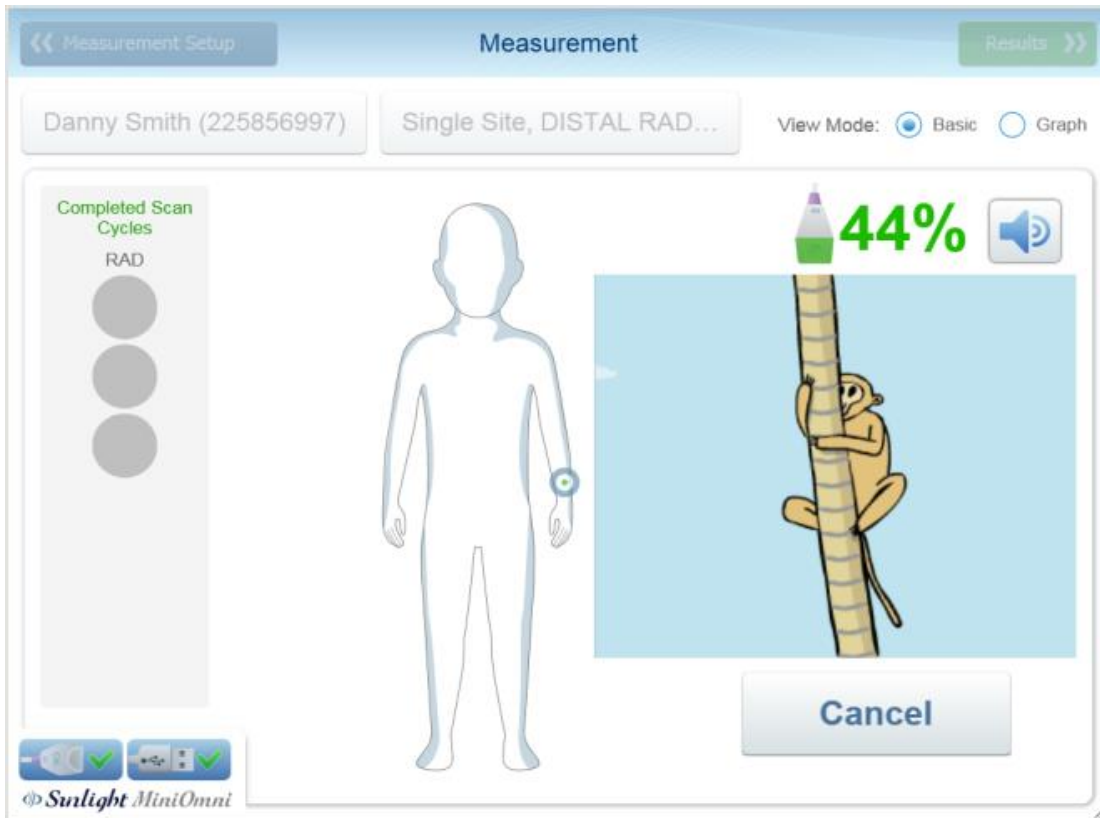
Family history of osteoporosis or osteoporotic fractures

Key to Screen			
<< Back	Show previous screen	Measure >>	Perform measurement
Current age	Appears automatically after entering Birth Date on New Patient/Pediatric/General (See Section 16.1. New Patient – Pediatric – General)	Current height	Relevant for Anthropometric, appears on report
Current weight	Appears on report relevant for Anthropometric	BMI	Relevant for Anthropometric, appears on report
Gestational age	Factors that have been shown to negatively affect bone strength.	BMI percentile	Appears on report
Birth weight		Insufficient calcium intake	Related Clinical information
Born small for gestational age (SGA)		Repeated dieting over the last year	
Born at very low birth weight		Low or no physical activity	
Pubic hair	See Tanner stage, Section 26. Tanner Stages of Puberty	Overweight/obesity	
Breast		Number of previous fractures	
Precautious puberty		Family history of osteoporosis	
Menarchial age			

16.3. NEW PATIENT – PEDIATRIC – BOY – CLINICAL INFO

Key to Screen			
<< Back	Show previous screen	Measure >>	Perform measurement
Current age	Appears automatically after entering Birth Date on New Patient/ Pediatric/General (See Section 16.1. New Patient – Pediatric – General)	BMI	Relevant for Anthropometric, appears on report
Current weight	Appears on report relevant for Anthropometric	BMI percentile	Appears on report
Gestational age	Factors that have been shown to negatively affect bone strength.	Insufficient calcium intake	Related Clinical information
Birth weight		Repeated dieting over the last year	
Born small for gestational age (SGA)		Low or no physical activity	
Born at very low birth weight		Overweight/ obesity	
Pubic hair	See Tanner stage, Section 26. Tanner Stages of Puberty	Number of previous fractures	
Current height	Relevant for Anthropometric, appears on report	Family history of osteoporosis	

16.4. MEASUREMENT SCREEN – PEDIATRIC



The Pediatrics measurement screen is essentially identical to the Adult measurement screen, with the addition of an entertaining video of a monkey climbing a tree.

16.5. PEDIATRIC MEASUREMENT RESULTS

Upon successful completion of a measurement, clicking on *Result* to display the Measurement Results screen, as shown below.



SOS measurement result screen

Key to Screen			
1	Go to main patients list	5	The measurement result values (SOS, Z-score, Percentile)
2	Go to the patient history tab in patient file	6	Result graph current measurement is purple dot, if this site measured before the previous results will be blue dots)
3	Go to patient file	7	Comments that will appear on the measurement report and will not be saved in patient file
4	Go to measurement setup screen		

16.5.1. SOS VALUE, PERCENTILE AND Z-SCORE FOR PEDIATRIC MEASUREMENTS

The absolute value of an SOS measurement typically has no significance. Results are meaningful in relation to a reference database of SOS values taken from a large representative population.

A graph of reference SOS values for the current patient's gender is displayed. Speed of Sound (SOS) is plotted as a function of age. The thin lines above and below the bold reference curve represent one standard deviation above and below average, respectively. The SOS value obtained for the current measurement is shown as a purple round dot on the graph with dotted lines extended to show the corresponding points on the horizontal and vertical axes. In the example, the patient has an SOS of 3,865 m/sec, equivalent to a Z-score of 0.3, because the result stands at 0.3 standard deviations above the line of the mean SOS value for his/her age and at a percentile rank of 60% compared to age and gender-matched peers. If previous measurements were performed on this patient, they will be displayed in the graph as gray round dots.

Displayed at the left of the screen below patient information are two types of statistical information derived from the basic SOS value. The following table explains these statistical values.

Measure	Meaning
Percentile	The percentile rank to which the patient belongs with respect to his or her gender and age-matched peers
Z-Score	The difference between the patient's SOS result and the average SOS of a population of the same age and gender in units of population standard deviation

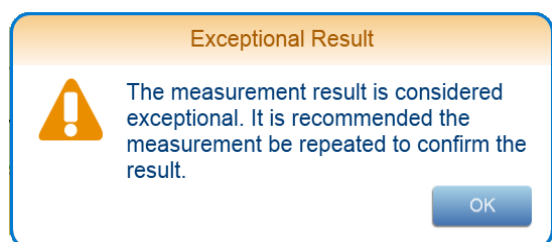


Note: For children aged 0-5, a separate result graph is shown, which includes only the reference range of ages 0-5. This is designed to allow the physician to better follow up on young children's bone development, as these are years of more pronounced changes and therefore more frequent measurements.

The meaning of a particular SOS value requires interpretation based on clinical experience. The percentile and the Z-score values compare the patient to his peers. A set of measurements performed in the past together with the current result can indicate either normal growth, a relative improvement in bone strength or a relative deterioration in bone strength, according to the observed trend compared to the changes of the reference curve.

Under certain conditions, the Z-score value of a measurement can be outside 97%.

Whenever a Z-score result falls outside 97%, a re-measure is suggested. In such a case, a pop-up box will appear, reading: "The measurement result is considered exceptional. It is recommended to repeat the measurement to certify the result":



"Suggest to re-measure" pop-up box

Click **OK** to close the pop-up box, and then decide whether to proceed to measure the same bone in the contra-lateral limb, or carry out a new measurement of the same site.

16.6. BONE DENSITY MEASUREMENT -- PEDIATRIC

BeamMed - Focused On Bone Health

BeamMed Address: 8 Ha-lapid St., Petach Tikva, Israel.
Tel: 972-3-9236869 Fax: 972-3-9236867
Email: www.beamed.com

Test Date:
11/06/2019

Bone Density Measurement Report

Patient ID: 225856997 Name: Danny Smith

Gender: **Female**

Age: **12.0**

Weight: **88.0**

Height: **4.0**

BMI: **27**

Week of birth: **0**

Date of birth: **01/01/1900**

Referring Physician: **None**

Reporting Physician: **None**

Operator: **sunlight**

Measurement Results (Site: DISTAL RADIUS - Ped)

The graph plots Speed of sound (m/s) on the y-axis (ranging from 2700 to 4500) against Age (years) on the x-axis (ranging from 0 to 20). Multiple curves represent different percentiles. A purple dot is placed at age 12, with a horizontal line extending to the y-axis at approximately 3833 m/s. A vertical line also extends from the x-axis at age 12 to the purple dot.

SOS Results: 3833 (m/s)

Z-score: 0.3 (Number of standard deviations from the mean of age matched population)

Percentile: 60.0 (Percentile rank to which patient belongs relative to age matched peers)

A horizontal scale from 3 to 97 with major ticks at 3, 10, 25, 50, 75, 90, and 97. A teal bar highlights the area from 0 to 60.0.

Key to Screen			
1	Patient details	3	SOS value of current measurement
2	Result graph current measurement is purple dot, if this site measured before the previous results will be blue dots)	4	Percentile result numeral view and graphic view

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Page 82 of 116

16.7. GROWTH REFERENCE REPORT – PEDIATRIC

BeamMed - Focused On Bone Health
BeamMed Address: 8 Ha-lapid St., Petach Tikva, Israel.
 Tel: 972-3-9236869 Fax: 972-3-9236867
 Email: www.beamed.com

Test Date:
11/06/2019

Growth Reference Report

Patient ID: 225856997 Name: Danny Smith

Gender: **Female** Age: **12.0**

1

Measurement Results

Height (%;SDS): **4.0 ft (3%; -3.9)** Head C: - Wt.Ch: -

Weight: **88.0 Lbs (42%)** W/H: **-100%**

BMI: **27 kg/m2 (97%; 1.9)** Ht.Ch: -

Ht.Ch - the height change rate in cm or ft/in per year Wt.Ch - the height change rate in cm or kg/lbs per year

Weight [Lbs] vs Age [Years] graph showing percentile curves and a data point at 12 years, 88 lbs.

Height [ft] vs Age [Years] graph showing percentile curves and a data point at 12 years, 4.0 ft.

BMI [kg/m2] vs Age [Years] graph showing percentile curves and a data point at 12 years, 27 kg/m2.

Weight [Lbs] vs Height [ft] graph showing percentile curves and a data point at 4.10 ft, 88 lbs.

SOS measurement result screen

Key to Screen			
1	Patient details	4	Height per age graph
2	Growth clinical info	5	BMI per age graph
3	Weight per age graph	6	Weight per height graph

17. CLEANING AND DISINFECTING

17.1. GENERAL INSTRUCTIONS



Warning: The MiniOmni probe should not be used on subjects with breached skin or open sores on the skin area that comes into contact with the probe.

The MiniOmni probe requires proper cleaning and disinfecting between each patient use. Doing so may help prevent any potential transmission of infection between patients. Protective gloves are recommended for cleaning and disinfecting procedures. Soiled materials should be disposed of in appropriate waste receptacles.

17.2. THE MINIOMNI DEVICE

17.2.1. CLEANING THE MINIOMNI DEVICE

Cleaning should be done with the probe connected, to make sure that no liquid gets into the probe socket. No disinfection is required for the MiniOmni since there are no patient contact surfaces.

The following steps should be followed for cleaning the MiniOmni:

1. Use a soft cloth, lightly moistened with liquid detergent or mild soap, to wipe down the MiniOmni surface.
2. Use any cleaning detergent or mild soap suitable for external cleaning of electrical equipment to clean the MiniOmni. Follow the instructions of the detergent or soap manufacturer.

17.3. THE ULTRASONIC PROBE

17.3.1. CLEANING PRECAUTIONARY NOTES FOR THE ULTRASONIC PROBE

Do not immerse the probe in water, liquid detergents or soaps.

DO NOT USE scrubbing materials or hard brushes that might scratch the probe head surface.

Do not use cleaning agents that can damage or destroy plastics, such as ammonia, acetone, (HCl), chloride bleach, etc.

17.3.2. CLEANING THE ULTRASONIC PROBE

The patient contact surface of the probe should be cleaned immediately after use. For cleaning, it is not necessary to disconnect the probe from the MiniOmni unit.

The following steps should be followed for cleaning the probe:

1. To clean the probe of any acoustic gel or residues, use only dry, soft tissues or towels. If required, use towels that are pre-moistened with a mild detergent, Alcohol wipes or soap.
2. The probe should be allowed to air dry if pre-moistened towels are used for cleaning.
3. Visually inspect the probe to ensure cleanliness.

17.3.3. DISINFECTION PRECAUTIONARY NOTES FOR THE ULTRASONIC PROBE

Do not immerse the probe in liquid disinfectants.

To avoid possible damage to the probe, do not employ sterilization methods that would expose the probe to heating, steam, pressure increase or decrease, or ethylene oxide (EtO) gas.

17.3.4. DISINFECTION FOR THE ULTRASONIC PROBE

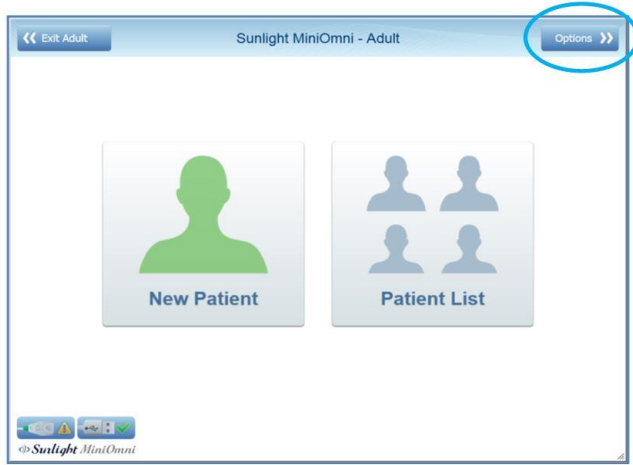
Immediately after cleaning, the patient contact surfaces of the probe should be disinfected. For disinfection, it is not necessary to disconnect the probe from the MiniOmni unit.

The following steps should be followed for disinfecting the probes:

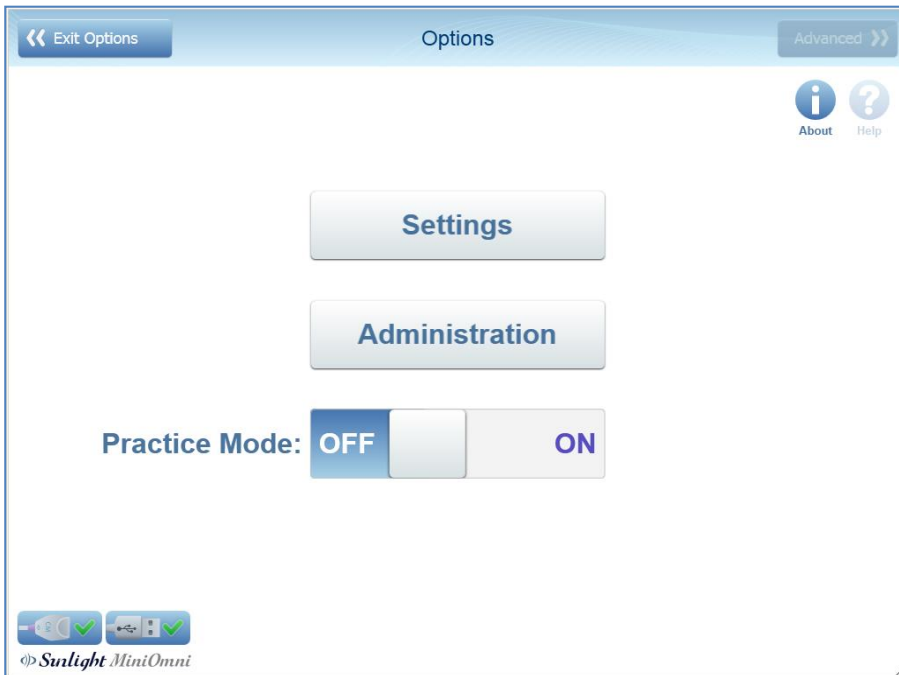
- The patient contact surfaces of the probe should be wiped dry to remove soil and debris before disinfection with a towelette or Alcohol wipes is used.
- Thoroughly wet surface with towelette. Ensure surface remains for a 10-minute contact time at room temperature (20°C/68°F or above).
- Discard used towelettes and empty container in regular trash.

18. OPTIONS SCREEN

The Options screen is displayed by clicking on Options in the main Menu:



The Options screen appears as follows:

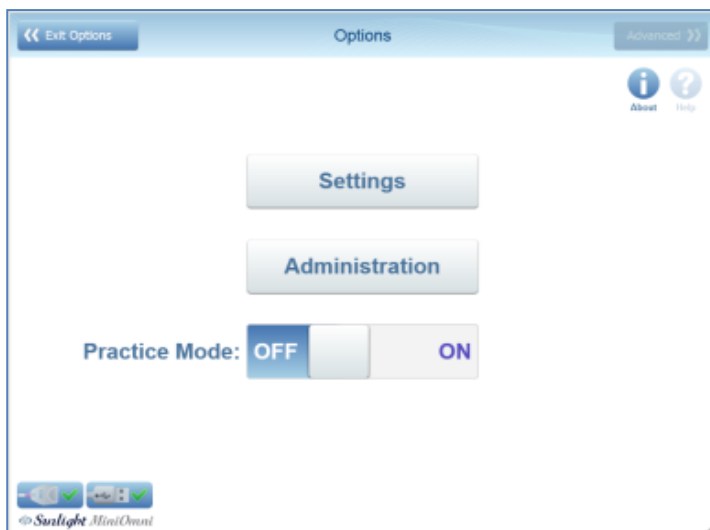


Each option is discussed in the following sections.

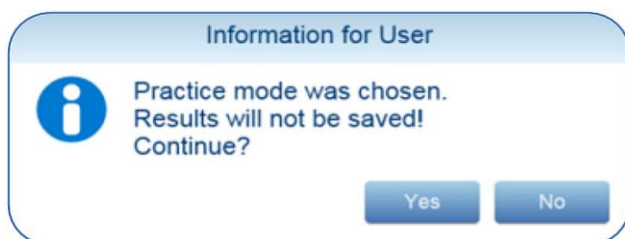
18.1. PRACTICE MODE

The purpose of this feature is to allow the user to practice the specified bone-measurement methodology and receive feedback on his/her performance and measurement precision.

The Practice Mode is accessed from the Options Menu (*Options>Practice Mode*). When this feature is operated, the screen header changes color to light purple, and remains so until the user exits this mode.



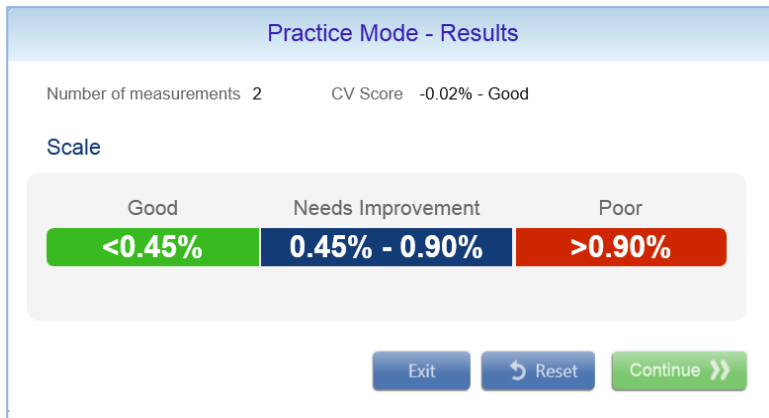
When entering the Practice Mode, a warning appears in the dialog box shown below. You are prompted to confirm the operation by pressing *yes*, or abort by pressing *No*.



When using the practice mode, the application operates in the same manner as in the regular measurement mode described in [Section 11. Performing the Patient Measurement](#), except for the following differences:

- After the user carries out the second measurement, the application calculates and provides the Coefficient of Variance (CV) value and measurement results by means of *a score*, according to a CV score (precision-score) table (see below). From that point on, following each new measurement, the application provides the recalculated CV score.
- The CV score is given per measurement site, and the CV score is site dependent, accordingly.

CV score is a function of the Standard Deviation and your average measurement values. Your CV score should fall in the range stated in the column labeled “Good”, as shown in the table below, for each skeletal site before you start measuring patients.



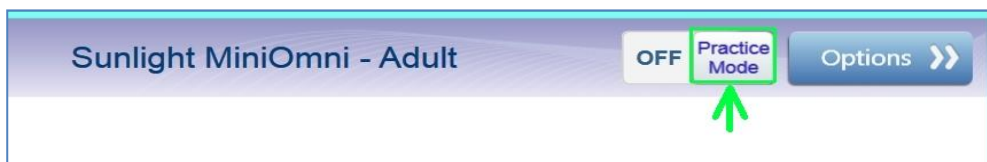
- The user can print the practice session results or data, but these cannot be saved.
- If the software license is of a Pay-Per-Scan type, the following restrictions apply:

1. The user cannot print the practice results or data.
2. Both the measurement results graph and the T and Z-scores are not available.

18.1.1. RESETTING YOUR CV SCORES

If you wish to see your improvement over time, you should reset the CV score after several trials, and begin again. Otherwise, the system will keep averaging your previous “bad” scores against the new ones, lowering your overall score. Resetting your CV scores is done by clicking **Reset** on the Practice Mode Result Box.

You can exit practice mode at any time by simply pressing the **Practice Mode** button on the top of the screen, as show below:



18.2. OPTIONS – ABOUT

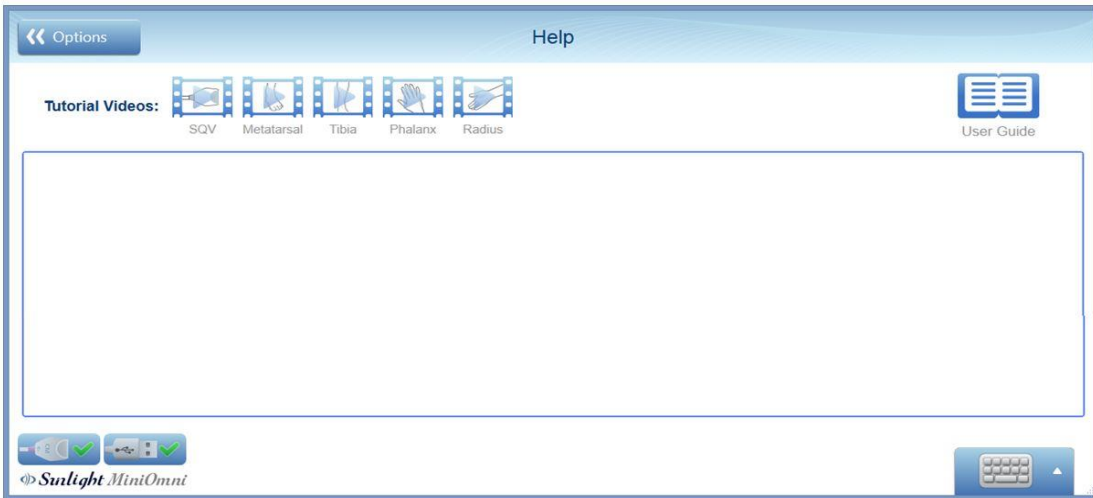
The **About** screen lists system information and other application details.



Sample about screen

18.3. OPTIONS – HELP

The **Help** screen includes icons to display instructional videos, and a searchable online help file.



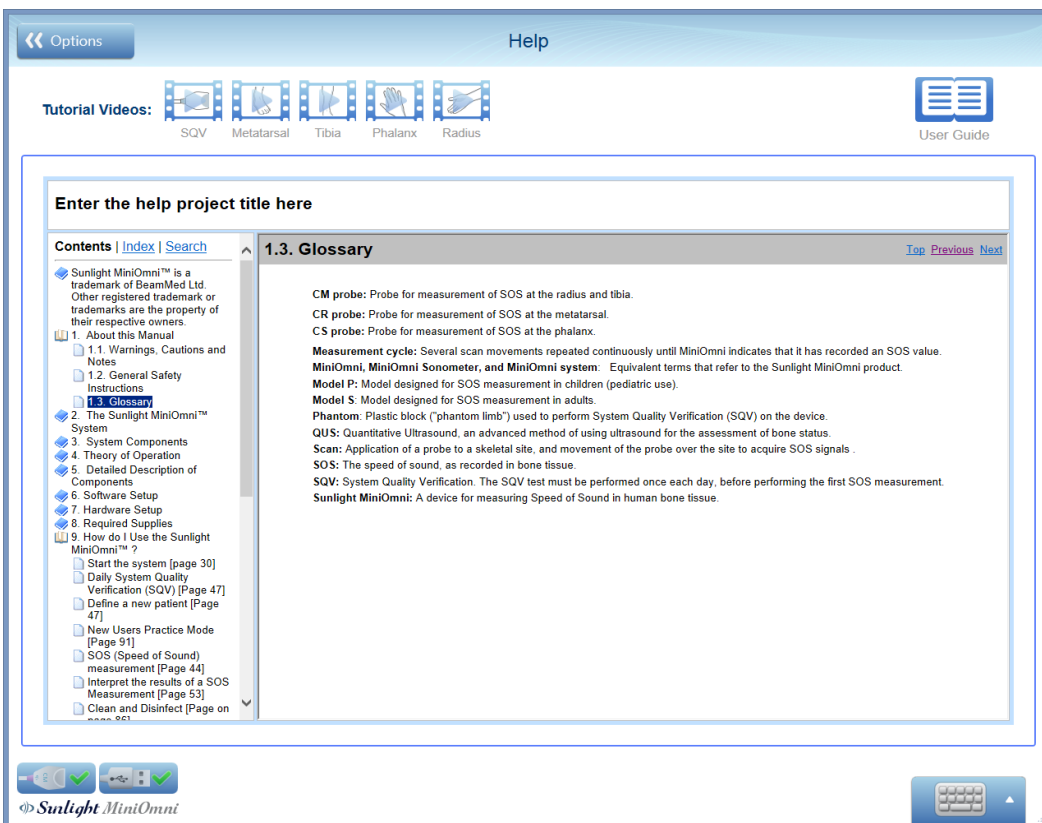
Tutorial Videos – Press to view a brief tutorial on how to perform a measurement on the desired area.

User Guide – Press to see the online Help File.

This is a searchable Help database with detailed information on the MiniOmni system, as shown below.



Note: Please note that Help is available in English. When a device is configured for a language in which a Help program is not available for MiniOmni, the English Help will be displayed instead.



Help screen

18.4. OPTIONS – SETTINGS – DEFAULT VALUES

Information entered on this screen will be used as default values in the appropriate screens in the MiniOmni system.

The screenshot shows the 'Settings' screen for Sunlight MiniOmni. The interface includes a sidebar on the left with 'Defaults' selected, and a main content area with various configuration options. The 'Defaults' section includes text input fields for 'Country' and 'City', dropdown menus for 'Country Code', 'Area Code', 'Ethnicity' (set to 'Caucasian'), 'Measurement units' (set to 'Kg/cm'), and 'Growth Reference' (set to 'USA'). A 'Measurement mode' dropdown is set to 'Graph'. The 'Customize' section contains five unchecked checkboxes: 'Graph time interval (years/months)', 'Print Results history table', 'Physician only', 'Automatic keyboard pop-up', and 'Automatic exporting result as XPS'. At the bottom left, there are icons for a mouse and keyboard with green checkmarks, and the Sunlight MiniOmni logo. At the bottom right, there is a keyboard icon.

Follow on-screen instructions to enter data.

Please note:

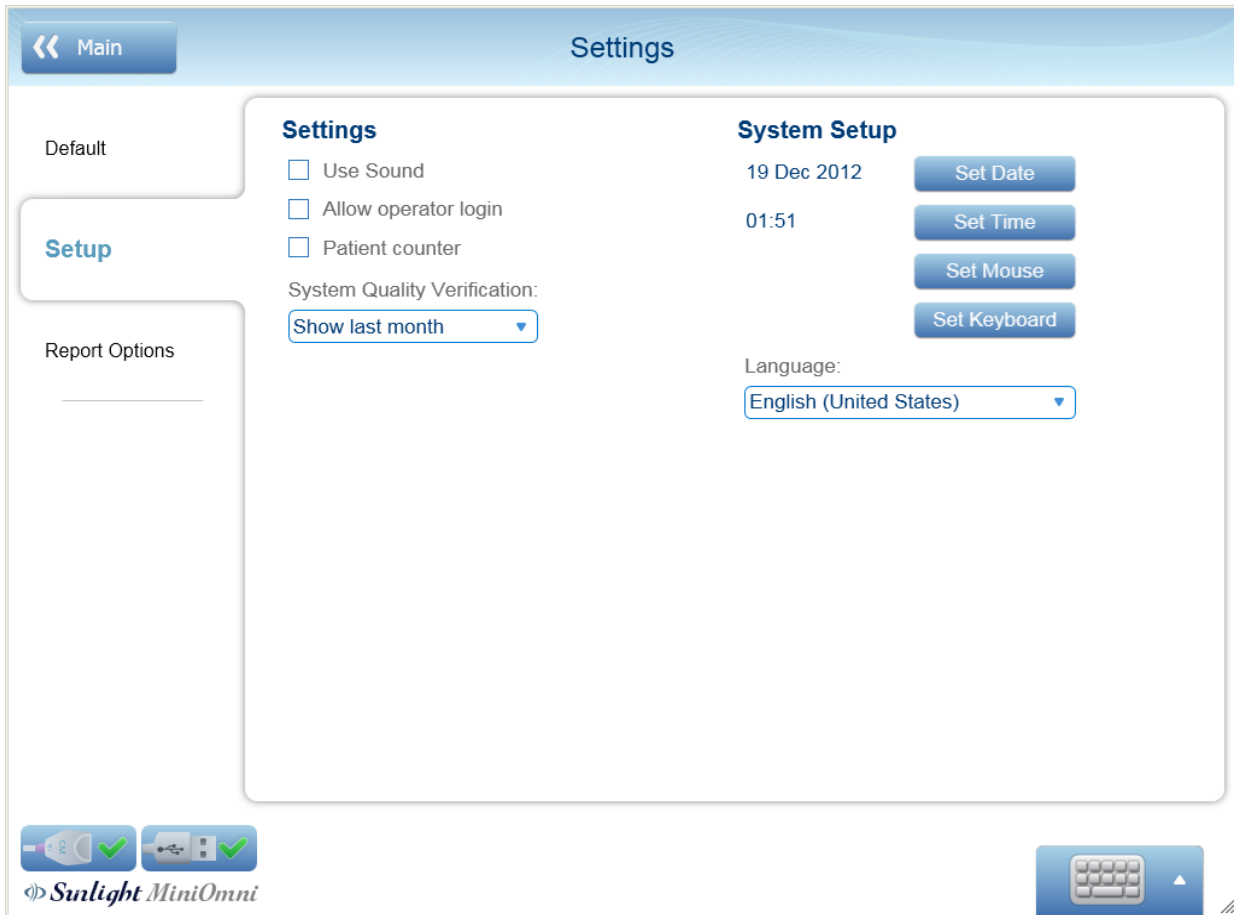
- Data entered for **Country, City, Country Code, Area Code, Ethnicity** and **Measurements units** will appear as patient's details while creating a new patient.
- The selected **Measurement mode** will be the default mode while starting measurement.
- **Growth Reference** will appear in the pediatric patient when opening a new patient file.

Note the following options under **Customize**:

- **Graph time interval** – If checked, change the graph scaling
- **Print Results history table** – If checked, add table of history results to printout
- **Physician only** – If checked, only Physician can see his associated patients.
- **Automatic Keyboard pop-up** – If checked, any text box will pop-up the touch keyboard.
- **Automatic exporting result as XPS** – If checked, only if "Export to HIS" feature activated the SW will automatic save the printed report as XPS format file in the patient folder.

18.5. OPTIONS – SETTINGS – SETUP

This screen allows you to set various system values and options.



Follow on-screen instructions to enter data

Settings:

- **Use Sound** – If checked, the measurement sound will be enabled.
- **Allow operator login** – If checked, the operator can access Physician patients with his password.
- **Patient counter** – If checked, when opening a new patient the application will automatically create patient ID, Name & Last name in sequential order (a1, a2, a3 etc.)
- **System Quality Verification** – The value chosen here will determine time period of the SQV Report History results.

System Setup:

- Invoke the Windows setup screens for the date, time, mouse and keyboard.
- **Language** – Specify the User Interface language.

18.6. OPTIONS – SETTINGS – REPORT OPTIONS

This screen allows you to customize the information that will appear on the printed report.

Settings

← Main

Defaults

Setup

Report Options

Clinic Name: BeamMed Ltd.

Address: 8 Ha-Lapd Str.
Petach-Tikva
ISRAEL

Phone: 972-3-9236869

Email: Support@beammed.com

Fax: 972-3-9236867

Disclaimer: Here your disclaimer will be shown

Text: BeamMed - Focused On Bone Health

Logo Customization:

Import Logo

Remove Logo

Wi-Fi

USB

Sunlight MiniOmni

Keyboard

Follow on-screen instructions to enter data.

All text entered in **Clinic Name**, **Address**, **Phone**, **Email**, **Fax** and **Text** will appear on the printed report header.

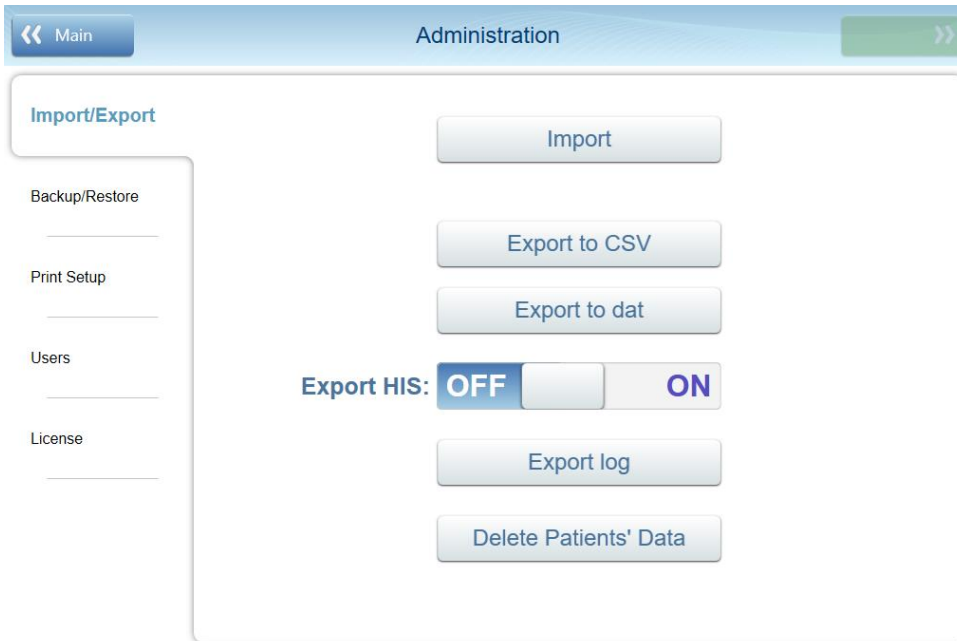
The information entered in **Disclaimer** will be shown on the bottom of the printed report below the device details.

Import Logo – Choose a picture to use as a logo. The logo will be on the printed report header on the left side.

After you import a logo, the **Remove Logo** button is available. Press **Remove Logo** to remove the logo from the printed report header.

18.7. OPTIONS – ADMINISTRATION – IMPORT/EXPORT

The Import/Export options are used by the System Administrator to transfer data to or from another MiniOmni system.

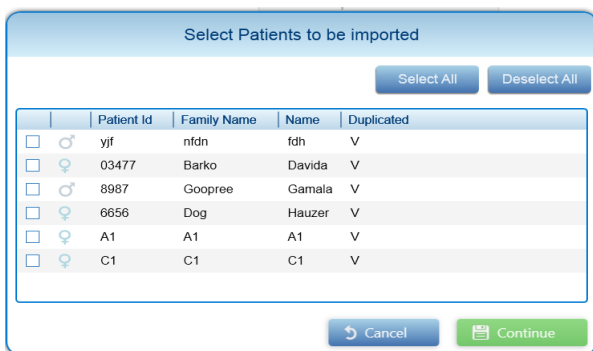


Follow on-screen instructions to enter data.

Import – Import data from another MiniOmni application. The file to be imported must have been created by the **Export to CSV** option discussed below.

Press **Import** to show a standard Windows dialog box to select the file to be imported.

After you open the file, a list of patients will appear. Select one or more patients and press **Continue**.



A confirmation message will appear. Press **OK**. The patients will be available in the patient list.



18.7.1. EXPORTING PATIENT DATA FROM MINIOMNI:

There are several ways of exporting patient data. Depending on how you plan to use the exported data, you can choose from the following options:

- **Export to CSV** – Create a CSV-format file output file. CSV export must be used if you intend to transfer the data to another MiniOmni system.
- **Export to DAT** – Create a DAT format file, the file can be opened with any data reader and it contains the following data –

Patient ID	Patient First Name	Patient Last Name	Patient Date of Birth
Patient Gender	Patient Height	Patient Weight	Measurement Date
Measurement Site Day	Measurement SOS Velocity		Patient T-Score
Patient Z-Score	Patient Percentile (for Pediatric)		

After you press one of these buttons, a screen will display allowing you to choose which patients' information to export:



Select one or more patients. Press **Select Destination** to show a standard Windows dialog box to specify the file name and location for the exported data.

A confirmation message will appear:



Press **OK**.

Exporting log data from MiniOmni:

When working with BeamMed Customer Support, you may be requested to provide system log data.

Click on **Export to log** to create a log data file. A standard Windows dialog box will display to specify the file name and location for the exported log data. Specify the desired file name and location and save the data. Click **OK** on the confirmation screen to complete the process.

18.7.2. OPTIONS – ADMINISTRATION – EXPORT HIS

This feature is an option and should be purchased separately

This feature allows to define a local network target location for automatic export. The exported file type is CSV.

The local hospital information administrator can easily access the file and by defining a relevant script, incorporate the patient measurement data into the patient file on the HIS

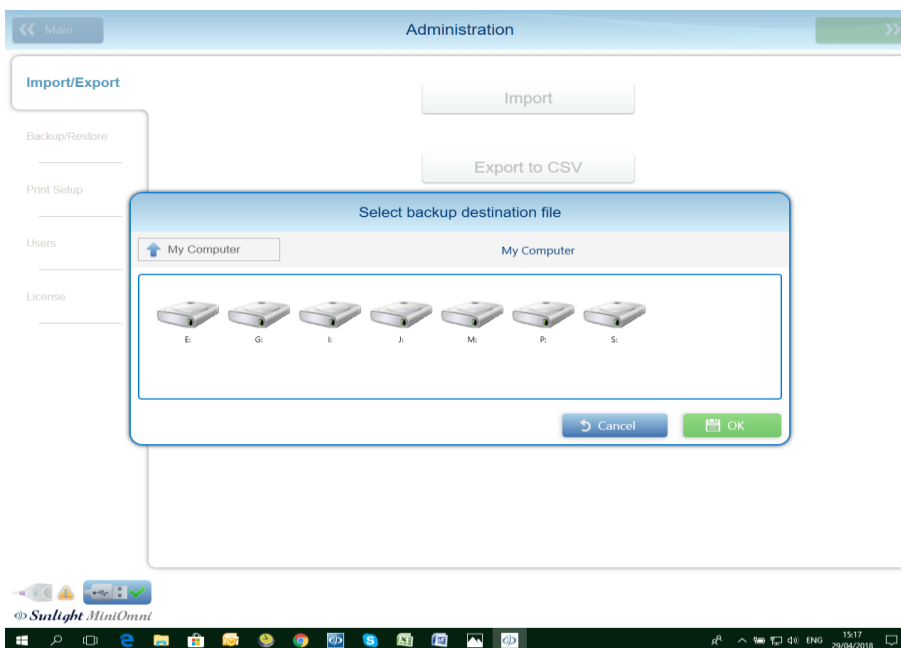
In order to verify that the HIS feature is installed in your system view the license screen as described below:

Omnisense/MiniOmni License screen (Options ► Administration ► License)

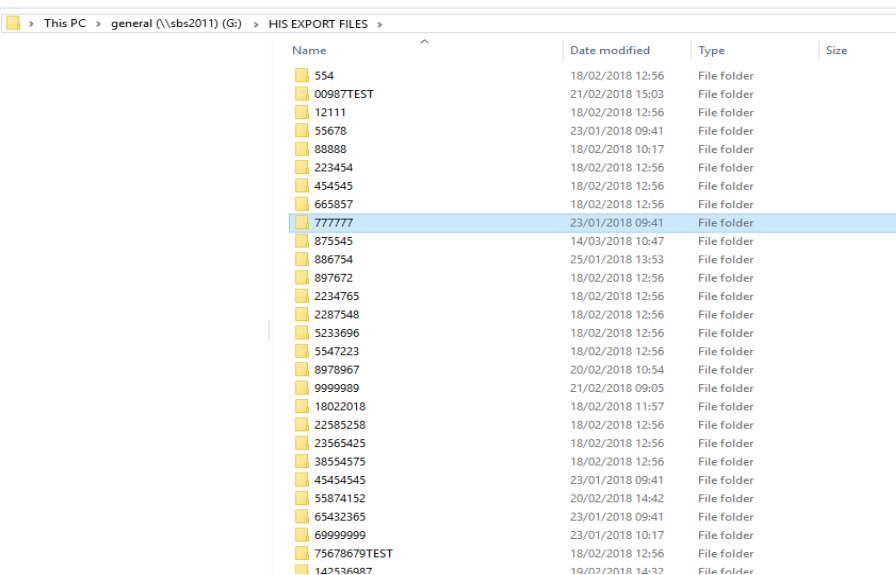
Step 1 - Activating the HIS export function.

Options ► Administration ► Import/Export - click the "Export HIS" activation button.

Step 2 – Define the Export destination.



In the "HIS EXPORT FILES" list, a list of all patients' sub-folders, titled with the patients' ID number shall appear. (see picture below).



Step 3 (Optional) – Export the measurement report

A soft copy of the measurement report can be automatically created. In order to activate this feature, please follow the below instructions:

Click Option ► Settings ► Defaults

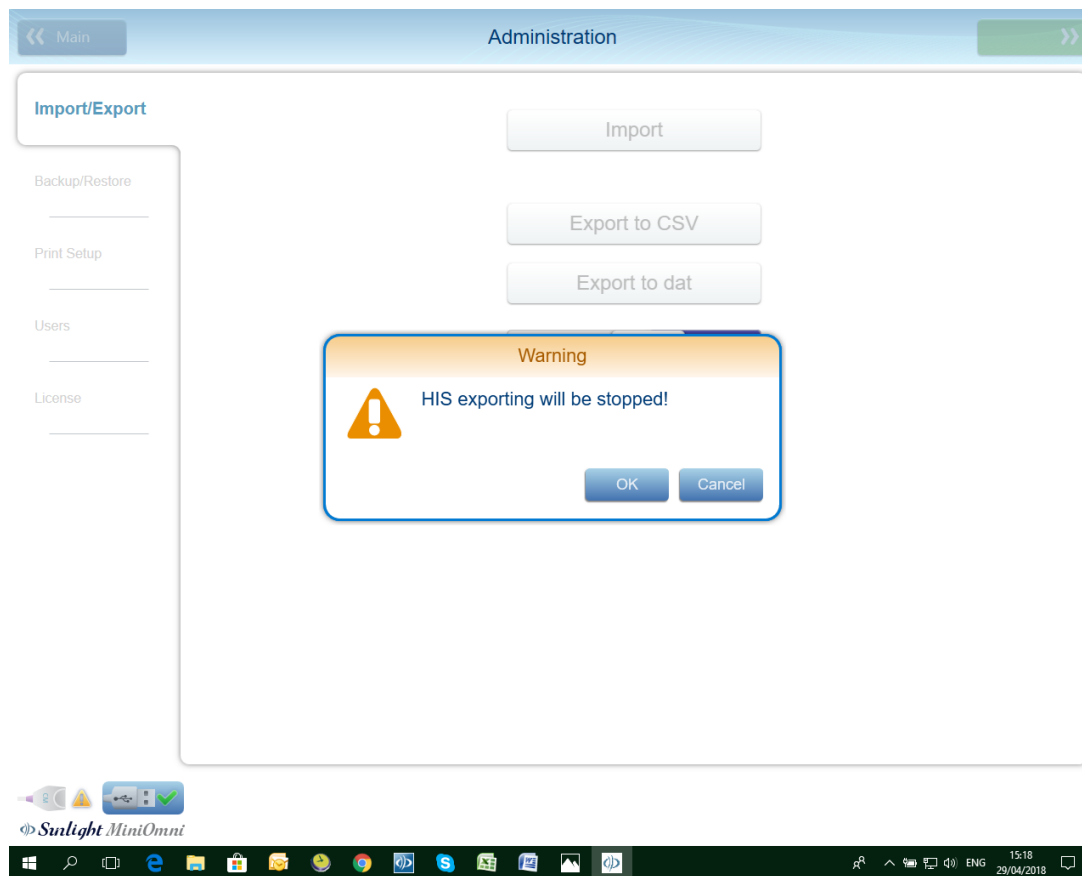
Check the “Automatic exporting results as XPS”.

The image will be saved in the same folder as the previously exported CSV file (see step 2 above)

Step 4 – Canceling the Export to H.I.S function

Click ► Administration ► Import/export

Click the “Export HIS” button, confirm that the warning message and the export deactivates.

**18.7.3. THE CSV FILE STRUCTURE**

The exported file type is CSV –

Microsoft Office Excel Comma Separated Values File (.csv)

The file name consists of the patient ID and the Measurement date.

(For example the file name below shall be 001Testcase_20180430)

The file contains the following information –

Column 1 row 2 – Patient ID

Column 2 row 2 – Patient first name

Column 3 row 2 – Patient last name

Column 4 row 2 – Patient Birth day

Column 5 row 2 – Patient Gender

Column 6 row 2 – Measurement date

Column 7 row 2 – Patient Height (only if inserted in patient file)

Column 8 row 2 – Patient Weight (only if inserted in patient file)

Column 9 row 2 – The measurement Site (Radius, Tibia, Phalanx or Metatarsal)

Column 10 row 2 – Average speed of sound during of measurement

Column 11 row 2 – Patient T score

Column 12 row 2 – Patient Z score

Column 13 row 2 – Percentile (for Pediatric application only)

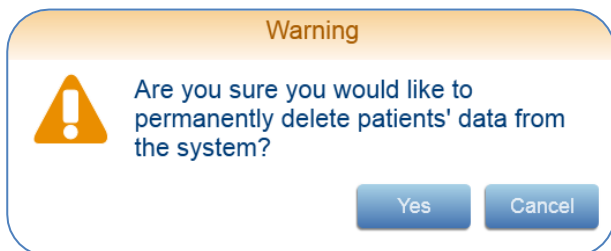
	1	2	3	4	5	6	7	8	9	10	11	12	13
1	ID	FirstName	LastName	BirthDay	Gender	MeasureDate	CurrentHeight	CurrentWeight	SiteName	VelocityAverage	TScore	ZScore	Present
2	001testcase	case	test	30/04/1942	Female	30/04/2018	155	68	DISTAL RADIUS	3837	-3.36735	-0.87755	0

18.7.4. OPTIONS – ADMINISTRATION – DELETE PATIENTS' DATA

This feature allows you to remove patients from the system.

In order to delete patients, proceed as follows:

1. Press **Delete Patients' Data**. The following warning message will appear:



Press **Yes** to continue, or **Cancel** to terminate the request.

2. The application will display a message asking you to confirm your authorized User Name and Password:

A form with a blue border. The text at the top says: "To delete patients' data please enter your operator user name and password and press OK". Below this are two input fields: "User Name" and "Password". At the bottom are two buttons: "OK" and "Cancel".

Enter the requested data and press **OK** to continue, or **Cancel** to cancel the request.

3. The following screen will appear, asking you to indicate which patients to delete:

The screenshot shows a 'Customize Table' dialog box. At the top left is a link 'Customize Table'. At the top right are two buttons: 'Select All' and 'Deselect All'. Below these is a table with the following columns: Gender, ID, First Name, Family Name, Ethnicity, and Date of Birth. The table contains six rows of patient data, each with a checkbox in the first column. At the bottom of the dialog are two buttons: 'Cancel' and 'Delete Selected'.

	Gender	ID	First Name	Family Name	Ethnicity	Date of Birth
<input type="checkbox"/>	♀ Female	049	Elizabeth	e	Caucasian	05/02/
<input type="checkbox"/>	♂ Male	050	s	s	Caucasian	09/08/
<input type="checkbox"/>	♀ Female	051	Satomi	Y	Asian	02/09/
<input type="checkbox"/>	♀ Female	052	Anahid	Mamasyan	Caucasian	01/01/
<input type="checkbox"/>	♀ Female	053	Rositsa	R	Caucasian	06/10/
<input type="checkbox"/>	♂ Male	054	Kula	Kula	Asian	12/11/

Select the patients you wish to delete and press **Delete Selected** to delete them, or **Cancel** to terminate the request.

Note that you may also press **Customize Table** and follow the onscreen instructions to filter the list of patients to only some of the patients in the system. For example, you may wish to only see the list of female patients, or only those patients born after a certain date.

4. The following message will appear, asking you to provide final confirmation to delete the selected patients:

The warning dialog box has a title bar 'Warning' and a yellow warning icon. The text inside asks 'Are you sure you want to remove the selected patients?'. At the bottom are two buttons: 'Yes' and 'No'.

Press **Yes** to delete the patients, or **No** to terminate the request.

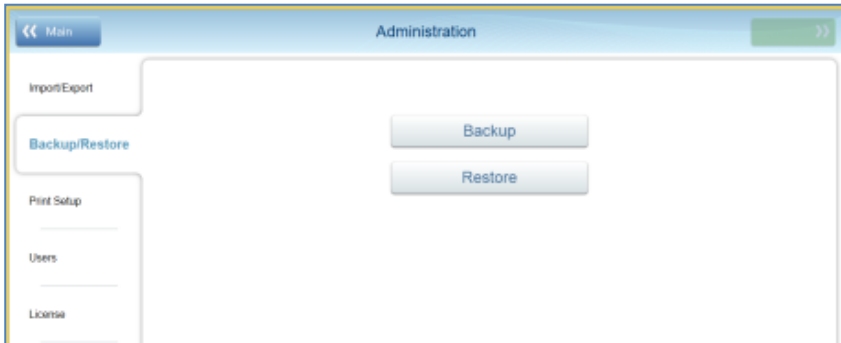
5. If you chose **Yes**, the data is deleted and the following confirmation message will appear:

The confirmation dialog box has a title bar 'Delete succeeded' and a blue information icon. The text inside says 'Patient data was deleted successfully'. At the bottom right is an 'OK' button.

The selected patient data is now deleted from the system.

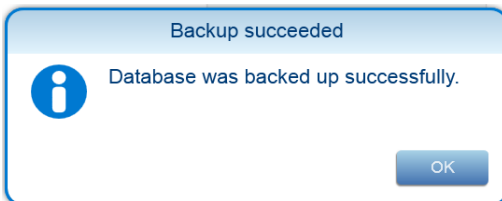
18.8. OPTIONS – ADMINISTRATION – BACKUP/RESTORE

The Backup and Restore options are used by the System Administrator to save the data in the MiniOmni system. In the event of a system failure, the data previously backed up can be used to restore the system.



Backup – Save MiniOmni data to an external location. It is highly recommended to back up your data once a week on removable media, so that in the event of a system problem, you can restore your data.

Press **Backup** to begin the backup process. A standard Windows dialog box will display to specify the file name and location for the backup data. Specify the desired file name and location and save the data. A confirmation screen will display:

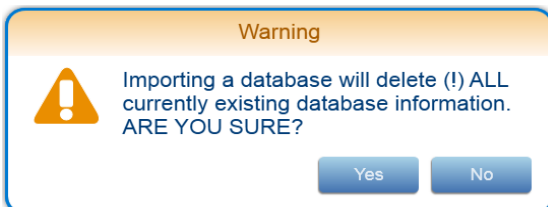


Click **OK** on the confirmation screen to complete the process

Restore – Restore MiniOmni data from an external location. In the event of a system problem, you can use the data that you previously created via Backup to restore your data.

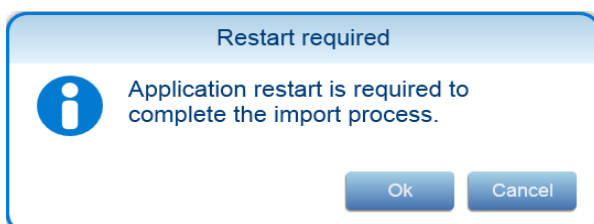
Restore can also be used when migrating data from the DB (database) Converter, as described below.

Press **Restore** to begin the restore process. A standard Windows dialog box will display to allow you to choose a backup file to use as your new MiniOmni data. When you choose a backup file, a warning message will appear:



Press **Yes** to proceed with the Restore function, or **No** to cancel the Restore.

The system will respond with the following message:



Press **OK** to continue the Restore process, or **Cancel** to not restore the data.

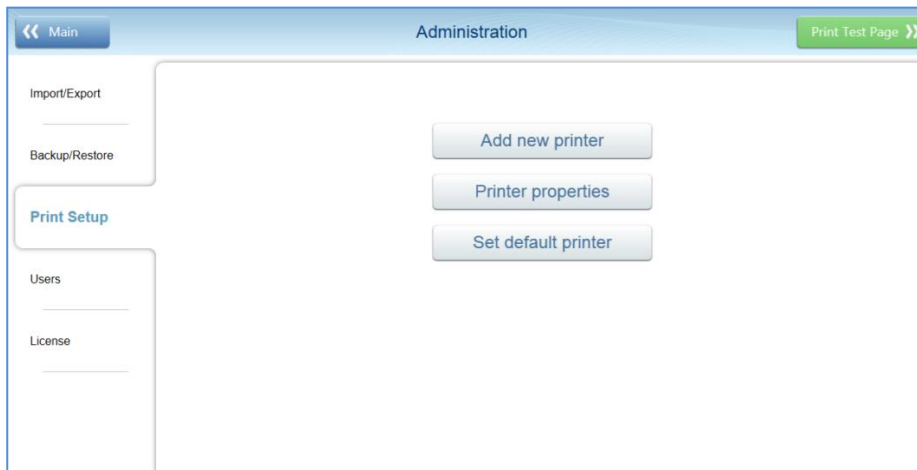
After successful importing the backup data, this message will display:



Press **Restart** to restart MiniOmni and complete the Restore procedure.

18.9. OPTIONS – ADMINISTRATION – PRINT SETUP

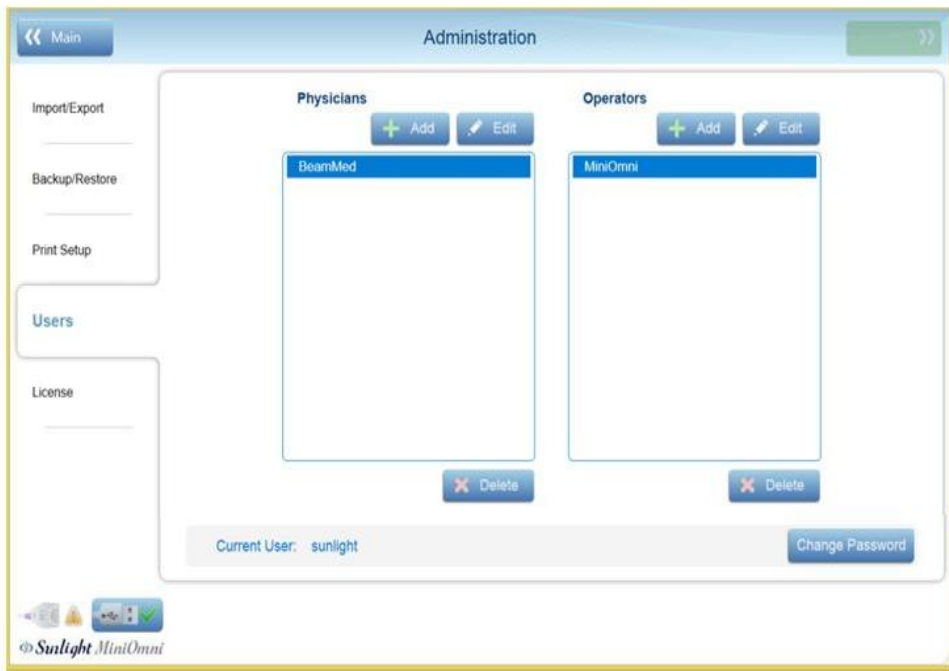
Print Setup is used by the System Administrator to define the characteristics of the printers used with the MiniOmni system.



- | | | |
|------------------------------------|---|--|
| New printer | – | Open the standard Windows screen to add a printer |
| Printer properties | – | Open the standard Windows default printer properties screen |
| Set default printer | – | Open the standard Windows screen to define the default printer |
| Print test page (top right button) | – | Print a standard Windows test page |

18.9.1. OPTIONS – ADMINISTRATION – USERS

This tab allows the System Administrator to manage the list of Physician and Operator users.



The screen presents two lists of users: Physicians and Operators. You can add, edit, and delete users, and change the user's password, subject to the following restrictions:

- All users can edit their own user information (user name and password).
- All users can add, edit and delete the list of Operators.
- The System Administrator can also edit and delete the list of Physicians.

To make a change to the list, first press on the user name that you wish to modify, and then press **Add**, **Edit** or **Delete**.

You may also change your own password (the password for the currently logged-in user) by pressing **Change Password**.



Note: Follow the on-screen prompts to enter the required information.

Edit Physician

User name:

Enter new password:

Reenter new password:

Add new Operator

User name:

Enter new password:

Reenter new password:

Add new Physician

User name:

Enter new password:

Reenter new password:

 **Are you sure you wish to delete Physician BeamMed from the list?**

Change password of sunlight

Enter old password:

Enter new password:

Reenter new password:

18.10. OPTIONS – ADMINISTRATION – LICENSE

This tab allows the System Administrator to manage details of the system license.



License status –

- **Serial** – show the connected device serial number
- **Scans left** – Number of scans remaining (Pay Per Scan option), or "Unlimited".
- **Days left** – If the device has a time limitation, this indicates the days left until license expires
- **Available PC License** – indicates on how many more computers the device can be registered.

License includes – check list that indicates which features are included in the device license.

License PC's –

- License this PC button – Register a new PC to the device (see [Section 7.2. First-Time PC Registration](#)).
- PC ID – show the list of PCs already registered with the device.

Support license code – Press **Copy** to copy the Support License Code to the PC clipboard. You may then paste the code into another application, such as Microsoft Word or Gmail.

Update – Press to enter a new Support License Code. The **Update License** screen will display:



Enter your new license number and press **Update**. You may also **Copy** the license to the clipboard, or **Close** the screen without changing the license.

19. TROUBLESHOOTING



Note: If the Recommended Action does not solve the problem, contact your local dealer.

Condition	Possible Cause	Recommended Action
The MiniOmni Power indicator is not illuminated	DC power cable not connected	Verify that the DC power cable is connected properly, at both ends.
The "USB " Icon is marked with red X.	DC power cable or USB communication cable are disconnected	If the LED indicators are not illuminated, the DC power cable may be disconnected. Make sure that the power cord is connected both at the device end and the wall. Ensure that the device is plugged into the PC's USB port and the device side panel
Message "Disconnected Probe"	Probe is disconnected or USB power is on "power save" mode	Ensure tight connection of the probe. Verify that the USB power save is disabled
Measurement does not start (indicators remain red)	Start button (or foot-pedal) has not been pressed	Make sure to press the Start button (or foot-pedal) have been pressed.
	Insufficient coupling gel	Apply more coupling gel. Check that the probe is in good contact with the patient's skin.
	Measurement is conducted on the wrong location	Measurement is conducted on the wrong location
	Probe not properly connected	Check that the probe is tightly attached to the probe connector and that the screws are tight
	Probe is not in good contact with the patient's skin	Make sure that the probe's surface is in complete touch with on the patient's skin (see Chapter 11 – Performing The Patient Measurement)
	Power is connected through extension cords and/or power splitters	Make sure that power is directly connected to the wall and the original power cord is connected.
The probe image/graph progress and percentage number doesn't progress	Probe is improperly positioned.	Check that the probe is properly positioned for the specific site being measured.
	Patient's soft tissue is too thick or the BMI higher than 35	Use additional pressure to bring the probe closer to the bone. Consider measuring other sites

Condition	Possible Cause	Recommended Action
Results of System Quality Verification are out of phantom range	Test it not according to the instructions.	See Chapter 8 (System Quality Verification Test)
	Device malfunction	Repeat the SQV test, after verifying that there are no air bubbles or dirt between the probe and the phantom and after making sure that the phantom's temperature is fits the room temperature. If the malfunction persists, contact your local dealer for service.
Results do not make sense	Measurement is not performed in line with the instructions	See Chapter 11 PERFORMING THE PATIENT MEASUREMENT for how to perform SOS Measurement. Then, train yourself using Practice Mode (Section 18.1. Practice Mode).

20. OPERATING AND STORAGE CONDITIONS

To ensure warranty coverage and reliable system operation, defective system components should be serviced and/or replaced exclusively by BeamMed authorized personnel, and replacement parts should be those specified by the manufacturer.

Operating environment	Temperature: +10° to +40° C Humidity: 30% to 75% non-condensing Atmospheric pressure: 700hPa to 1060hPa
Storage and transportation conditions	Temperature: 0° to +50° C (32-122° F) Humidity: 10% to 90% non-condensing Atmospheric pressure: 700hPa to 1060hPa

20.1. CONFORMANCE TO STANDARDS

The Sunlight MiniOmni conforms to U.S. and international standards, as described below, for safety, electromagnetic compatibility and acoustic output relative to ultrasound devices. The Sunlight MiniOmni Bone Sonometer generates and emits ultrasonic energy. Emissions have been tested and found to be in conformance with the accepted standard limits for medical diagnostic devices of this type.

Non-clinical testing demonstrated conformance to the following international standards:

IEC 60601-1 (EN 60601-1) Medical electrical equipment, Part 1: General requirements for safety.

IEC 60601-1-2 (EN 60601-1-2) Medical electrical equipment electromagnetic compatibility Requirements and tests.

EN 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.

IEC 61157 Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment.

EN 62304 Medical device software –Software life-cycle processes.

ISO 10993 -1 "Biological evaluation of medical devices": evaluation and testing.

ISO 10993-5 "Test for cytotoxicity: in vitro methods"

ISO 10993-10 "Test for irritation and sensitization"

Monitors, PC's printers and other interfacing accessories used with the Sunlight MiniOmni must meet IEC 601-1, IEC 950, UL 2601 or equivalent safety standards.

21. MINIOMNI TECHNICAL SPECIFICATIONS

Measurement	Speed of Sound (SOS)
Technology	Ultrasound Omnipath® Axial Transmission
Probes	Proprietary multi-transducer probe Center frequency = 1.25 MHz
Measurement Precision & Accuracy	0.25% to 0.6% instrumental accuracy, depending on type of probe
Measurement Time	Approximately 1 minute per skeletal site
User Interface	Start/Stop measurement switch and MiniOmni application screens
Calibration	Calibration is not required. Daily System Quality Verification procedure using the phantom is required.
Display Options	User PC
OS Environment	Windows 10
Conformance to Standards	IEC 60601-1:2005/A1:2012; IEC 60601-1-2:2014.
Power	MiniOmni medical grade power supply 7.5V 1.5A
Power input	Rated steady state input consumption: Max 0.4A
Rating	AC/DC adapters Class I/ Class II
Type of protection against electric shock	Internally powered equipment complies with requirements for Class I or Class II equipment. IPX0 for equipment IPX1 for ultrasonic transducer
Degree of protection against electric shock	BF Type applied part
Main Unit Dimension W H D	W H D 140mm x 223mm x 140mm Not including probe holder
Main Unit Weight (Approximately)	About 1 kg
Interface	USB

22. PC SPECIFICATIONS

Sunlight MiniOmni requires a PC with the following minimum specifications:

Windows 10

1 gigahertz (GHz) or faster 32-bit (x86) or 64-bit (x64) processor,

1 gigabyte (GB) RAM (32-bit) or 2 GB RAM (64-bit),

16 GB available hard disk space (32-bit) or 20 GB (64-bit),

DirectX 9 graphics device with WDDM 1.0 or higher driver,

Super VGA (800 x 600) or higher-resolution video adapter and monitor,

Keyboard and Mouse,

Sound card with speakers or headset,

8 MB of video RAM.

23. MANUFACTURER DECLARATION

23.1. GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS


The MiniOmni is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniOmni should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The MiniOmni 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		The MiniOmni is suitable for use in all establishments, including domestic establishments and those directly
CISPR 11	Class B	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

23.2. GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The MiniOmni is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniOmni should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	6 kV contact discharge 8 kV air discharge	Floors should be wood, concrete, ceramic tile, or covered with synthetic material. The relative humidity should be 30 % -75% non-condensing.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	100 and 230 Vac mains: ±2kVTr/Th -5/5- ns, 5 kHz Probe cable ±1kV	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 line(s) to earth	100 and 230 Vac mains: ±2cm/±1.0 KV DM Tr/Th -1.2/50 (8/20) µs	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 25 cycles <5 % UT (>95 % dip in UT) for 5 s	100 and 230 VAC mains; > 95% -10ms; 60% -100ms; 30% -500ms; >95% -5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME 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 50Hz/ 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

23.3. GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The MiniOmni is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniOmni should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the MiniOmni, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ <p style="text-align: right;">80 MHz to 800 MHz</p> $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ <p style="text-align: right;">800 MHz to 2,5 GHz</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	<p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.</p> <p>If interference may occur in the vicinity of equipment marked with the following symbol:</p> 

23.4. GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC EMISSIONS			
The MiniOmni is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniOmni should assure that it is used in such an environment.			
Emissions (IEC 60601-1-2 section 7)			
Conducted emission Freq. range: 150 kHz-30 MHz	CISPR 11	Group 1 Class B 230, 120 & 100 VAC mains (PS)	Complies
Radiated emission Freq. range: 30-1000 MHz	CISPR 11	Group 1 Class B	Complies
Harmonic current emission test	IEC 61000-3-2	203 VAC mains (PS)	Test N/A
Voltage changes, voltage fluctuations and Flicker test	IEC 61000-3-3	203 VAC mains (PS)	Complies
Immunity (IEC 60601-1-2 section 8)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	10.0 V/m; 80MHz ÷ 2.7 GHz, 80% AM, 1kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies (Table 9 of the standard), from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	± 2.0 Kv; Tr/Th – 5/50 ns, 100 kHz on AC mains (PS)	Complies
Immunity from Surge	IEC 61000-4-5	± 1.0 kV DM/±2.0 kV CM on AC mains (PS); Tr/Th – 1.2/50 (8/20) µs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	6.0 Vrms, On AC mains, Probe and USB cables; 0.15÷80MHz, 80% AM 1 kHz	Complies
Immunity from voltage dips, short interruptions and voltage variations	IEC 61000-4-11	0% - 0.5 cycle & 1 cycle; 70%-25 cycles; 0% - 250 cycles on AC mains (PS)	Complies

23.5. RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE [ME EQUIPMENT OR ME SYSTEM]

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

	Separation distance according to frequency of transmitter		
	m		
Rated maximum output power of transmitter W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5
	$d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

24. SOFTWARE LICENSE AND WARRANTY

SOFTWARE LICENSE AND WARRANTY

SOFTWARE LICENSE, WARRANTY AND LIMITATION OF LIABILITY

Sunlight MiniOmni^(TM)

The terms of the Software License, Product Warranty and Limitation of Liability specified below are an essential part of your agreement with BeamMed Ltd. {hereinafter, BeamMed} By using any BeamMed equipment and/or product and/or software described in this manual, you agree to be bound by these terms. If you do not agree to these terms, please contact your local dealer within five days of receipt of any BeamMed equipment and/or product and/or software and return it.

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Limitation of Liability

In no event shall BeamMed be liable for any direct, indirect, special, incidental or consequential losses, damages or expenses whether based on contract, tort, or any other legal theory and whether or not advised of such damages.

BEAMMED LTD.**SUNLIGHT MiniOmni UNIT/ULTRASONIC PROBES EXCLUSIVE AND LIMITED ONE YEAR WARRANTY****A. Warranty Coverage**

1. The products covered by this warranty are the following: (i) Sunlight MiniOmni System Unit, and (ii) Ultrasonic Probes (hereinafter the Product or Products).
2. Products manufactured by BeamMed Ltd. ("the Company") are covered by a warranty against defects in materials or workmanship. If the Company receives notice of such defects during the warranty period, the Company shall either repair the Product or replace it, with a new Product or equivalent, at its sole discretion. If the Company is unable to repair or replace a defective Product, it shall refund the Product's purchase price to the Company's customer, provided that the customer has returned the Product to the Company. Any transport costs will be paid by the customer. Any Product so replaced or repaired shall be subject to this warranty for the remaining of the warranty period or 30 days, whichever is later.
3. This warranty is valid in any country in which the Company's Products are distributed by the Company or its authorized distributor.

B. Duration and Commencement of Warranty Period

1. The warranty period for each Product is one year. The warranty period begins on the date the Product was purchased.

C. Limitation of Warranty

1. The Company does not warrant that the operation of Products will be uninterrupted or error-free.
2. The foregoing warranty applies only to defects resulting from normal use of the Products within the country in which it was purchased, and does not apply to defects resulting from:
 - (a) Improper or inadequate maintenance;
 - (b) Use of any parts or software not supplied by the Company;
 - (c) Unauthorized modification or misuse of the Product;
 - (d) Operation outside the range of the environmental specifications of the Product;
 - (e) Improper site preparation or maintenance;
 - (f) Accidental damage, whether in transit or otherwise.
3. Except as provided for in this warranty, neither the Company nor any of its suppliers makes any other warranties, whether express or implied and whether statutory or otherwise, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. The remedies herein contained are the sole and exclusive remedies of the customer.
4. This warranty gives the customer specific legal rights, but applicable local laws may provide additional legal rights or prohibit certain terms or conditions of this warranty. Any provision of this warranty that is prohibited by local law is therefore null and void.

25. CLINICAL STUDIES

Please contact the BeamMed Ltd representative for Clinical Studies Information.

26. TANNER STAGES OF PUBERTY

The Tanner stages of puberty¹ are well-known classification tables used to classify pubertal individuals according to the stage of puberty. Classification is made according to patient self-report or physical examination by the physician. Tables for males and females appear below.

26.1. TANNER STAGES OF MALE PUBERTY

STAGE	GENITAL STAGE	PUBIC HAIR STAGE
1 (preadolescent)	Testes, scrotum, and penis are about the same size and proportion as those in early childhood.	Vellus over the pubes is no further developed than that over the abdominal wall, i.e., no pubic hair.
2	Scrotum and testes have enlarged, and there is a change in the texture of scrotal skin and some reddening of scrotal skin.	There is sparse growth of long, slightly pigmented, downy hair, straight or only slightly curled, appearing chiefly at base of penis.
3	Growth of the penis has occurred, at first mainly in length but with some increase in breadth. There has been further growth of the testes and the scrotum.	Hair is considerably darker, coarser, and more curled and spreads sparsely over junction of pubes.
4	The penis is further enlarged in length and breadth, with development of glans. The testes and the scrotum are further enlarged. There is also further darkening of scrotal skin.	Hair is now adult in type, but the area covered by it is smaller than that in most adults. There is no spread to the medial surface of the thighs.
5 (adult)	Genitalia are adult in size and shape. No further enlargement takes place after stage 5 is reached.	Hair is adult in quantity and type, distributed as an inverse triangle. There is spread to the medial surface of the thighs but not up the linea alba or elsewhere above the base of the inverse triangle.

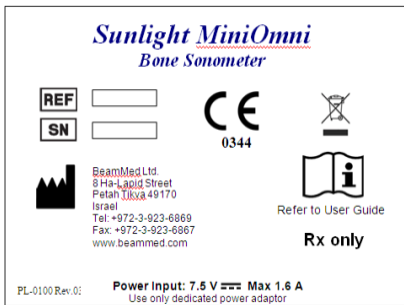
¹ W. A. Marshall, J. M. Tanner, "Variations in the pattern of pubertal changes in boys," Archives of Disease in Childhood, London, February 1970, 45 (239): 13-23. and W. A. Marshall, J. M. Tanner, "Variations in pattern of pubertal changes in girls," Archives of Disease in Childhood, London, June 1969, 44 (235): 291-303

26.2. TANNER STAGES OF FEMALE PUBERTY

STAGE	BREAST	PUBIC HAIR
1 (preadolescent)	Only papillae are elevated.	Vellus hair only and hair is similar to development over anterior abdominal wall (i.e. no pubic hair).
2	Breast bud and papilla are elevated and a small mound is present; areola diameter is enlarged.	There is sparse growth of long, slightly pigmented, downy hair or only slightly curled hair, appearing along labia.
3	Further enlargement of breast mound; increased palpable glandular tissue.	Hair is darker, coarser, more curled, and spreads to the pubic junction.
4	Areola and papilla are elevated to form a second mound above the level of the rest of the breast.	Adult-type hair; area covered is less than that in most adults; there is no spread to the medial surface of thighs.
5 (adult)	Adult mature breast; recession of areola to the mound of breast tissue, rounding of the breast mound, and projection of only the papilla are evident.	Adult-type hair with increased spread to medial surface of thighs; distribution is as an inverse triangle.

27. LABELS AND SYMBOLS

27.1. LABELS



Sample labeling

27.2. SYMBOLS

A number of internationally recognized symbols are found on the MiniOmni unit. These relate to safety requirements and standards and are briefly reviewed below.

Symbol	Meaning
	Caution, consult accompanying documents
SN	Serial number and date of manufacture
REF	Catalog number
	Manufacturer
	Consult instructions for use
	The System cannot be disposed as unsorted municipal waste. Please contact your local distributor for unit disposal.
	CE Mark, indicating that the device complies with the Council Directive 93/42 EEC (MDD), amended by Council Directive 2007/47/EC.
	Authorized representative in the European community.

27.3. ELECTRONIC DISPOSAL

This product must NOT be disposed of with other household waste. Instead, it is the user's Responsibility to dispose of their waste electrical and electronic equipment by handing it over to an Approved re-processor or by returning it to BeamMed or their distributor for recycling.