User Guide

Sunlight MiniOmni™

Ultrasound Bone Sonometer

BeamMed

Focused On Bone Health

GENERAL

Software Version 2.1

Text Revised: January 17, 2022 © BeamMed Ltd.

Document Number DUM-0081 Revision 08

Note: The information in this document is confidential and proprietary. It is provided to customers and authorized representatives of BeamMed Ltd. only.

Sunlight MiniOmni™ is a trademark of BeamMed Ltd. Other registered trademark or trademarks are the property of their respective owners.

The Quality Management System of BeamMed Ltd. complies with applicable regulaory requirements.

CONTACT INFORMATION

Customer satisfaction is a BeamMed priority. To help us in providing you with the best possible product and support, please send us your comments and suggestions.

BeamMed Ltd.

8 Ha-Lapid Street

Petah Tikva 4925822

Israel

Tel. +972 (3) 923 6869

Fax. +972 (3) 923 6867

E-mail: info@BeamMed.com

TABLE OF CONTENTS

GENERAL 2

CONTACT INFORMATION 2

TABLE OF CONTENTS 3

1. ABOUT THIS MANUAL 6

1.1. GLOSSARY 6

2. ESSENTIAL PRESCRIBING INFORMATION 7

2.1. DEVICE DESCRIPTION 7

2.1.1. Probes 7

2.2. INTENDED USE 7

2.3. CONTRAINDICATIONS 8

2.4. WARNINGS AND PRECAUTIONS 9

2.5. GENERAL SAFETY INSTRUCTIONS 9

2.6. ADVERSE EVENTS 12

3. SYSTEM COMPONENTS 13

3.1. IDENTIFYING SYSTEM COMPONENTS 13

3.1.1. Standard Components 13

3.1.2. Optional Accessories 15

4. DETAILED DESCRIPTION OF COMPONENTS 16

4.1. MINIOMNI MAIN UNIT 16

5. SOFTWARE SETUP 17

5.1. PRIOR TO INSTALLATION 17

5.2. SETUP 18

5.3. MICROSOFT .NET FRAMEWORK AND MICROSOFT VISUAL STUDIO 18

5.4. MINIOMNI SOFTWARE INSTALLATION 18

5.5. RUN MINIOMNI 19

5.6. MINIOMNI – SOFTWARE UPDATE 19

6. HARDWARE SETUP 21

6.1. STEP 1 – CONNECTOR CABLES, POWER SUPPLY AND FOOT PEDAL (OPTIONAL) 21

6.1.1. MiniOmni USB Data Connector 21

6.1.2. Power Supply 22

6.1.3. Foot Pedal 22

6.2. STEP 2 – CONNECTING THE PROBE 22

6.3. STEP 3 – VERIFY APPLICATION-DEVICE COMMUNICATION 23

7. STARTING THE SYSTEM 24

7.1. WELCOME AND LOGIN 24

7.1.1. A Note on User Names in MiniOmni 24

7.2. FIRST-TIME PC REGISTRATION 24

7.3. AUTOMATIC SQV OPTION ON FIRST LOGON EACH DAY 25

7.4. OVERVIEW OF THE MINIOMNI SCREEN 26

8. SYSTEM QUALITY VERIFICATION (SQV) 27

8.1. WHAT IS SQV? 27

8.2. PERFORMING SYSTEM QUALITY VERIFICATION 28

© 2022 BeamMed Ltd.

8.2.1. Finding the SQV Screen *28*
8.2.2. Using the SQV Screen *29*
8.2.3. Prepare probe *30*
8.2.4. Position the phantom and probe *30*
8.2.5. Check for acoustic coupling *30*
8.2.6. Execute the measurement *31*
8.2.7. Determine the Expected SOS Value for the Phantom SQV Test *31*
8.2.8. Enter the Expected SOS Value *32*
8.2.9. Check the result *33*
8.2.10. Print Result *34*
8.3. Patient Selection and Options 35

9. PATIENT MAINTENANCE 36

9.1. New Patient – General 36
9.2. New Patient Clinical Info 37
9.3. selecting a patient from the Existing Patient List 38
9.4. Deleting a Patient 39

10. PERFORMING THE PATIENT MEASUREMENT 40

10.1. Locating the Measurement Site for the Distal ⅓ Radius 40
10.1.1. Position the patient and the limb *40*
10.1.2. Identify the Region to be measured *40*
10.1.3. Mark the exact half point *41*
10.2. Understanding the MiniOmni Measurement Screen 41
10.2.1. Terms and Definitions *41*
10.3. Measurement Screen Formats 42
10.3.1. Measuring SOS at the Radius *42*
10.3.2. Completing the Measurement - steps *43*

11. MEASUREMENT RESULTS 46

11.1. Measurement Results screen 46
11.2. Printing/Saving the report 47
11.3. Bone Density Measurement 48
11.4. Guidelines to Evaluating the SOS Measurement 49
11.4.1. SOS Value, T-score and Z-score *49*
11.5. Measurement History 50
11.6. Deleting a Measurement Result 51

12. MULTI-SITE MEASUREMENTS 52

12.1. Preparing for the SOS Measurement 52
12.2. Proximal Phalanx of the Third Finger Site 53
12.2.1. Position the patient *53*
12.2.2. Identify the Region to be measured *53*
12.3. Metatarsal V Site 55
12.3.1. Positioning the patient *56*
12.3.2. Determining the area to be scanned *56*
12.3.3. Measuring SOS at the Metatarsal V *57*

13. CLOSING THE MINIOMNI APPLICATION 59

14. CLEANING AND DISINFECTING 60

14.1. General Instructions 60
14.2. The MiniOmni Device 60

© 2022 BeamMed Ltd.

14.2.1. Cleaning the MiniOmni Device *60*
14.3. The Ultrasonic Probe 60
14.3.1. Cleaning Precautionary Notes for the Ultrasonic Probe *60*
14.3.2. Cleaning the Ultrasonic Probe *60*
14.3.3. Disinfection Precautionary Notes for the Ultrasonic Probe *61*
14.3.4. DisinfectinG the Ultrasonic Probe *61*

15. OPTIONS SCREEN 62

15.1. Practice Mode 63
15.1.1. Resetting your CV scores *64*
15.2. Options – About 64
15.3. Options – Help 65
15.4. Options – Settings – Default Values 66
15.5. Options – Settings – Setup 67
15.6. Options – Settings – Report Options 68
15.7. Options – Administration – Import/Export 69
15.7.1 Exporting patient data from MiniOmni *70*
15.7.2. Options – Administration – Export HIS *71*
15.7.3.The CSV file structure *72*
15.7.4. Options – Administration – Delete Patients' Data *73*
15.8. Options – Administration – Backup/Restore 75
15.9. Options – Administration – Print Setup 76
15.9.1. Options – Administration – Users *77*
15.10. Options – Administration – License 78

16. TROUBLESHOOTING 79

17. OPERATING AND STORAGE CONDITIONS 81

17.1. Conformance to Standards 81

18. MINIOMNI TECHNICAL SPECIFICATIONS 82

19. PC SPECIFICATIONS 83

20. MANUFACTURER DECLARATION 84

20.1. Guidance and manufacturer's declaration – electromagnetic emissions 84
20.2. Guidance and manufacturer's declaration – electromagnetic immunity 84
20.3. Guidance and manufacturer's declaration – electromagnetic immunity 85
20.4. Guidance and manufacturer's declaration – electromagnetic emissions 85
20.5. Recommended separation distances between portable and mobile RF communications equipment and the [ME Equipment or ME System] 86

21. SOFTWARE LICENSE AND WARRANTY 87

22. CLINICAL STUDIES 89

23. LABELS AND SYMBOLS 90

23.1. Labels 90
23.2. Symbols 90
23.3. ElectRonic disposal 90

© 2022 BeamMed Ltd.

1. ABOUT THIS MANUAL

This guide provides the information necessary to operate the Sunlight MiniOmni™ system in a safe and efficient manner. Please read and thoroughly understand the guide before operating the system. If any part of this guide is not clear, contact your distributor or BeamMed's customer support for clarifications.

1.1. GLOSSARY

CM probe: Probe for measurement of the Speed of Sound (SOS) at the radius.

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 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.

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 Device Description*, 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 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 FDA.

It is comprised of a Main Unit and 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.

No calibration is required. Daily system verification is accomplished by 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.
- **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.

2.2. INTENDED USE

© 2022 BeamMed Ltd.

The Sunlight MiniOmni Ultrasound Bone Sonometer is a non-invasive device that is designed for the quantitative measurement of the signal velocity of ultrasound waves (“Speed of Sound” or “SOS” in m/sec) propagating at multiple skeletal sites (i.e., the distal one-third of the radius, the proximal third phalanx and the fifth metatarsal). SOS provides an estimate of skeletal fragility.

The output is also expressed as a T-score and a Z-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.

Multiple skeletal site testing provides clinicians with alternatives if one site is not accessible. It also provides additional skeletal information (i.e., from bones with different combinations of cortical and cancellous material and from weight bearing and non-weight bearing sites) that assists in diagnosing osteoporosis and 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 in the early years following menopause (i.e., age range of approximately 50-65 years).

2.3. CONTRAINDICATIONS

None.

© 2022 BeamMed Ltd.

2.4. WARNINGS AND PRECAUTIONS

Three types of special messages appear in this User Guide:

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 14.2.1*Chapter 14.2.1. 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: PCs, 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.

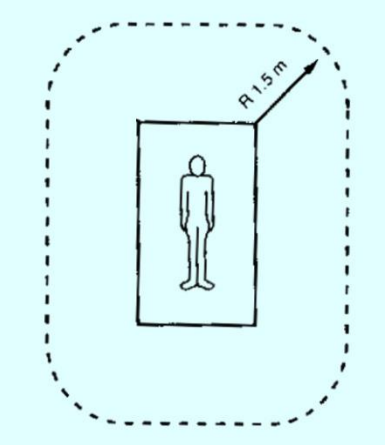
Warning: Medical device regulations restrict the operation of the BeamMed application to trained and qualified personnel.

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

© 2022 BeamMed Ltd.

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

- 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.
- 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.



- 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 Guide is intended for the sole and exclusive use of the Company's customers with the BeamMed application. Any other unauthorized use of this Guide 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.

© 2022 BeamMed Ltd.

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

Caution: Refer all service problems to qualified BeamMed representatives 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 59 and 86 degrees Fahrenheit (15-30 degrees Centigrade).

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 9.4. 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 13. 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, using different probes (CS for proximal Phalanx III or CR for the Metatarsal V)

© 2022 BeamMed Ltd.

2.6. ADVERSE EVENTS

Sunlight MiniOmni is based on the well-established Sunlight Omnipath™ technology and the predicate Sunlight Omnisense device, already CE marked and approved by FDA. 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 especially 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.

© 2022 BeamMed Ltd.

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 of damages. If it was damaged, please note this condition on the bill of landing 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 Standard Components* below.

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 19. 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		Use to measure the **radius**.

Standard Component		**Notes**
Radius measurement gauge		Used to locate the scan site for the Radius.
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).
USB connection cable		Dedicated USB cable for MiniOmni.

© 2022 BeamMed Ltd.

3.1.2. OPTIONAL ACCESSORIES

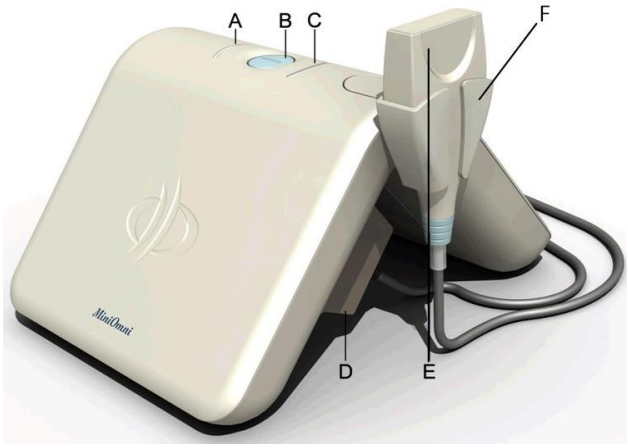
In addition, the MiniOmni system includes the following optional accessories:

Optional Accessory		**Notes**
CS ultrasound probe		Use to measure the **phalanx**. Requires Multi Site license
CR ultrasound probe		Use to measure 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.

© 2022 BeamMed Ltd.

4. DETAILED DESCRIPTION OF COMPONENTS

4.1. MINIOMNI MAIN UNIT

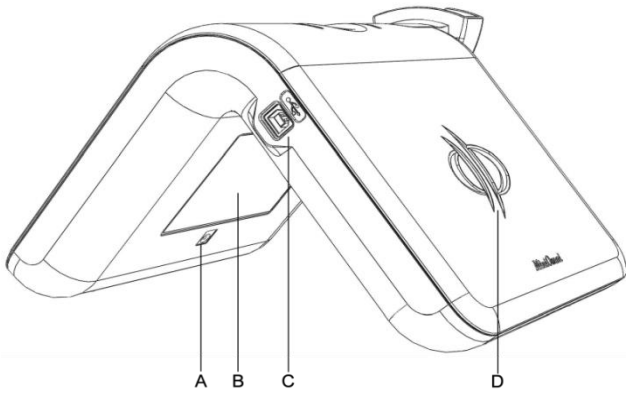


MiniOmni Indicators and Ports:

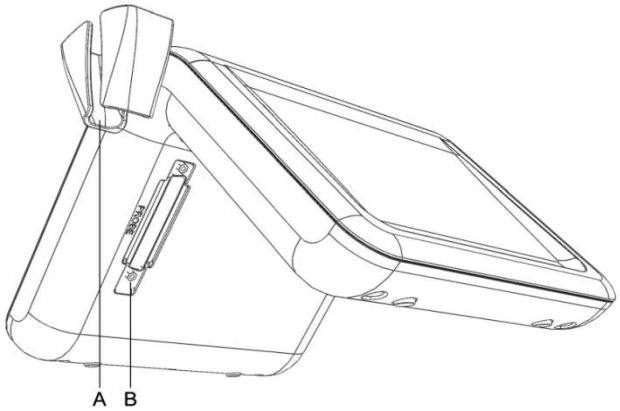
A. Connection Indicator LED
B. Measure button
C. Measure Indicator LED
D. Probe connector
E. MiniOmni probe
F. Probe holder

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 connector

When conducting an SOS measurement, the Operator uses a hand-held probe at the area of interest, applied directly on the patient's skin.

5. SOFTWARE SETUP

5.1. PRIOR TO INSTALLATION

Ensure that the PC / laptop you intend to use with MiniOmni meets the technical requirements given in *Section 19. PC Specifications*.

Note: It is recommended to install the MiniOmni software on a new or recently formatted PC/laptop.

1. SOFTWARE DOWNLOAD

Prior to downloading the software, please make sure that your laptop includes WinZip / WinRar, that allows exctraction of files in ZIP format.

To download the MiniOmni software, please visit the below web address:

https://www.beammed.com/software-download/

The password is – gili2020

After downloading the file, the Win RAR application would allow Extracting the software file.

Select "Extract To" and save the software to your own Local Computer drive or removable media (such as a thumb-drive).

Search for the new zipped file "MiniOmni FDA 2.1.0."

Click on it to open.

Keep opening the File name MiniOmni FDA 2.1.0.until you see file named -setup.exe.

Ensure that your user permission is set to “administrator”.

Note that in some cases, your firewall may need permission for any new installation. In this case, please contact your I/T deaprtment for their assistance.

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

Click the Start button windows .

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 your computer.

Follow the below user guide to install the MiniOmni software.

Follow this guide from *Step 5.2 Setup* to install the MiniOmni software.

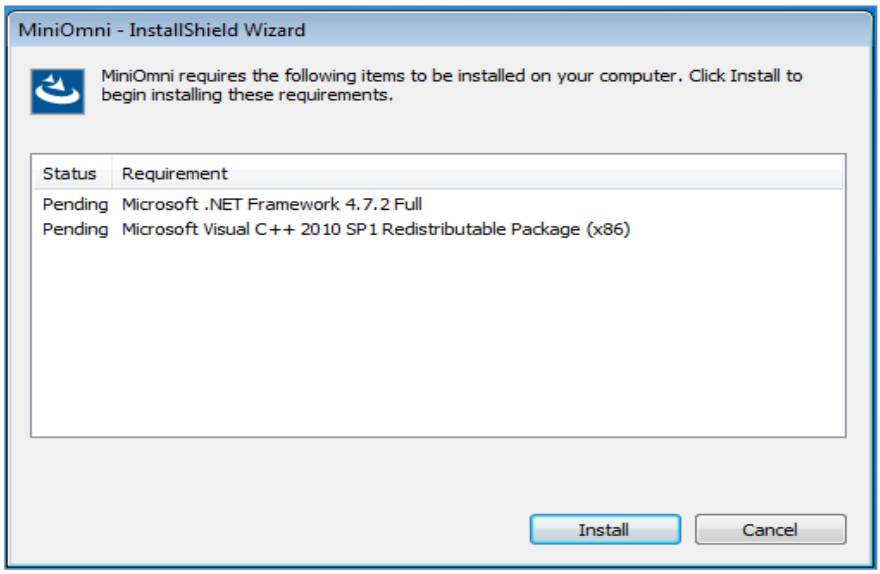
5.2. SETUP

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

5.3. MICROSOFT .NET FRAMEWORK AND MICROSOFT VISUAL STUDIO

Note: If your PC needs the required ".NET framework" environment and/or Microsoft Visual Studio environment the setup will automatically detect it and start the installation. If your PC already has the proper ".NET/Micorsof Visual Studio" version, this step will be skipped automatically.

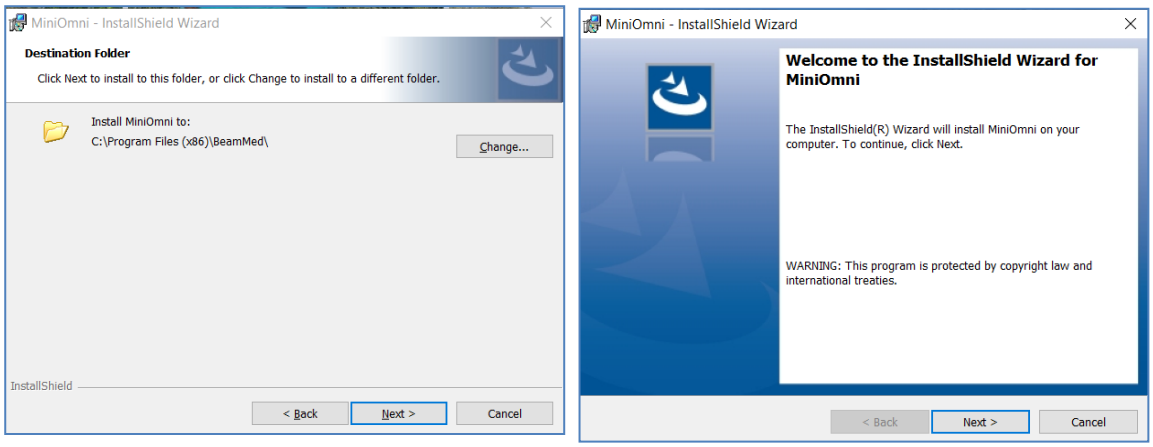
Follow the on-screen instructions to install.



Example screen for installation of the Microsoft .NET Framework and Microsoft Visual Studio environment

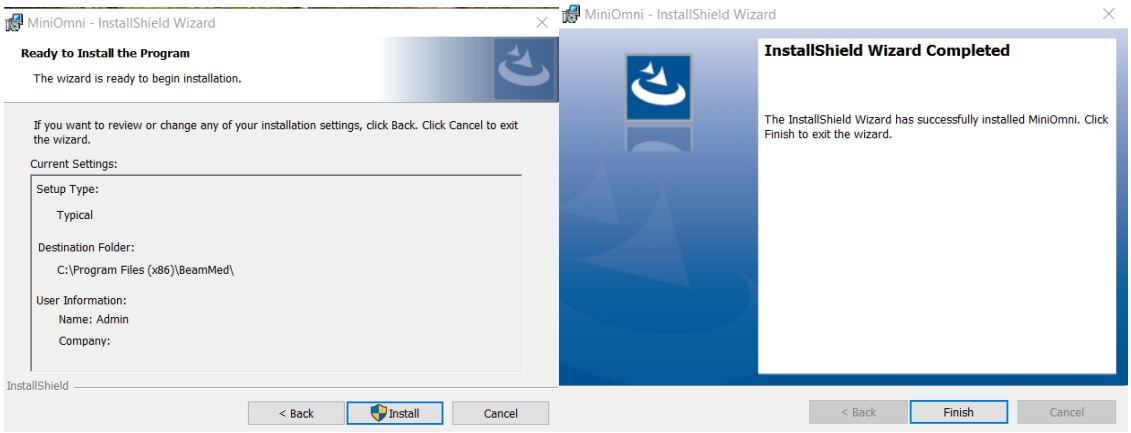
5.4. MINIOMNI SOFTWARE INSTALLATION

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



Follow on-screen instructions

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*.

5.6. MINIOMNI – SOFTWARE UPDATE

Occasionally, BeamMed releases new software versions (for software improvements, new features and compatibility with Windows). Please find below instructions on how to get this new software version installed and operatingwith your MiniOmni system.

Step 1 – Download the new setup file from BeamMed website - *https://www.beammed.com/software-download/*.

Step 2 – Plug in the MiniOmni device, Click > Options > Admin > Backup (should you wish to save your Patient History).

Step 3 – On your PC go to Control Panel add/remove programs and delete the current MiniOmni version.

Step 4 – install the new software version as described above (5.1 -5.4)

Step 5 - Click > Options > Admin > Restore (to restore your Patient History).

© 2022 BeamMed Ltd.

6. HARDWARE SETUP

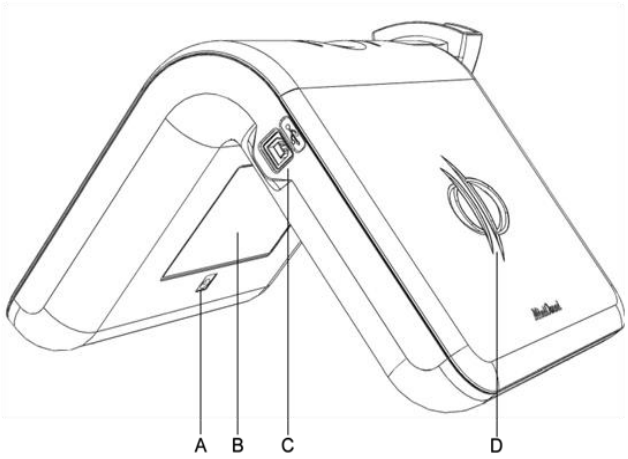
When attaching cables and connectors, insert each component's connector securely into the corresponding socket and tighten the screws, if required.

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 Plug 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

Carefully note the power rating of your MiniOmni unit (110V or 230 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 the MiniOmni system only with the dedicated power supply.

Attach the MiniOmni unit's power cable (see below) to the MiniOmni power inlet. The MiniOmni power inlet is shown as item A. in the *MiniOmni – USB View diagram*, above. Plug the other end of the cable into a standard electrical outlet.

Power supply and cable

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

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 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 system.

Carefully note the arrangement of pins on the probe's connector. Ensure that you insert the connector into the probe socket so that the corresponding pins are aligned. Press the connector firmly into its socket and tighten the locking screws, as this ensures proper electrical ground.

© 2022 BeamMed Ltd.

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 cable are disconnected, the *No Connection* icon is displayed:

© 2022 BeamMed Ltd.

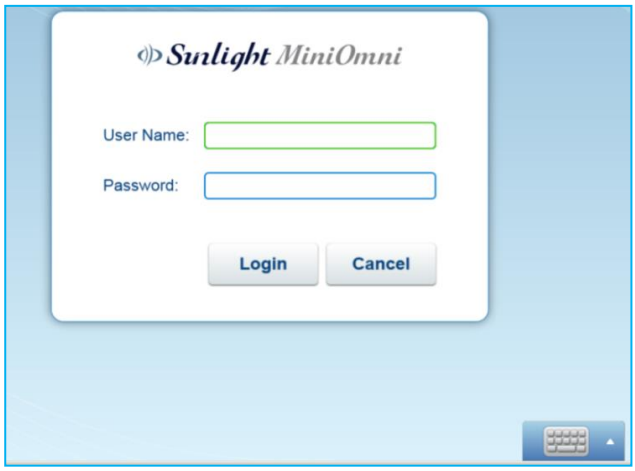
7. STARTING THE SYSTEM

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 described in *Section 6. Hardware Setup*, which has detailed instructions for setting up the MiniOmni cables and other components.

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

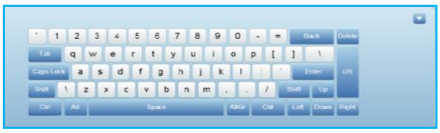
7.1. WELCOME AND LOGIN

The user Login screen appears as follows:



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

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 three types of users:

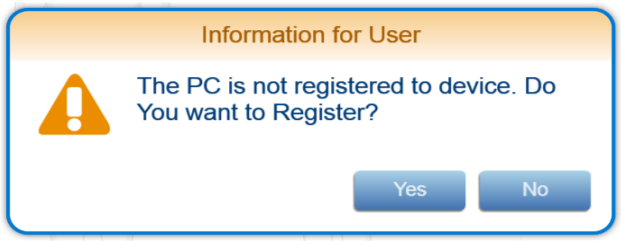
- System Administrator – Has access to all system functions. The default name for the System Administrator is **sunlight** and the initial password is **omni**.
- Physician/Operator – Has the ability to limit the access to patients' information to himself only.

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 users list, see *Section 15.9.1 Options – Administration – Users*.

7.2. FIRST-TIME PC REGISTRATION

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



Press **Yes** to register the PC and approve the software license. For more information, see *Section 15.10. 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 Logon Each Day*. Otherwise continue with *Section 8.3. Patient Selection and Options*.

7.3. AUTOMATIC SQV OPTION ON FIRST LOGON EACH DAY

On the first login to MiniOmni each day, a message will display, with the option of performing an SQV test procedure:

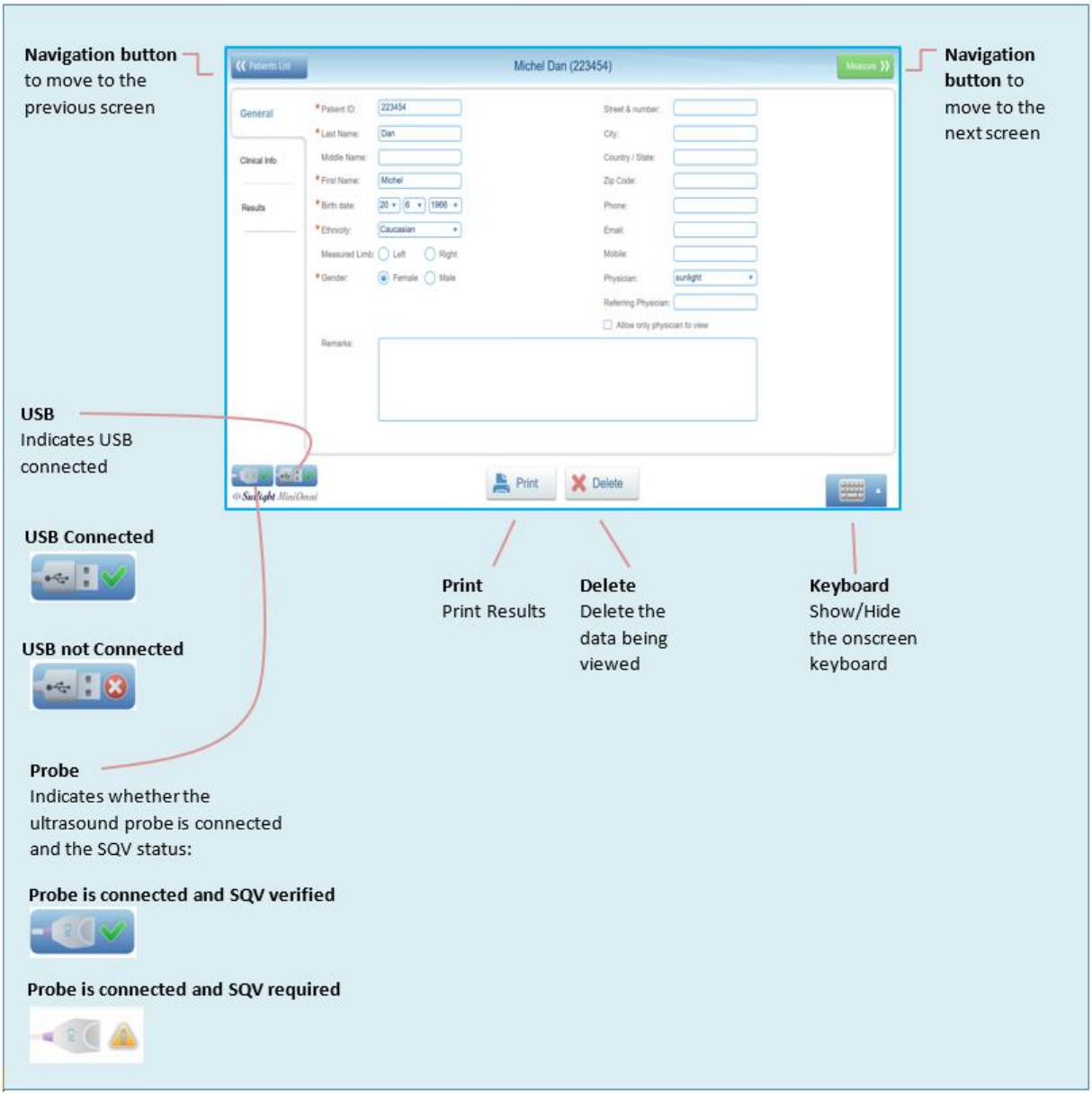
You may press **OK** to perform an SQV procedure, as detailed in *Section 8. System Quality Verification (SQV)*, or press **Ignore** to skip SQV

Note: If you proceed with SOS measurements without SQV, the system will display a warning that no verification has been conducted (see section 8.1)

© 2022 BeamMed Ltd.

7.4. OVERVIEW OF THE MINIOMNI SCREEN

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



Layout of the MiniOmni screen

8. SYSTEM QUALITY VERIFICATION (SQV)

SQV is performed once per day, before beginning the first 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 8.3. Patient Selection and Options*.

Note: The phantom and the probe must be at room temperature when conducting SQV.

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.

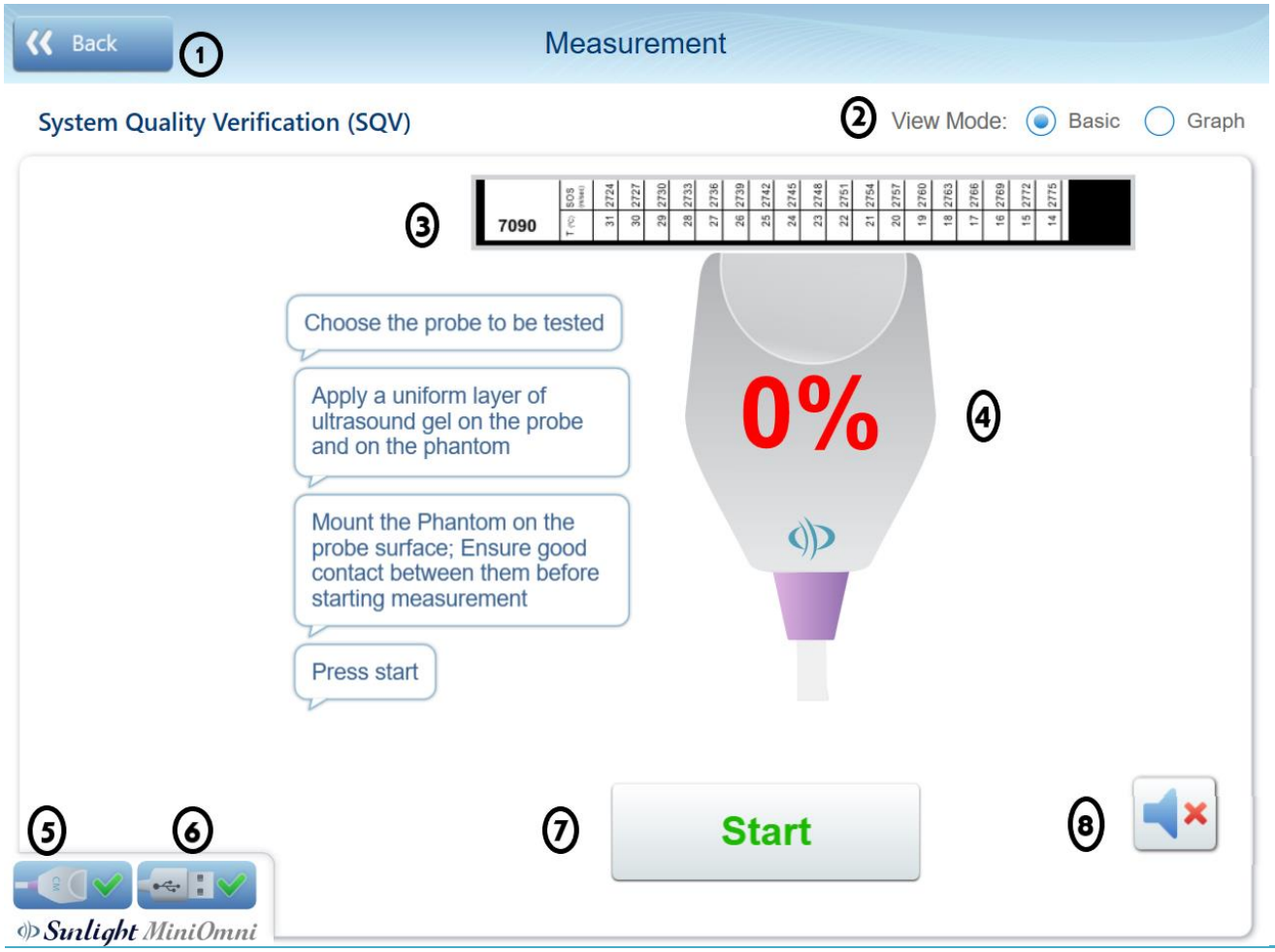
8.2. PERFORMING SYSTEM QUALITY VERIFICATION

8.2.1. FINDING THE SQV SCREEN

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

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	5	Status indicator for probe connection
2	View progress of SQV as progress bar or graph	6	Status of USB connectivity
3	Representation of Phantom	7	Start SQV
4	Progress bar	8	Audible alarm on/off

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;
- **See results** to veew the previous 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, active surface facing upwards, and place the phantom directly on top of it, as seen below.

Positioning the phantom on the probe for SQV

The phantom rests on the probe; the probe is held steadily, 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. Since the phantom is transparent, you can easily check for any bubbles by visual inspection. The figure below illustrates the orientation of the probe-phantom combination for the visual inspection.

Caution: Visually inspect the contact between probe and phantom, to ensure that no air bubbles 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.

© 2022 BeamMed Ltd.

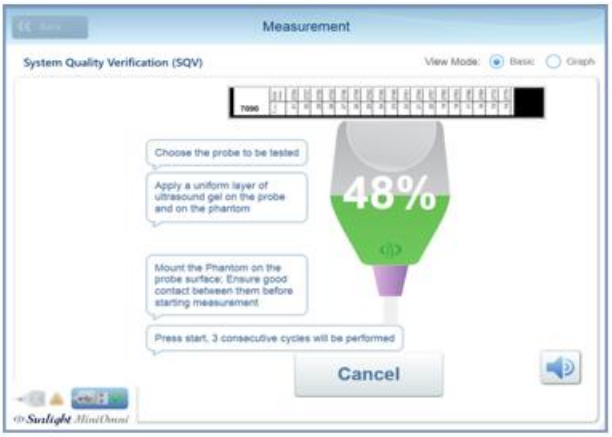
8.2.6. EXECUTE THE MEASUREMENT

Press **Start** on the screen, or press 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 to the graph/probe image.

Graph measurement mode (recommended)

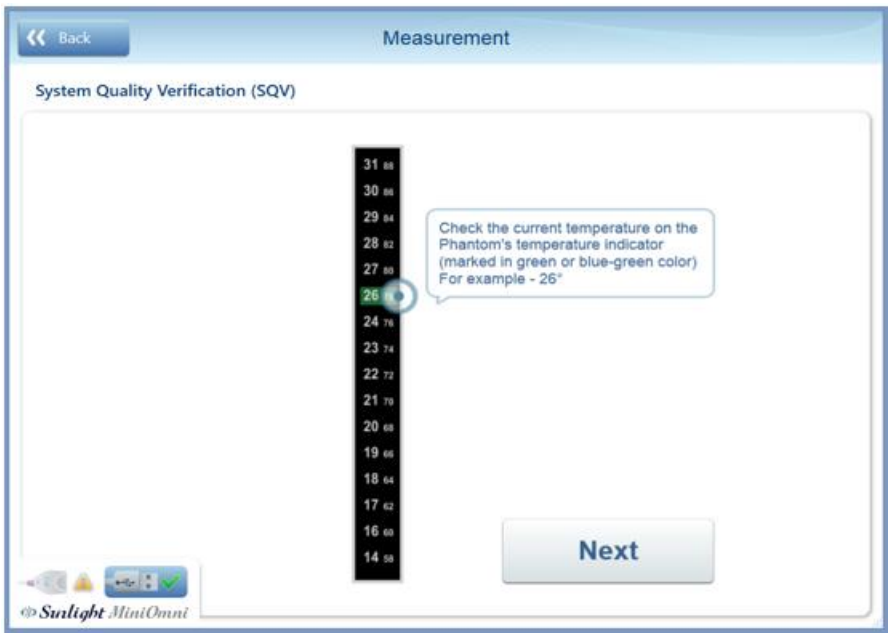
Basic measurement mode



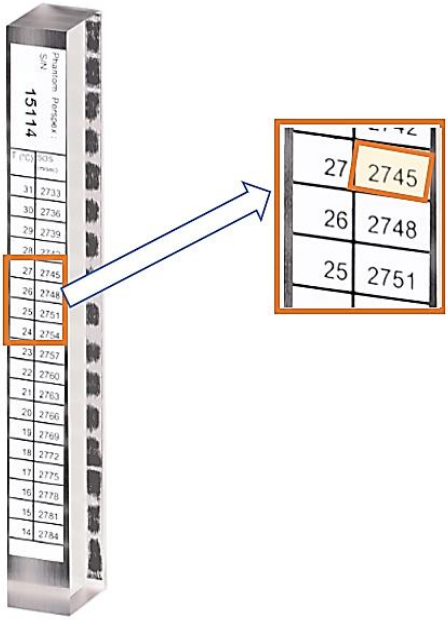
Caution: If the results of the measurement cycle are not accepted by MiniOmni, check that no air bubbles are trapped between the probe and the phantom, and that sufficient ultrasound gel has been applied. If results are still not accepted, your probe may be defective. Contact Your Local Dealer.

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

In order to complete the SQV test, the **expected SOS value** is required. 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 display:



This screen is requesting 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**.

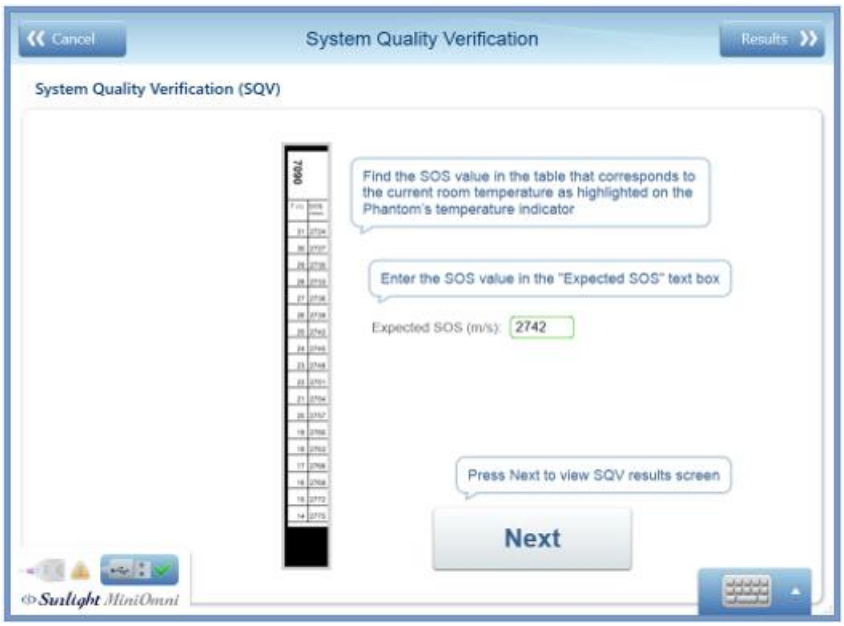


Click on **Results >>** to see the next screen, where you will enter the **corresponding** SOS value **2745**.

Caution: SQV must be conducted with the phantom temperature between 59 and 86 degrees Fahrenheit (15-30 degrees Centigrade).
The phantom material conducts heat slowly; it may take some time to stabilize in the room temperature. Wait until a reading can be obtained before continuing 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.

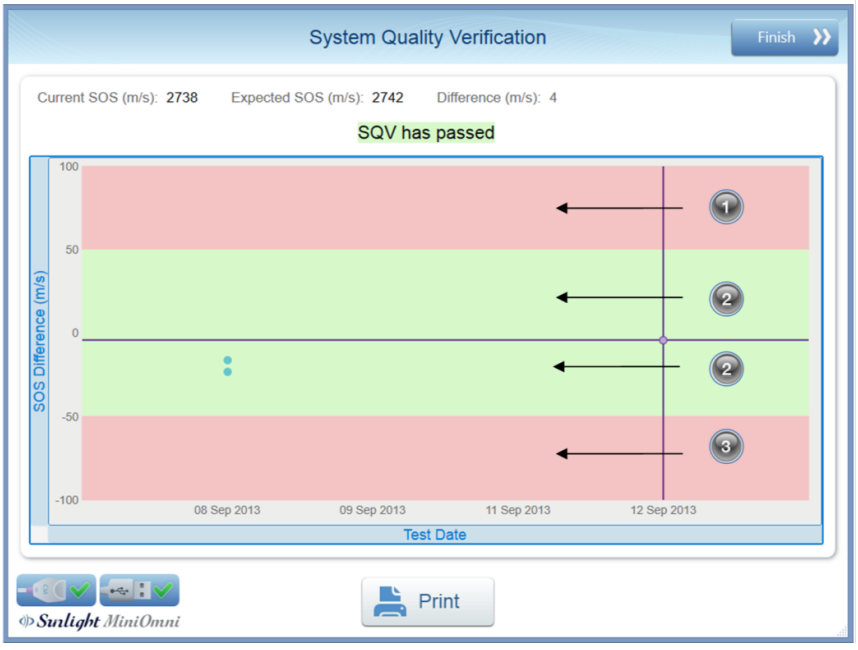


Entering the expected phantom SOS value

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 SQVs, as shown below.

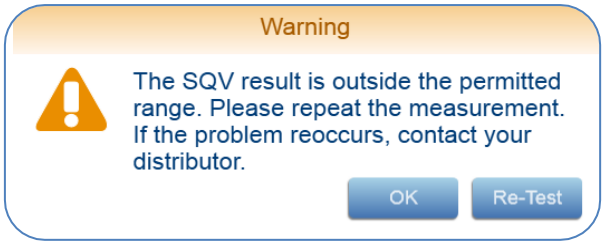


SQV result screen

An SQV result in ranges **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.

8.3. PATIENT SELECTION AND OPTIONS

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

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 HAS NOT YET BEEN ENTERED INTO THE MINIOMNI SYSTEM, Click **New Patient**. The procedure for defining a new patient is described in *Section 9. Patient Maintenance*.

IF YOU ARE WORKING WITH A PATIENT WHO HAS ALREADY BEEN DEFINED IN THE MINIOMNI SYSTEM, click on **Patient List** to select the patient from a list of patients in the system. The Patient List screen is described in *Section 9.3. Selecting a patient from the Existing Patient List*.

IF YOU'RE NOT SURE IF THE PATIENT IS NEW, click on **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.

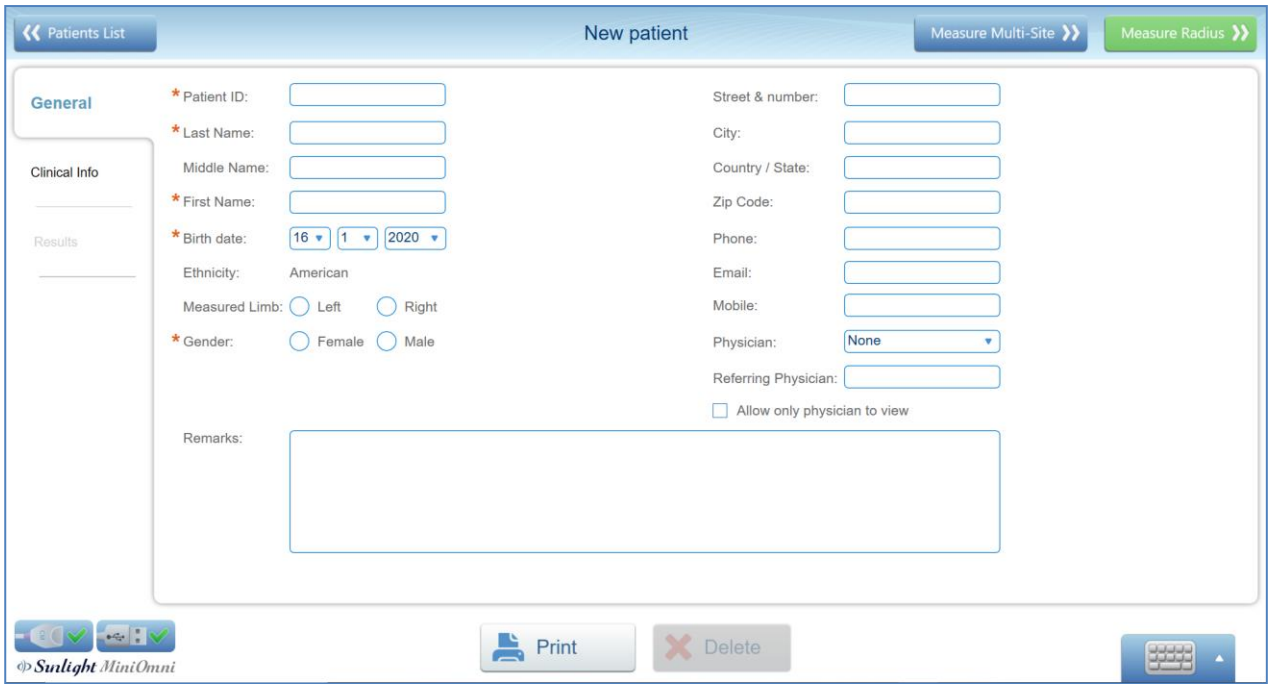
A discussion of the **Options >>** screen is given in *Section 15. Options Screen*.

© 2022 BeamMed Ltd.

9. PATIENT MAINTENANCE

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

9.1. NEW PATIENT – GENERAL

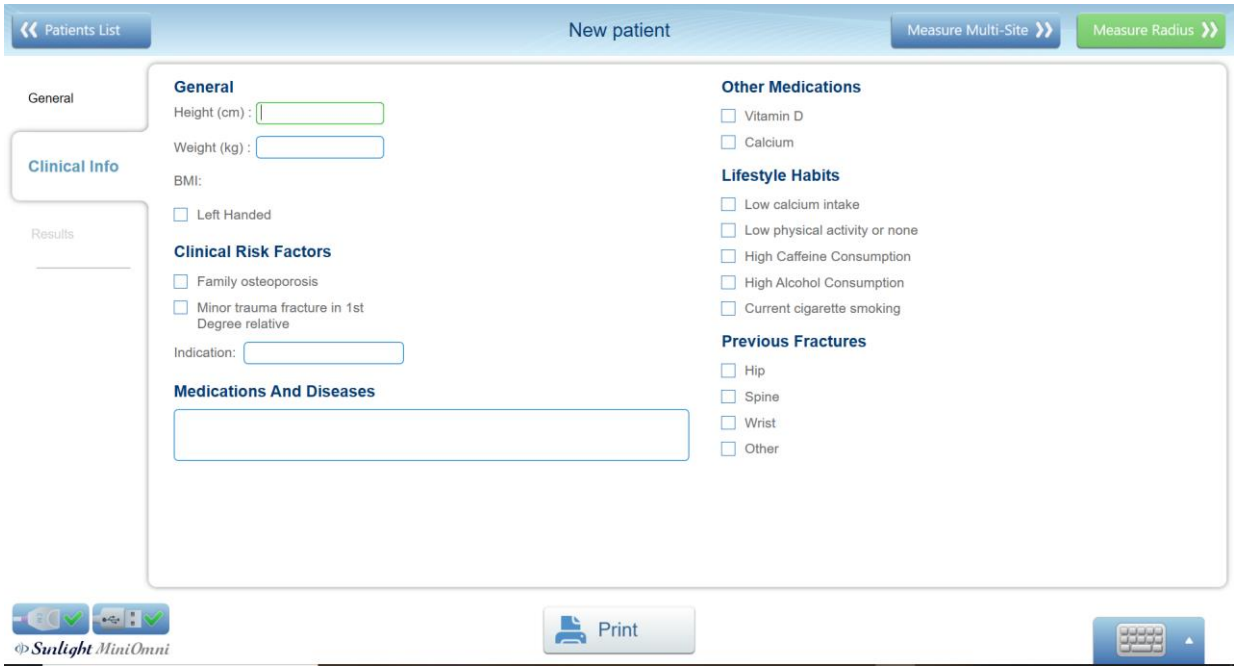


Key to Screen

<< Back	Show previous screen	**Measure >>**	Starts the Radius site measurement; must be clicked after patient positioning. Clicking the measurement button will start the measurement automatically
Patient ID	Required. Can be automatically filled. See *Section 15.5. Options – Settings – Setup*.	**Multi-Site**	Allow selecting Phalanx/Metatarsal sites (requires additional license) Clicking the measurement button will start the measurement automatically
Family Name	Required. Can be automatically filled. See *Section 15.5. Options – Settings – Setup*.	Gender	Required
Middle Name	Optional	Remarks	Any remark written here will be added to measurement report and will be saved.
First Name	Required. Can be automatically filled. See *Section 15.5. Options – Settings – Setup*.	**Referring Physician**	Type the referring physician. This information will appear on the measurement report.
Birth Date	Required. Ensure the correct age is entered.	**Allow only physician to view**	If clicked, only a physician user associated with this patient can see the patient's file.
Ethnicity	Required. Can be automatically filled. See *Section 15.5. Options – Settings – Setup*.	**Physician**	Select physician from the users list. The selected name will appear on the measurement report.
Measured Limb	Optional – allow to repeat the same measurement next patient visit.		

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

9.2. NEW PATIENT CLINICAL INFO

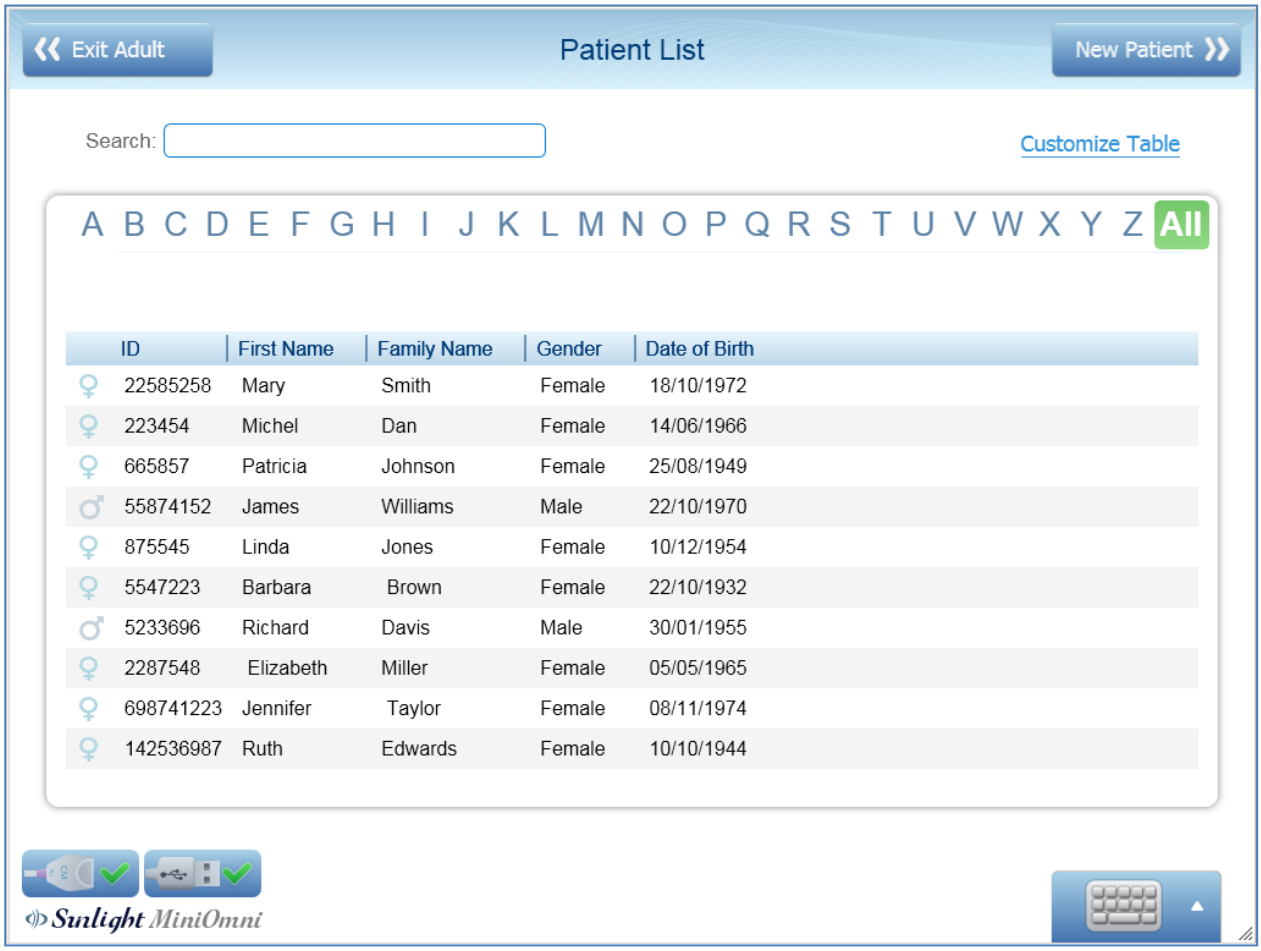


Key to Screen			
<< Back	Show previous screen	**Measure/Multi-Site >>**	Perform measurement
Height	Patient height, appears on report	**Vitamin D**	Related Clinical information
Weight	Patient weight, appears on report	**Calcium**	
BMI	Automatically shown. If Height and Weight entered, appears on report	**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.

© 2022 BeamMed Ltd.

9.3. SELECTING A PATIENT FROM THE EXISTING PATIENT LIST



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

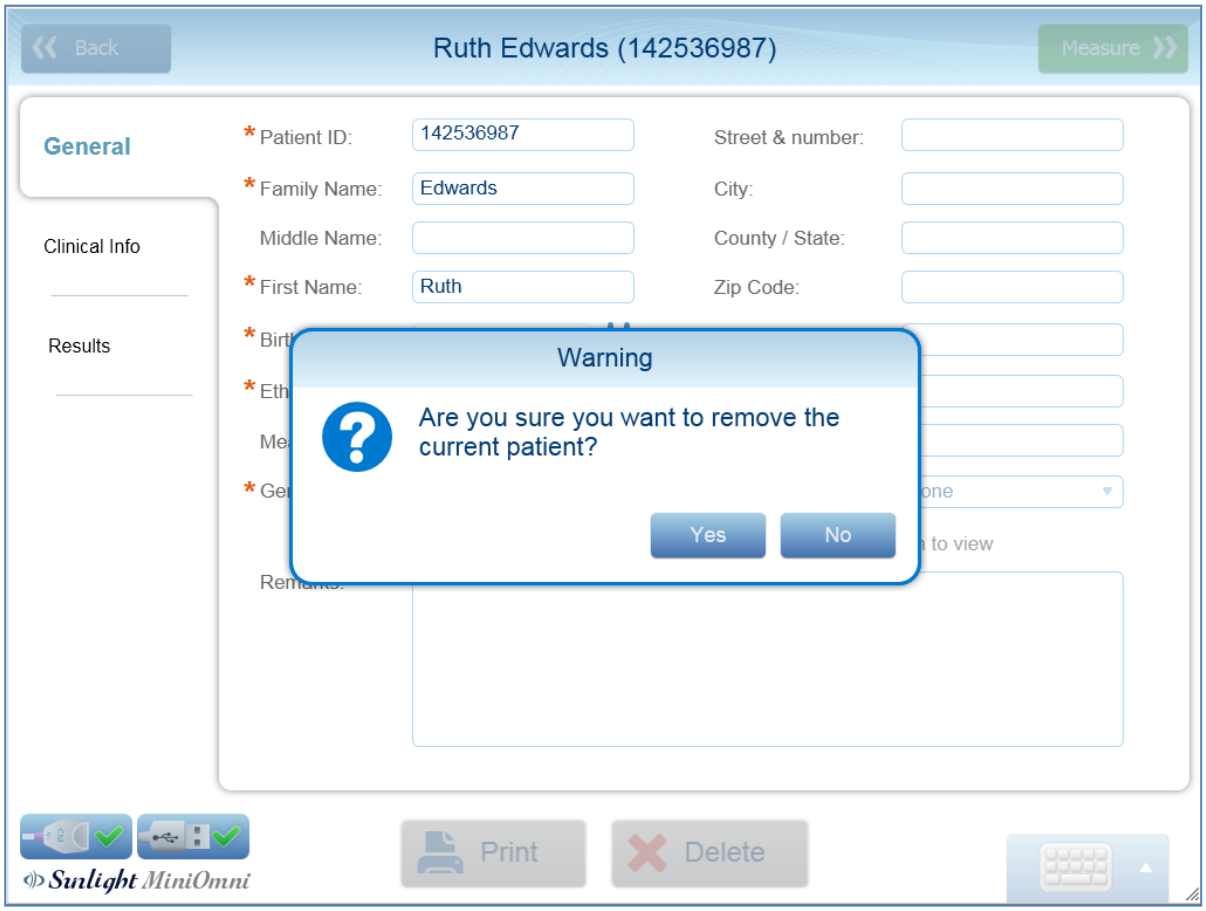
Type the first few characters of the patient's name to search for the patient. Double click on the patient's name to select the patient and go to the Measurement Startup screen.

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 9. Patient Maintenance*.

© 2022 BeamMed Ltd.

9.4. DELETING A PATIENT

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



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

To delete more than one patient, see *Section 15.7.4. Options – Administration – Delete Patients' Data*.

10. PERFORMING THE PATIENT MEASUREMENT

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

10.1. LOCATING THE MEASUREMENT SITE FOR THE DISTAL ⅓ RADIUS

10.1.1. POSITION THE PATIENT AND THE LIMB

SOS measurement at the Distal ⅓ 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, undetachable ring, or IV line, use the contra-lateral side instead.

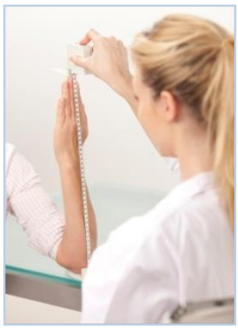
Seat the patient in a chair, opposite the operator and close to a standard desk.

10.1.2. 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.

© 2022 BeamMed Ltd.

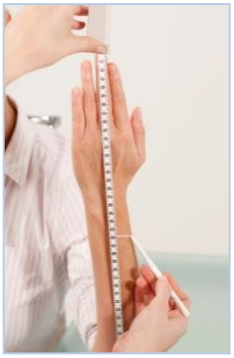
Place the gauge on the desktop and set the patient's non-dominant elbow on a table with the forearm vertical and the palm open and extended vertically. All parts of the arm distal to the elbow should be aligned as straight as possible, but without noticeable muscular tension.

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

10.1.3. 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.

10.1.3.1. 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.

10.2. UNDERSTANDING THE MINIOMNI MEASUREMENT SCREEN

10.2.1. 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***.

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

© 2022 BeamMed Ltd.

10.3. MEASUREMENT SCREEN FORMATS

There are two formats for the Measurement screen: Basic and Graph.

Basic

Graph

10.3.1. MEASURING SOS AT THE RADIUS

To start measurement, press Measure Radius.

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.

The marked line is your edge. The edge of the probe toward the palm side should follow the marked line on the skin at all times.

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.

During the measurement cycle, simply focus on the site and the correct application of the probe. Avoid looking at the screen. Instead, use the audible signal (beeps) to provide feedback and to guide you in correct execution of the scan.

© 2022 BeamMed Ltd.

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

- 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.
- Check to ensure that a scan movement through 140 degrees takes about 4-5 seconds.
- The Foot Pedal is allows hands-free operation of MiniOmni during a measurement cycle. Pressing on the foot pedal is equivalent to clicking on the Measure start 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.

Note: 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 not good (see below for reminders).
- In addition to the screen indicators, an audible tone is heard (beeps) when both the acoustic contact and acoustic signal acquisition indicators are green.

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.

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, using different probes (CS for proximal Phalanx III or CR for the Metatarsal V)

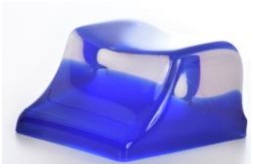
10.3.2. COMPLETING THE MEASUREMENT - STEPS

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. Follow the instructions provided by the manufacturer of the towelettes.

© 2022 BeamMed Ltd.

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

Refer to picture *Applying Ultrasound Gel*, above. 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.

© 2022 BeamMed Ltd.

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 Radius button (or 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 THE MEASUREMENT CYCLE

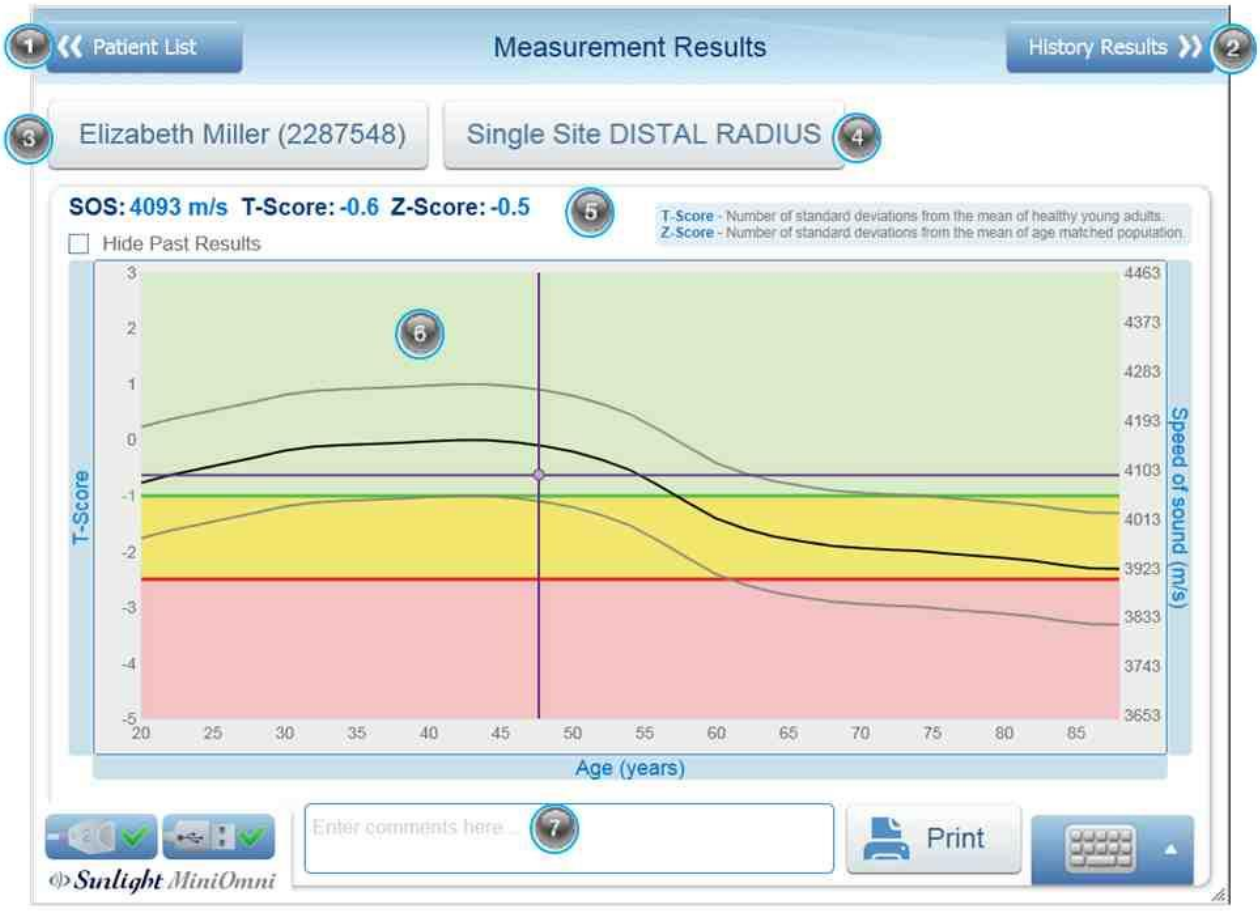
When you complete a measurement cycle, an audible beep is heard and the **Cancel** button changes to **Start**.

When the consistent cycle has been completed, you can view the results of the measurement.

© 2022 BeamMed Ltd.

11. MEASUREMENT RESULTS

11.1. MEASUREMENT RESULTS SCREEN



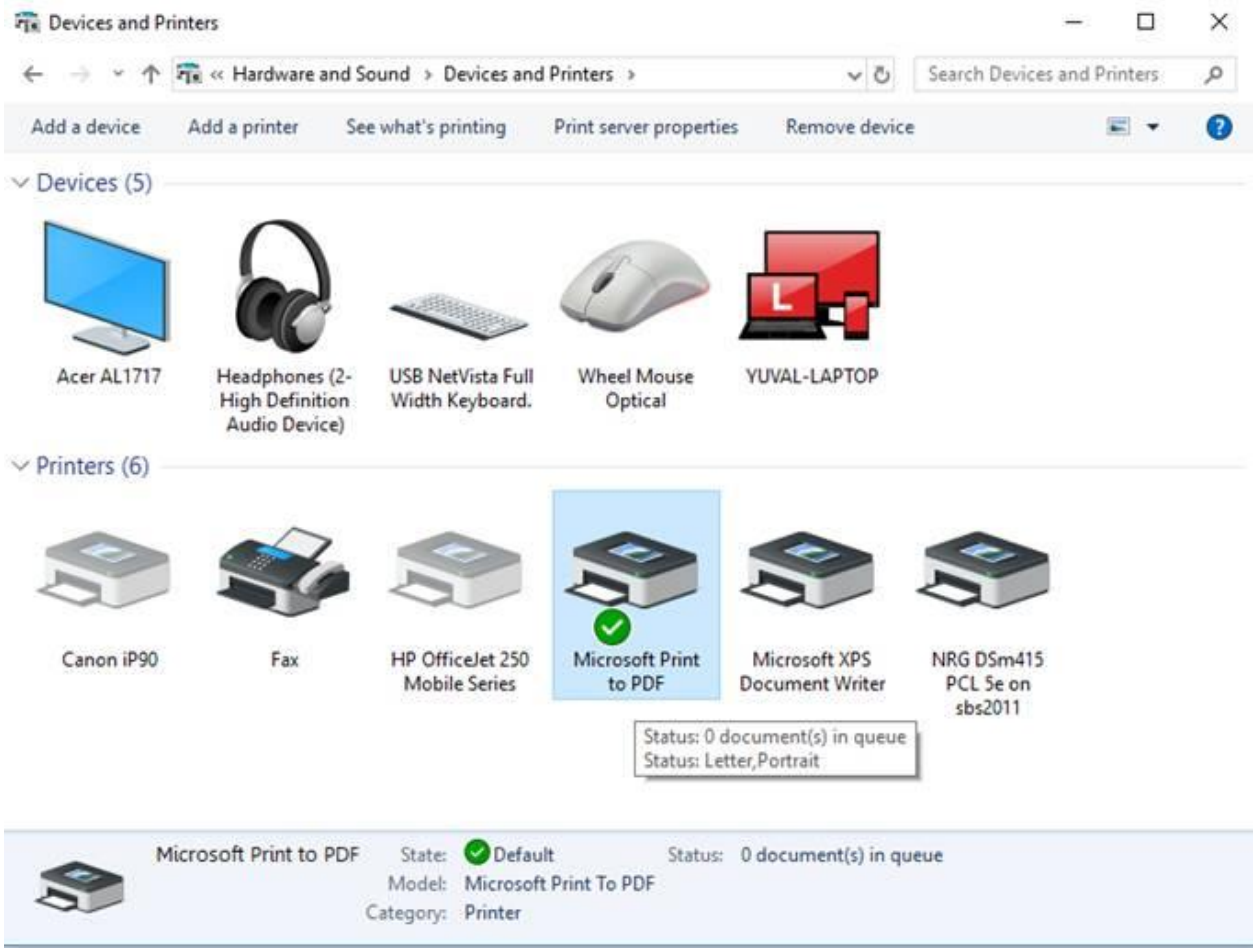
Key to Screen			
1	Back to the main patient list	5	The measurement result values (SOS, T & Z-scores)
2	Go to the patient history tab in patient file	6	Result graph current measurement is purple dot, if this site measured before the previous results will be blue dots)
3	Go to patient file	7	Comments that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

© 2022 BeamMed Ltd.

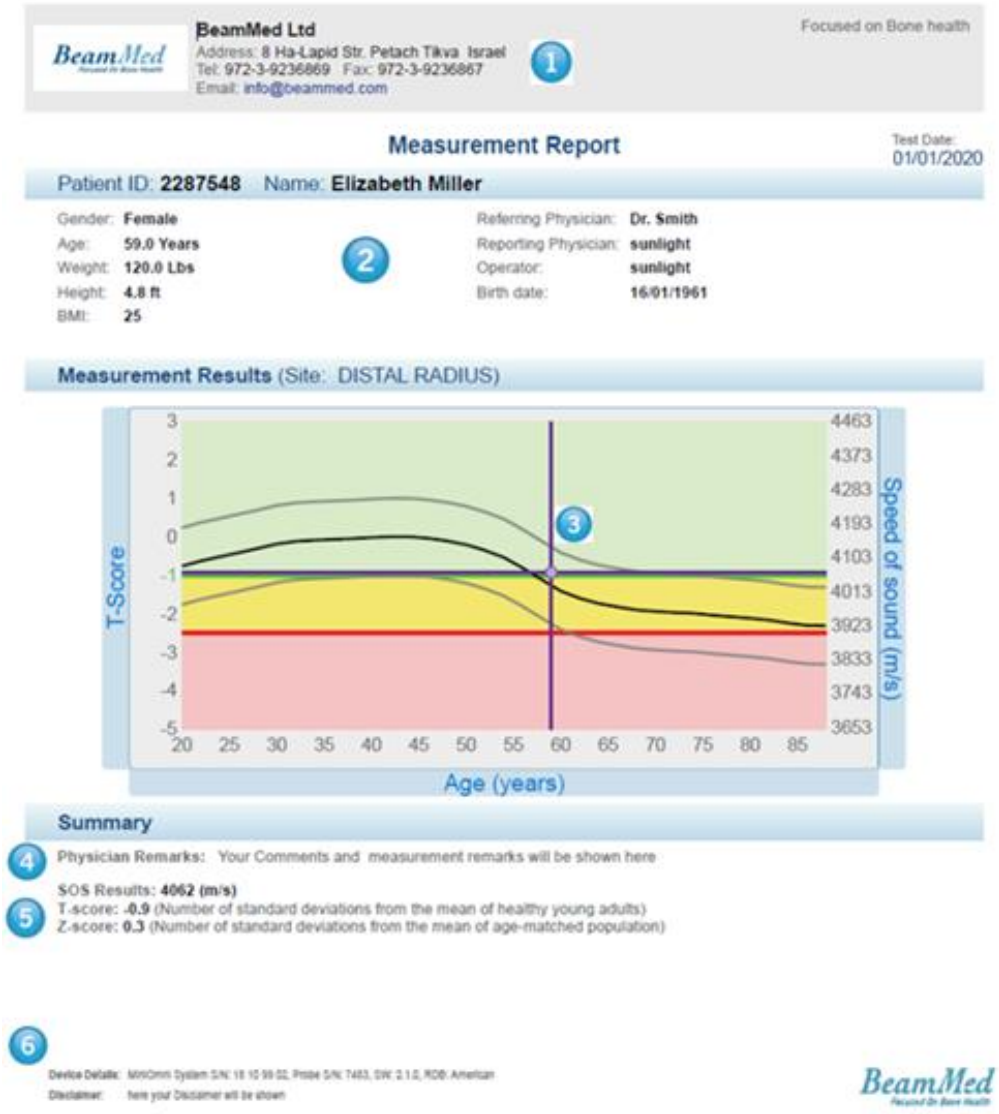
11.2.PRINTING/SAVING THE REPORT

When you click on Results, and press the PRINT button, you should see your own Printers list. 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 , or ask your IT team to do it for you.

Upon pressing Print, your own printer options should appear, click "Save As" the Print to PDF printer or select your own Printer as you normally do.



11.3. BONE DENSITY MEASUREMENT



Key to Screen			
1.	*Editable Header*	**4.**	*Physician remarks and Measurement comments*
2.	*Patient details*	**5.**	*The measurement result values (SOS, T & Z scores)*
3.	*Result graph for current measurement is displayed in purple dots. If a previous measurement/s was done it will appear as blue dots*	**6.**	*Device details and edibale disclaimer*

11.4. GUIDELINES TO EVALUATING THE SOS MEASUREMENT

11.4.1. 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.

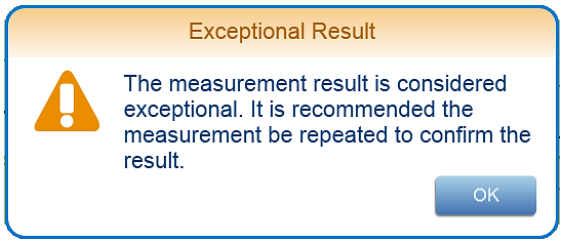
In the example, the patient has a T-score result of -0.9, equivalent to a Z-score of 0.3. The result falls 0.9 standard deviations below the mean SOS value for normal young adults and falls 0.3 standard deviations above the line of the mean SOS value for his/her age. If previous measurements were performed on this patient, they will be displayed in the graph as blue round dots.

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. A pop-up box will appear, as follows:



"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.

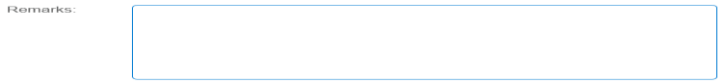
11.4.1.1. MEASUREMENT COMMENTS

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.

The Patient>General Remarks dialog box appears below.



Measurement Comments dialog box.

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

11.5. 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.

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.

11.6. DELETING A MEASUREMENT RESULT

In certain situations you may want to delete a particular measurement result for a patient.
To delete a measurement result, click on the measurement. Then click **Delete** and press **Yes** to confirm. The selected measurement is now deleted.

Caution: Deleted measurements are not recoverable.

© 2022 BeamMed Ltd.

12. MULTI-SITE MEASUREMENTS

In addition to the ⅓ Distal Radius site, two other sites are available for measurement and available if the "Multi Site" feature pre ordered:

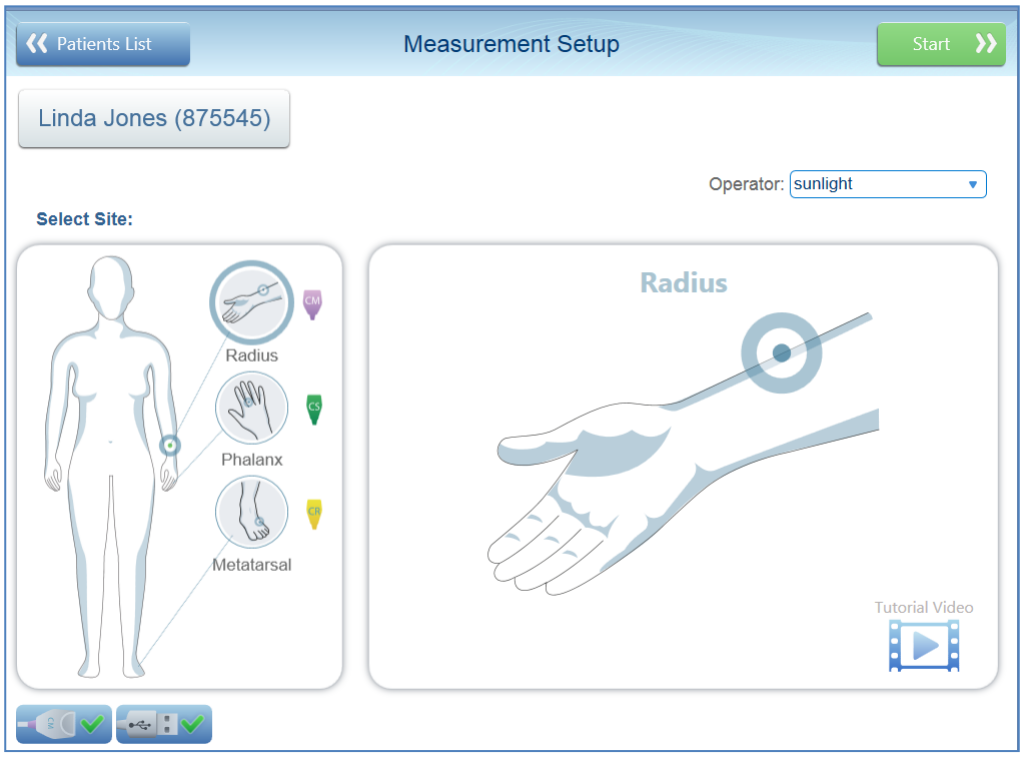
- PLX (Proximal Phalanx III)
- MTR (Metatarsal V).

Details of each of these measurement sites are provided below.

12.1. PREPARING FOR THE SOS MEASUREMENT

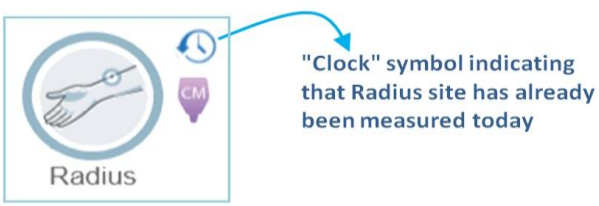
After selecting a patient (or entering a new patient's information) clicking the device measurement button will start the measurement automatically.

Clicking on the "Measure Multi-Site" button - the Measurement Setup screen appears:



Select the desired site: Radius, Phalanx, or Metatarsal. If you select 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: If the symbol of a **clock** appears next to a site, it means that the site has already been 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 9. Patient Maintenance*.

12.2. PROXIMAL PHALANX OF THE THIRD FINGER SITE

12.2.1. 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, or undetachable ring, or IV line, use the contra-lateral side instead.

12.2.2. IDENTIFY THE REGION TO BE MEASURED

DETERMINING THE AREA TO BE SCANNED:

STEP 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.

L-gauge for measuring the phalanx

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.

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.

STEP 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.

© 2022 BeamMed Ltd.

Marking the scan position – Illustration of mark on proximal phalanx

STEP 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. Follow the instructions provided by the manufacturer of the towelettes. Apply ultrasound gel to the probe surface.

STEP 4. 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

STEP 5.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.

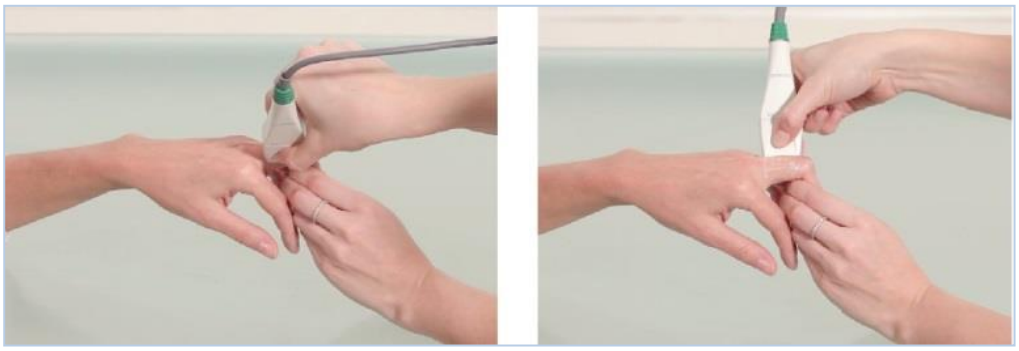
Grasping the patient's finger – Correct position of the proximal phalanx for scanning is maintained by the operator's grasp.

STEP 6.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.

STEP 7.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.

© 2022 BeamMed Ltd.

STEP 8.The scan is executed by moving the probe around the proximal phalanx, from its dorso-medial to its dorso-lateral 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. Move the probe 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 improve 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.

12.3. 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.

12.3.1.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:

12.3.2. DETERMINING THE AREA TO BE SCANNED

STEP 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.

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

STEP 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:

© 2022 BeamMed Ltd.

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 malelus, 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 malelus, 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.

12.3.3. MEASURING SOS AT THE METATARSAL V

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

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

STEP 3. Disinfect the probe.

Probes should be disinfected before using with each patient.

Disinfection must be done with specially pre-moistened towelettes/Alcohol wipes, and NOT by immersion of any kind. Follow the instructions provided by the manufacturer of the towelettes.

Apply ultrasound gel to the probe surface.

STEP 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.

STEP 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.

STEP 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.

STEP 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.

© 2022 BeamMed Ltd.

STEP 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.

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.

© 2022 BeamMed Ltd.

13. CLOSING THE MINIOMNI APPLICATION

From any Application screen click repeatedly 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 plug off the power supply. This could cause permanent loss of data. Follow the prescribed exit procedure.

14. CLEANING AND DISINFECTING

14.1. 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 patients. 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.

14.2. THE MINIOMNI DEVICE

14.2.1. 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 MiniOmni's 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.

14.3. THE ULTRASONIC PROBE

14.3.1. 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, hydrochloric acid (HCl), chloride bleach, etc.

14.3.2. 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 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.

© 2022 BeamMed Ltd.

14.3.3. 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.

14.3.4. DISINFECTING 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.

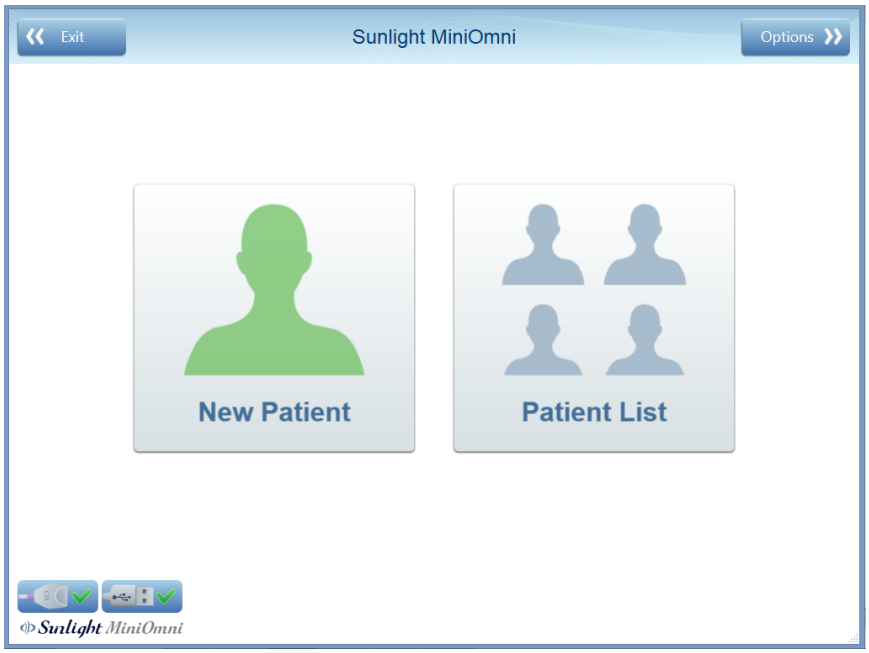
The following steps should be followed for disinfecting the probes:

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

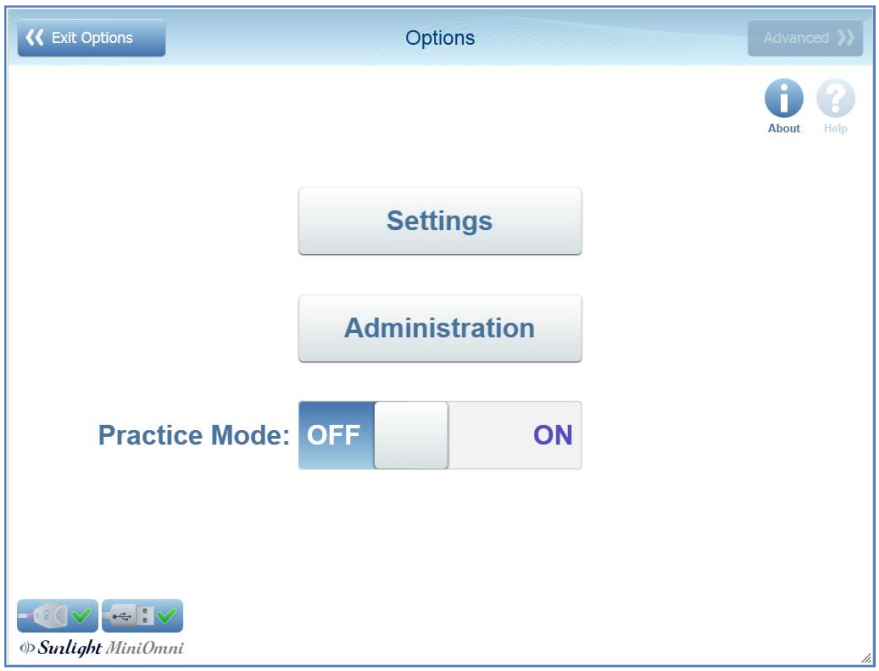
© 2022 BeamMed Ltd.

15. OPTIONS SCREEN

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



The Options screen appears as follows:

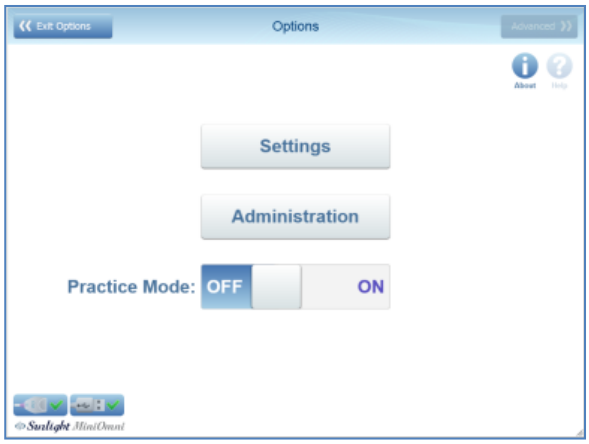


Each option is discussed in detail in the following sections.

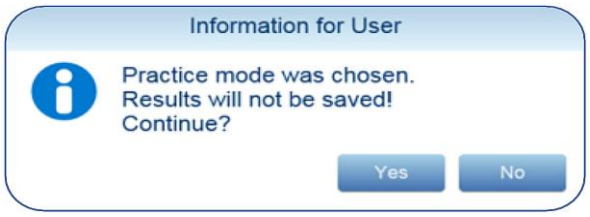
15.1. PRACTICE MODE

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.



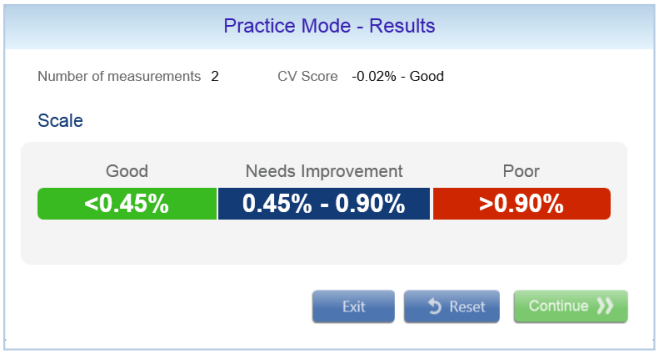
When entering the Practice Mode, a warning appears in the dialog box shown below. You are prompted to confirm the operation by pressing *yes,* or abort by pressing *No*.



When using the practice mode, the application operates in the same manner as in the regular measurement mode described in *Section 10. 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 CVscore (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:
  - The user cannot print the practice results or data.
  - Both the measurement results graph and the T and Z-scores are not available.

15.1.1. 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:

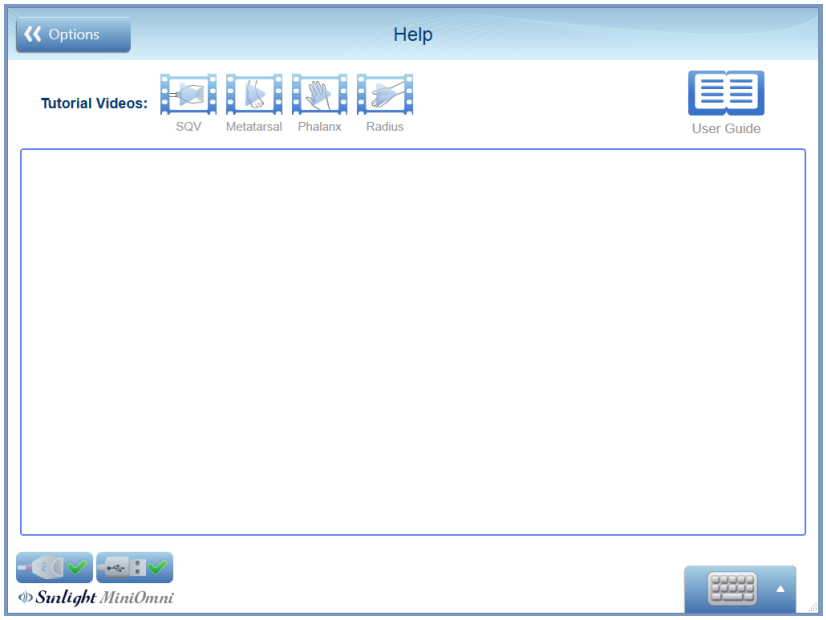
15.2. OPTIONS – ABOUT

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

Example of "about screen"

15.3. OPTIONS – HELP

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

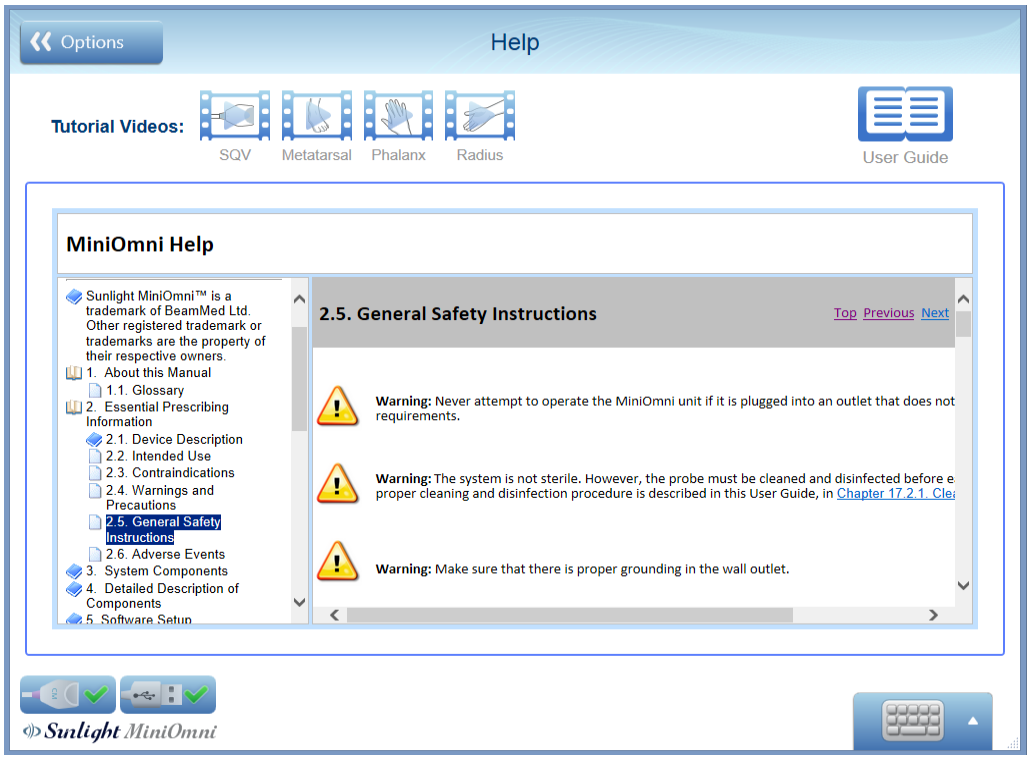


Tutorial Videos – Press to view a brief tutorial on how to perform a measurement on the desired area.

User Guide – Press to see the online Help File.

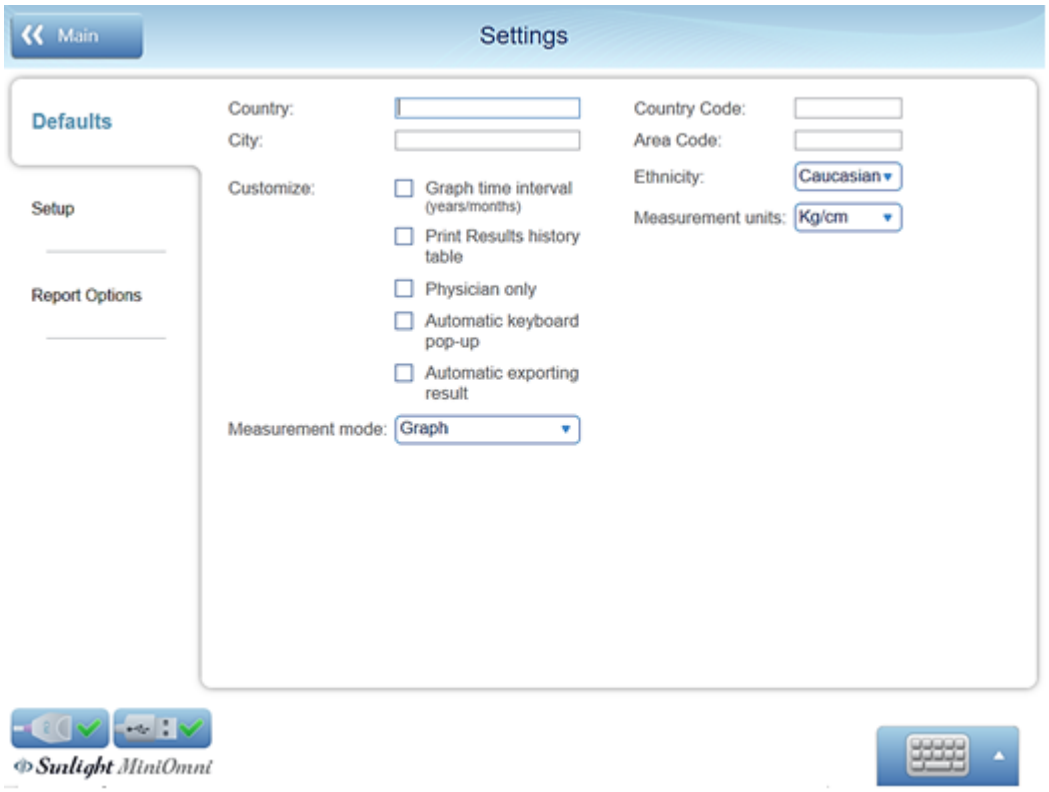
Note: When a device is configured for a language in which a Help program is not available for MiniOmni, the English Help will be displayed instead.

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



15.4. OPTIONS – SETTINGS – DEFAULT VALUES

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



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.

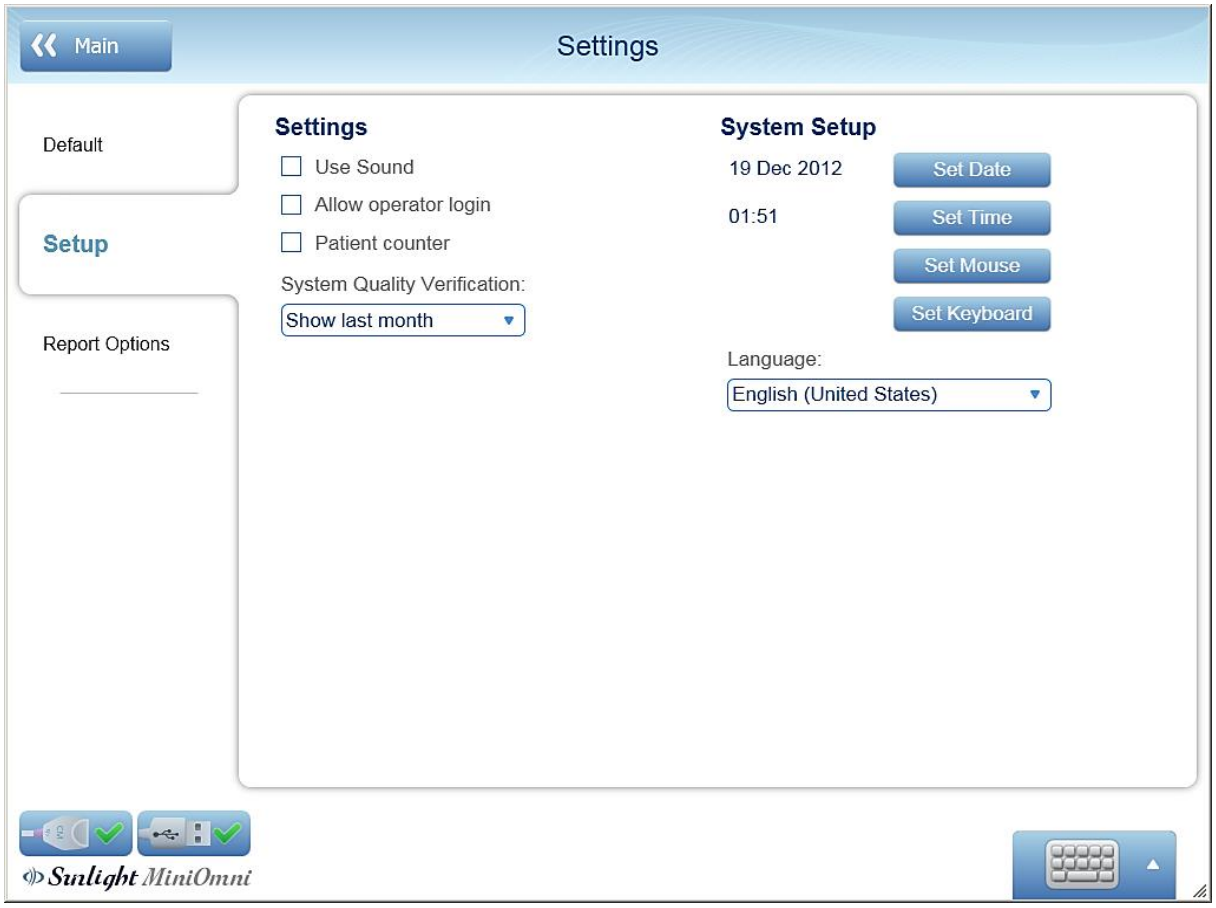
Note the following options under **Customize:**

- **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 –** If checked, only if "Export to HIS" feature activated the SW will automatic save the printed report as PDF format file in the patient folder.

© 2022 BeamMed Ltd.

15.5. 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.

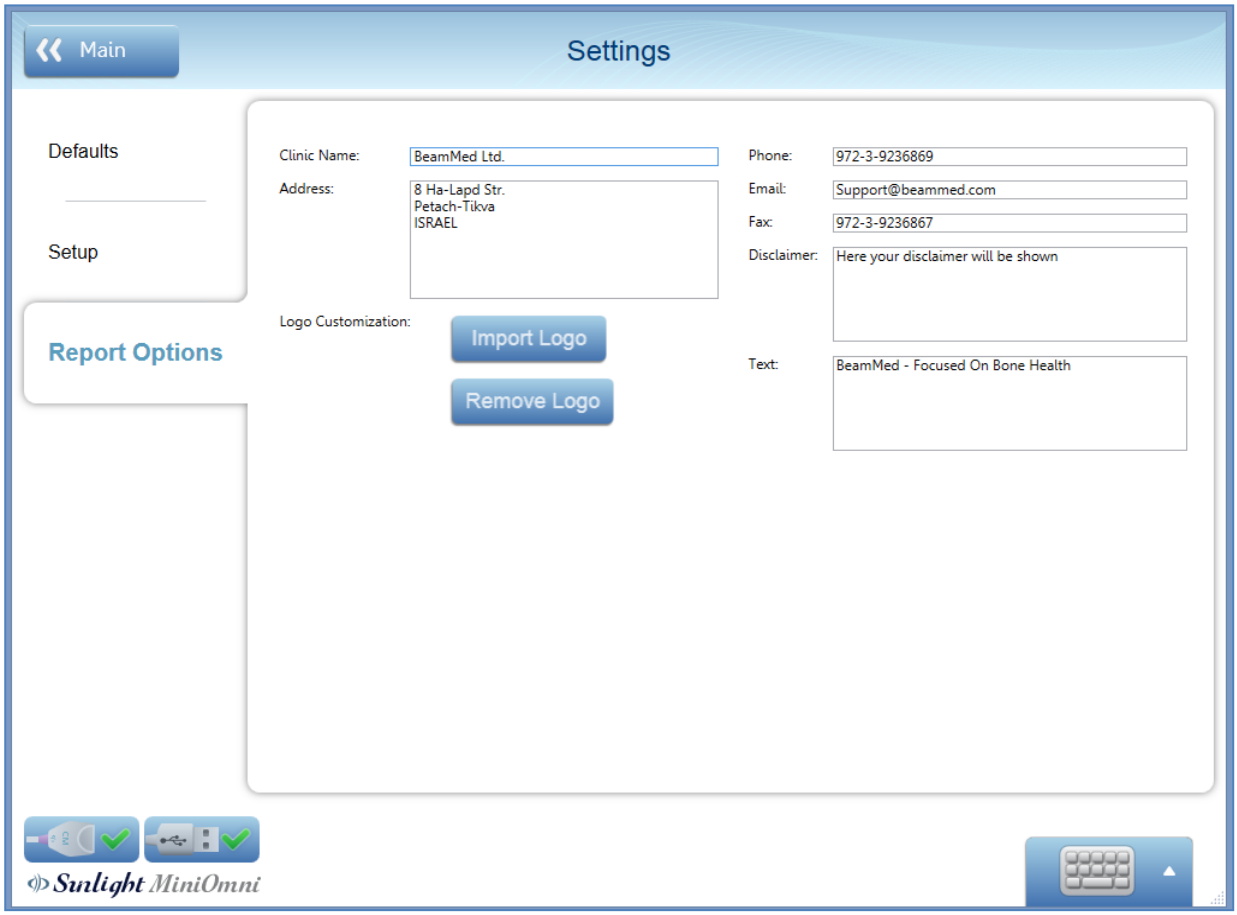
System Setup:

- Invoke the Windows setup screens for the date, time, mouse and keyboard.
- **Language** – Specify the User Interface language (Your PC must have the desired language kit installed on its windows OS in able to change language).

© 2022 BeamMed Ltd.

15.6. OPTIONS – SETTINGS – REPORT OPTIONS

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



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.

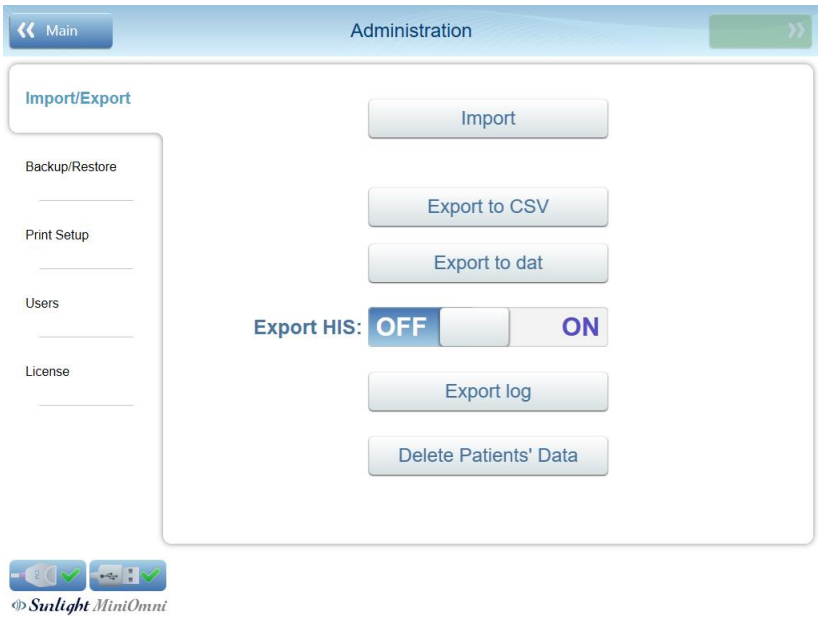
Import Logo – Select a picture to use as a logo. The logo will be on the printed report header on the left side.

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

© 2022 BeamMed Ltd.

15.7. OPTIONS – ADMINISTRATION – IMPORT/EXPORT

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

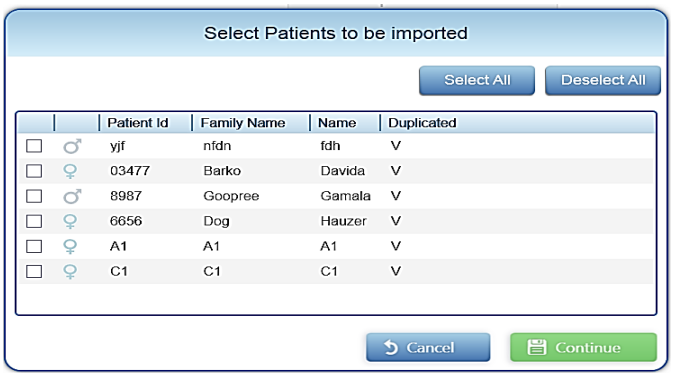


Follow on-screen instructions to enter data.

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.

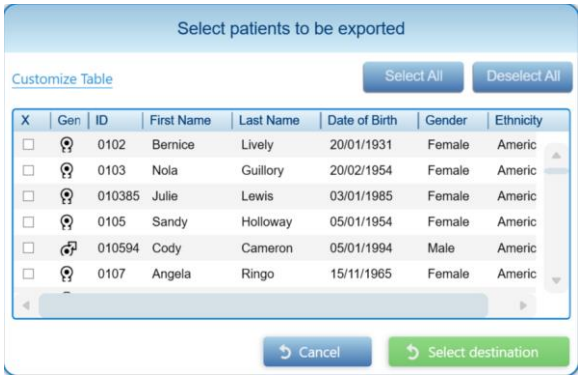
© 2022 BeamMed Ltd.

15.7.1 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 pressing one of these buttons, a screen will display allowing you to select 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.

© 2022 BeamMed Ltd.

15.7.2. 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's file on the HIS.

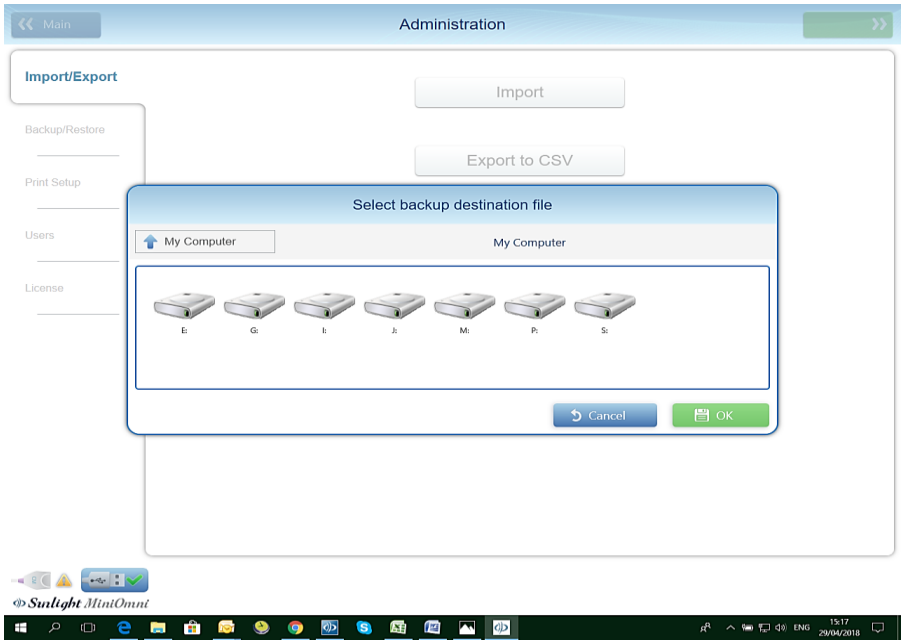
In order to verify that the HIS feature is installed in your system view the license screen as described below:

Omnisense/MiniOmni License screen (Options ▶Administration ▶ License).

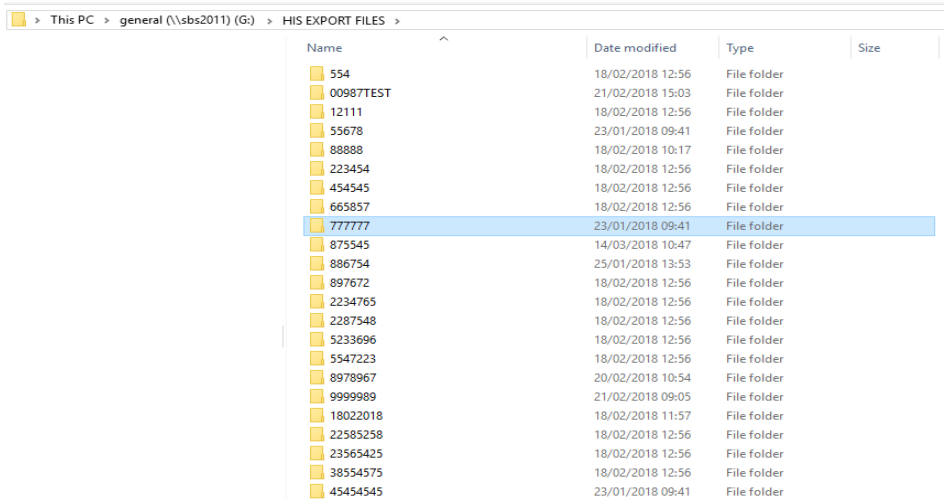
STEP 1 - Activating the HIS export function.

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 patinets' ID number shall appear. (see picture below).



© 2022 BeamMed Ltd.

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 instructions below:

Click Option ▶ Settings ▶ Defaults.

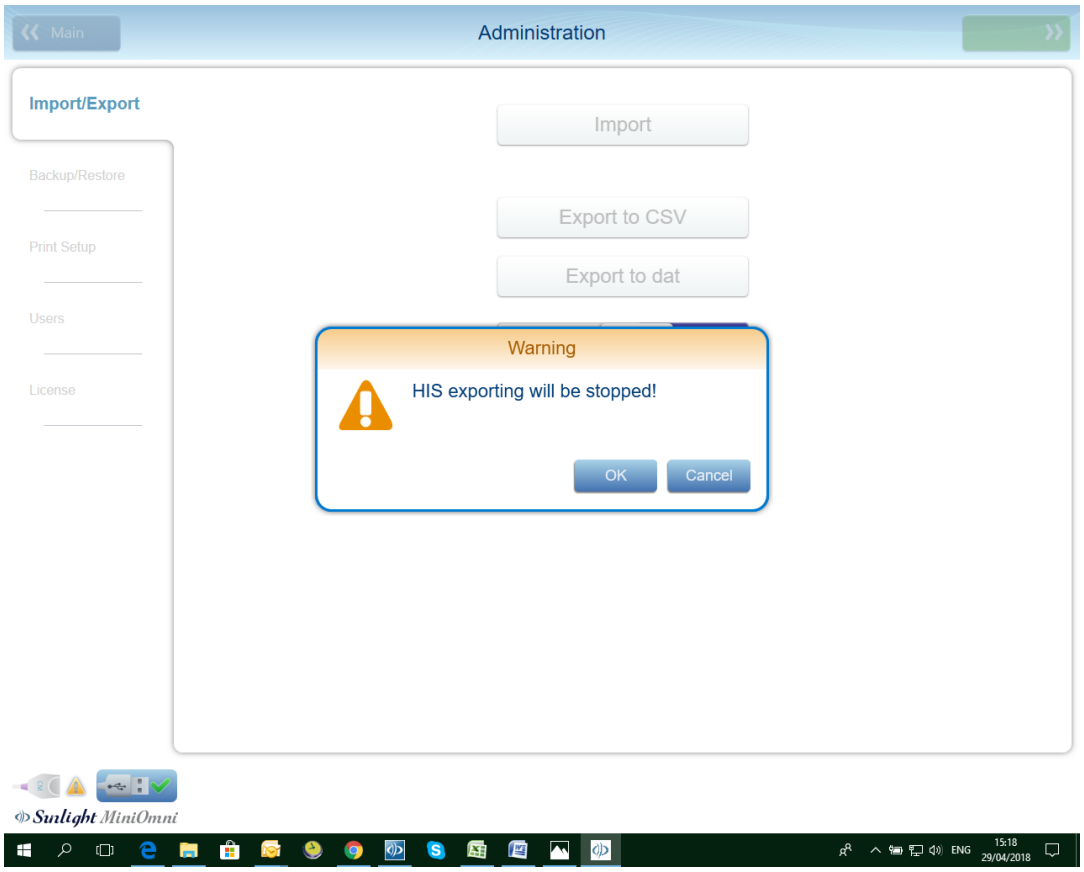
Check the “Automatic exporting results as PDF”.

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.



15.7.3.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 (N/A for patients above 88 years old);

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

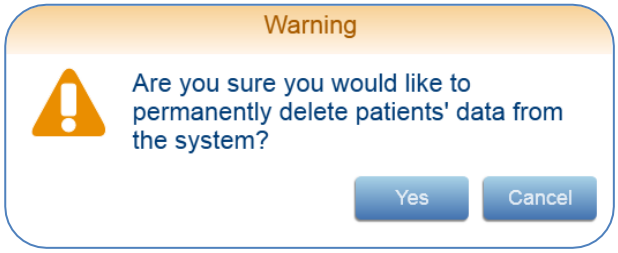
	1	2	3	4	5	6	7	8	9	10	11	12	13
1	ID	FirstName	LastName	BirthDay	Gender	MeasureDate	CurrentHeight	CurrentWeight	SiteName	VelocityAverage	TScore	ZScore	Present
2	001testcase	case	test	30/04/1942	Female	30/04/2018	155	68	DISTAL RADIUS	3837	-3.36735	-0.87755	0

15.7.4. OPTIONS – ADMINISTRATION – DELETE PATIENTS' DATA

This feature allows you to remove patients from the system.

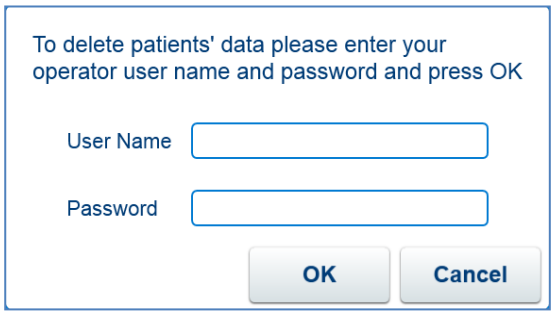
In order to delete patients, proceed as follows:

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



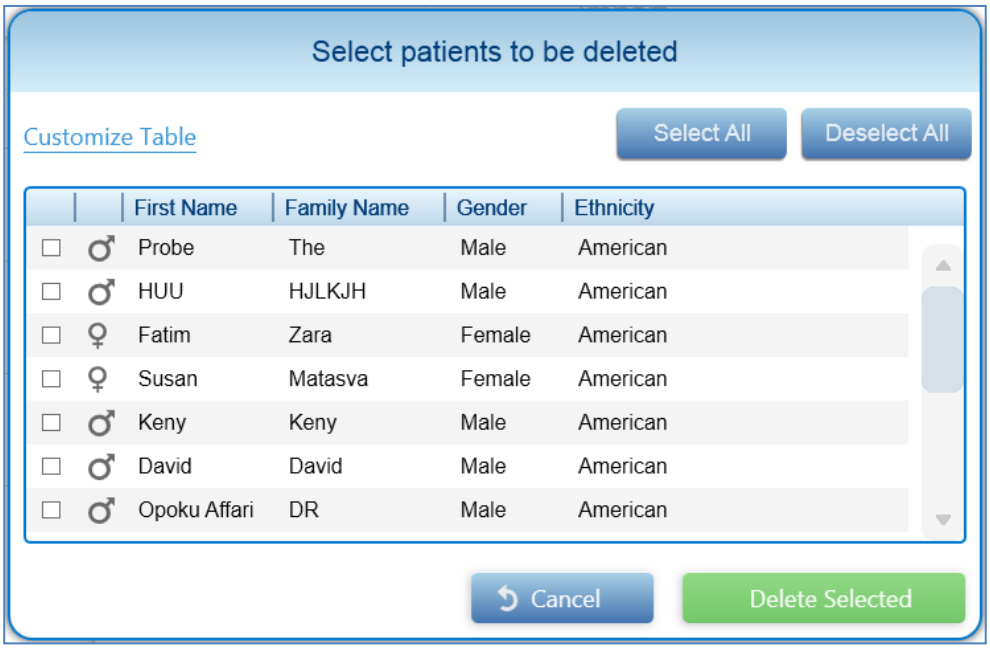
Press **Yes** to continue, or **Cancel** to terminate the request.

STEP 2 - The application will display a message requesting you to confirm your authorized User Name and Password:



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

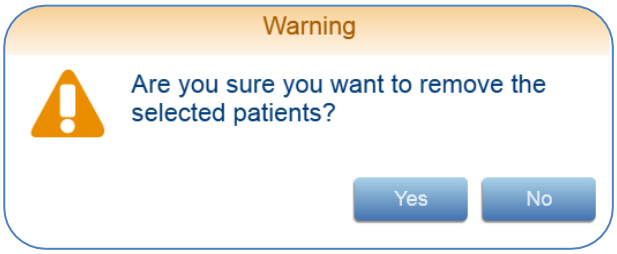
STEP 3 - The following screen will appear, requesting you to indicate which patients to delete:



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

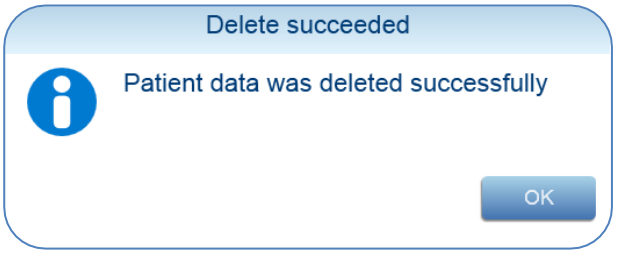
Note that you may also press **Customize Table** and follow the onscreen instructions to filter the list of patients to only some of the patients in the system. For example, you may wish to only see the list of female patients, or only those patients born after a certain date.

STEP 4 - The following message will appear, requesting you to provide final confirmation to delete the selected patients:



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:

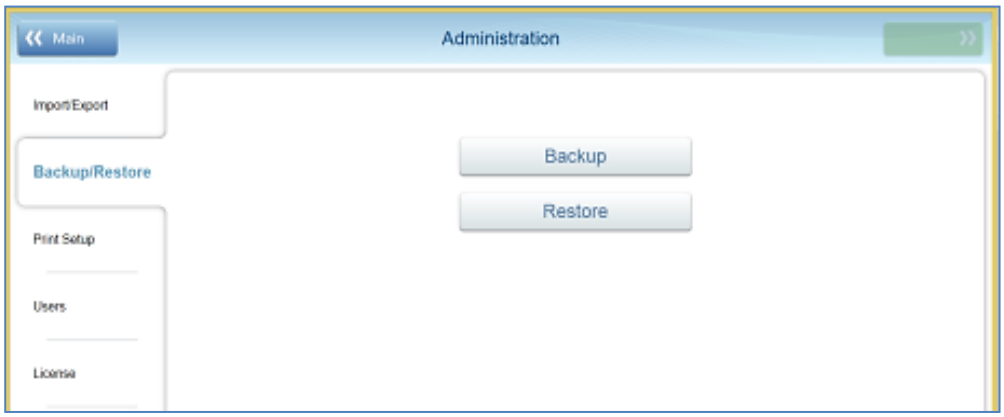


The selected patient data is now deleted from the system.

© 2022 BeamMed Ltd.

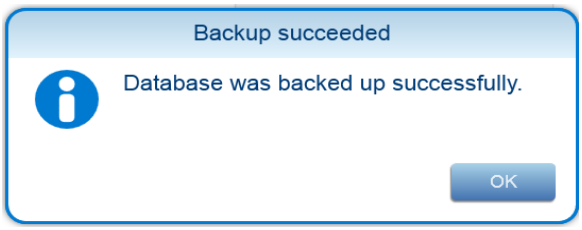
15.8. OPTIONS – ADMINISTRATION – BACKUP/RESTORE

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:

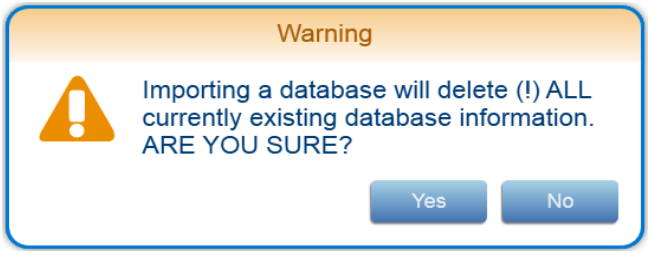


Click **OK** on the confirmation screen to complete the process.

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) Convertor, as described below.

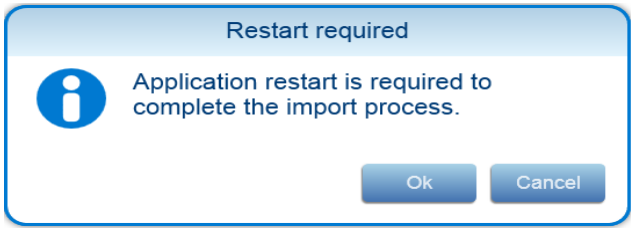
Press **Restore** to begin the restore process. A standard Windows dialog box will display to allow you to choose a backup file to use as your new MiniOmni data. When you choose a backup file, a warning message will appear:



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

© 2022 BeamMed Ltd.

The system will respond with the following message:



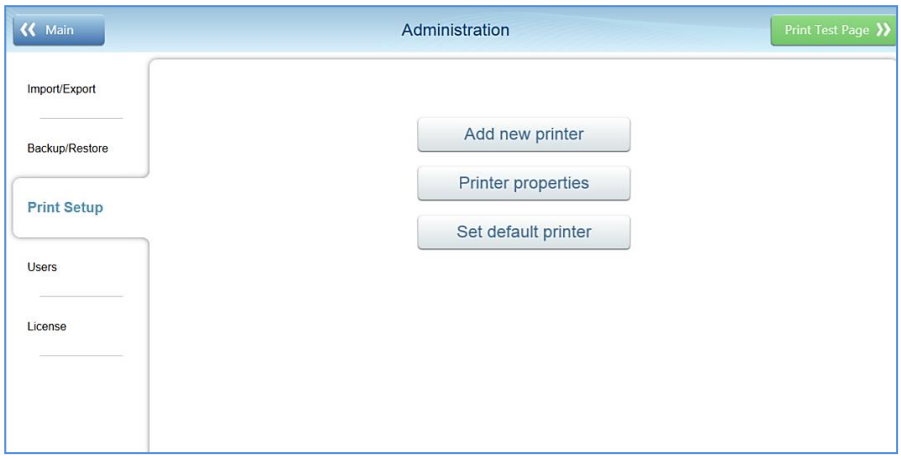
Press **OK** to continue the Restore process, or **Cancel** to not restore the data.

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

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

15.9. OPTIONS – ADMINISTRATION – PRINT SETUP

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



Add 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

© 2022 BeamMed Ltd.

15.9.1. 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.

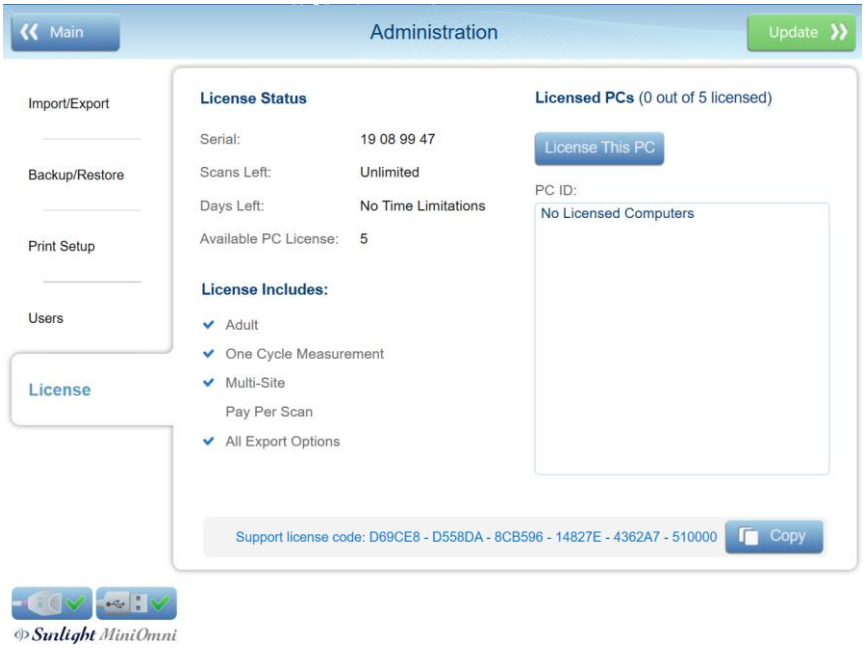
To make a change to the list, first press on the user name that you wish to modify, and then press **Add**, **Edit** or **Delete.**

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.

15.10. 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 is the days left until license expires.
- **Available PC License** – Number of computers on which the device can be registered.

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

License PCs:

- **License this PC**– 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 displays:

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.

16. 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 10 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.

© 2022 BeamMed Ltd.

Condition	Possible Cause	Recommended Action
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.
Results of System Quality Verification are out of phantom range	Test it not according to the instructions.	See *Chapter 8 System Quality Verification (SQV)*.
	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 10 Performing The Patient Measurement* on how to perform SOS Measurement. Then, train yourself using Practice Mode (*Section 15.1. Practice Mode*).

© 2022 BeamMed Ltd.

17. 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: 50° to 104° F (10° to 40° C) Humidity: 30% to 75% non-condensing Atmospheric pressure: 700hPa to 1060hPa
Storage and transportation conditions	Temperature: 32° to 122° F (0° to 50° C) Humidity: 10% to 90% non-condensing Atmospheric pressure: 700hPa to 1060hPa

17.1. 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".

Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Bone Sonometers (July 17, 2008).

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.

© 2022 BeamMed Ltd.

18. MINIOMNI TECHNICAL SPECIFICATIONS

Measurement	Speed of Sound (SOS)
Technology	Ultrasound Omnipath® Axial Transmission.
Probes	Proprietary multi-transducer probe family Center frequency = 1.25 MHz.
Measurement Precision & Accuracy	0.25% to 0.6% instrumental accuracy, depending on probe.
Measurement Time	Approximately 1 minute per skeletal site.
User Interface	Start/Stop measurement switch and MiniOmni application screens.
Calibration	Calibration free. Daily System Quality Verification procedure with phantom is recommended.
Display Options	User PC
OS Environment	Windows 10
Conformance to Standards	IEC 60601-1; IEC 60601-1-2.
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

© 2022 BeamMed Ltd.

19. 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.

© 2022 BeamMed Ltd.

20. MANUFACTURER DECLARATION

20.1. 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	

20.2. 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.

© 2022 BeamMed Ltd.

20.3. 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	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. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	

20.4. 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 dischages	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	10.0 V/m; 80MHz ÷ 2.7 GHz, 80% AM, 1kHz	Complies
Immunity from Prosimity 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 confucted 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 interuptions and voltage variations	IEC 61000-4-11	0% - 0.5 cycle & 1 cycle; 70%-25 cycles; 0% - 250 cycles on AC mains (PS)	Complies

© 2022 BeamMed Ltd.

20.5. 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 $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2,5 $d = [\frac{7}{E_1}]\sqrt{P}$
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

© 2022 BeamMed Ltd.

21. 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 guide, 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.

Software License

All software {hereinafter, the Software} is supplied under this license only. BeamMed retains all title to and all copyrights to the Software and any copies thereof. Purchaser is granted a personal, non-transferable, non-assignable, non-exclusive and limited rights to use the Software solely on the equipment on which it is installed at time of delivery {or on the equipment for which it is intended to be installed, if not installed when delivered}, for as long as purchaser shall own such equipment. The Software may be used for performing measurements on this equipment in the normal course of the purchaser's business, but for no other purpose or business. No license is provided to use the Software for Multi-Site quality control or data review purposes. Purchaser must maintain all copyright, proprietary or notices on the Software, must not decompile, disassemble or reverse engineer the Software and must not make it available to any party except those using the Software as part of Purchaser's organization.

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.

© 2022 BeamMed Ltd.

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.

© 2022 BeamMed Ltd.

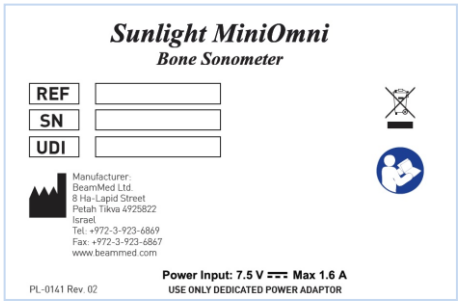
22. CLINICAL STUDIES

Please contact manufacturer for Clinical Studies Information.

© 2022 BeamMed Ltd.

23. LABELS AND SYMBOLS

23.1. LABELS



23.2. 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 YYYYMM	Serial number and date of manufacture.
REF	Catalog number.
UDI	Unique Device Identification
	Manufacturer.
	Consult instructions for use.
	The System cannot be disposed as unsorted municipal waste. Please contact your local distributor for unit disposal.

23.3. ELECTRONIC DISPOSAL

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

© 2022 BeamMed Ltd.