



OSTEOPROBE USER GUIDE



Copyright © 2017 Active Life Scientific, Inc. All Rights Reserved
OsteoProbe® is a registered trademark of Active Life Scientific, Inc.

Patent 7,878,987
Patent 7,966,866
Patent 8,398,568
Additional Patents Pending

27 East Cota Street Suite 503
Santa Barbara, CA 93101
www.activelifescientific.com

Table of Contents

0.0 Safety Warnings & Precautions.....	1
0.1 Environmental Conditions of Use	1
0.2 Safety Labels	1
0.3 Use of Sharps	3
0.4 Error Messages.....	4
0.5 Shutting Down Equipment	4
0.6 Recharging the Device.....	4
0.7 Cleaning & Maintenance.....	4
0.8 Modification of Equipment	4
0.9 Servicing	4
0.10 Disposal	4
1.0 Introduction	5
2.0 Getting Started.....	6
2.1 Charging the Laptop.....	6
2.2 Connect the Electronics	7
2.3 Connect the Stylus	8
2.4 Open Measurement Software	9
3.0 Key Features.....	10
3.1 Probe Assembly (Unsterilized).....	10
3.2 Stylus	11
3.3 Reference Material Holder.....	11
3.4 Electronics Box.....	12
3.5 Laptop Computer	12
4.0 Software Guide	13
4.1 Study Setup	13
4.2 Measurement Setup	14
4.3 Measurement.....	15
5.0 Instructions for Use.....	17
5.1 Indications for Use	17
5.2 Contraindications for Use	17
5.3 Instructions for Use.....	17
6.0 Training Procedure.....	20
6.1 Training on Reference Materials.....	20
6.2 Training on Cadaveric Tissue.....	21

6.3 Using the Green Zone	22
6.4 In Vivo Measurement.....	22
6.5 Training Report	25
7.0 Probe Sterilization.....	26
8.0 Maintenance and Cleaning	28
8.1 End User Maintenance.....	28
8.2 Recommended Cleaning	28
9.0 Technical & Performance Specifications.....	31
10.0 Troubleshooting.....	32
11.0 Contact Information.....	33

0.0 Safety Warnings & Precautions

0.1 Environmental Conditions of Use

OsteoProbe is designed for use in medical environments, ranging from small single-office clinics to large hospital medical centers. Operation, transport, and storage is recommended in the following conditions:

Temperature: -10°C – 40°C

Relative Humidity: 0% – 95%

Atmospheric Pressure: 80 kPa – 108 kPa

The OsteoProbe is *unsterile* so it is not suitable for an operating room environment.

All components of OsteoProbe should be stored and transported in the provided case.

0.2 Safety Labels

WARNING: To avoid the risk of electrical shock, only use the equipment with the provided power supply.

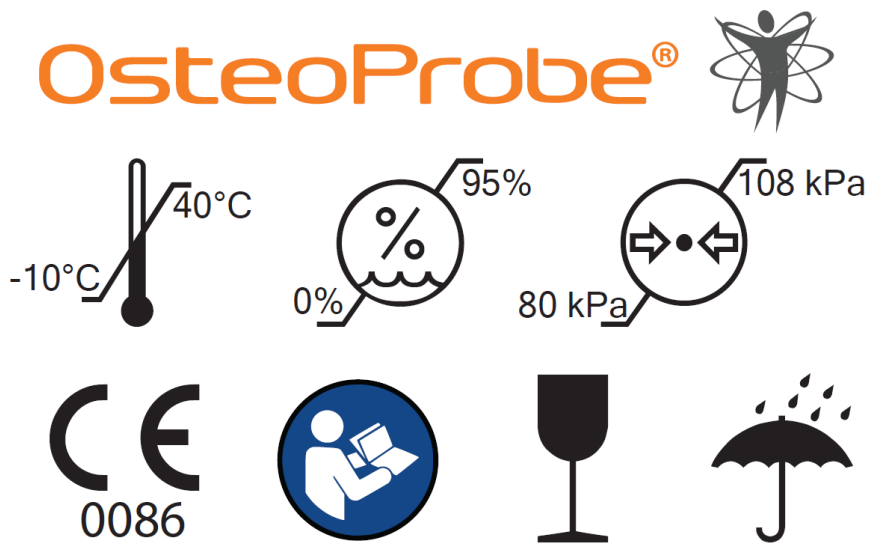
WARNING: To avoid risk of electrical shock, equipment must be used on battery power or only be connected to a supply mains with protective earth.

WARNING: To avoid the risk of electrical shock, do not contact the MHU to a source of voltage other than the MHU Cable and Electronics Box.

WARNING: To avoid accidental detachment of the USB Cable and loss of connectivity, always hold the MHU by the dark grey Outer Housing ABOVE the USB port on the Inner Housing during use.


There are no significant risks of reciprocal interference posed by the presence of the equipment during specific investigations or treatments. There are no significant risks of potential electromagnetic or other interference between the equipment and other devices.

To electrically isolate circuits from supply mains on all poles simultaneously, disconnect the Laptop Power Cable.



For Diagnosis of Bone Quality

[On exterior of Carrying Case]


 Active Life Scientific, Inc.
 27 E. Cota Street, Suite #503
 Santa Barbara, CA 93101 USA
 PHN: +1.805.770.2600




 0086



EMERGO EUROPE
 Prinsessegracht 20
 2514 AP The Hague
 The Netherlands



Power Rating: 5V == 100 mA



OP-100

[On exterior of Electronics Box]




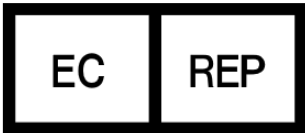











[On exterior of Electronics Box]



[On exterior of Electronics Box]

Key:

	<p>MANUFACTURER</p>
	<p>DATE OF MANUFACTURE</p>
	<p>CE LOGO</p>
	<p>AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY</p>
	<p>CATALOG NUMBER</p>

	SERIAL NUMBER
	REFER TO INSTRUCTION MANUAL/BOOKLET
	TYPE B APPLIED PART
<p>Power Rating: 5V \equiv 100 mA</p>	POWER RATING (DIRECT CURRENT)
	TEMPERATURE LIMITS
	HUMIDITY LIMITS
	ATMOSPHERIC PRESSURE LIMITS
	FRAGILE, HANDLE WITH CARE
	KEEP DRY

0.3 Use of Sharps

The Probe Assembly (probe) is sharp and may be hazardous to the user. Use caution when handling, using, and disposing of probes.

0.4 Error Messages

“Communication Error: Error communicating with instrument. Please check USB connections to the instrument and computer.”

The OsteoProbe software will display the error message above if the device is not properly connected prior to, or during measurement. To resolve this error, close the software, reconnect the device, and restart the software.

0.5 Shutting Down Equipment

To shut down the OsteoProbe, simply close the OsteoProbe software and shutdown the Laptop Computer. If you shut down during measurement, your results may not be saved.

0.6 Recharging the Device

To recharge the device, plug the Laptop Computer into an AC power outlet and let it charge for 1-2 hours. Power up the Laptop Computer to verify charging is complete. If more charging is required, leave plugged in for an additional 1-2 hours.

0.7 Cleaning & Maintenance

Cleaning of the device is described in Section 7.0. No other user maintenance is required.

0.8 Modification of Equipment

WARNING: No modification of this equipment is allowed.

0.9 Servicing

WARNING: No servicing of the OsteoProbe should be conducted by end-users. Contact Active Life Scientific, Inc. if the device is not performing.

0.10 Disposal

OsteoProbe should be disposed of according to local E-waste disposal regulations. Probe Assemblies are considered ‘sharps’ and should be handled and disposed of accordingly.

1.0 Introduction

Welcome to the OsteoProbe®!

OsteoProbe® is a simple, easy to use tool that measures bone quality in patients without the need for surgery or radiographic imaging.

A single-use, precisely-engineered disposable needle is mated to the OsteoProbe® stylus to make subcutaneous measurements on a patient's left or right tibia without the need for an incision.

The output of a test is the Bone Material Strength index (BMSi), or Bone Score™, which is a score that quantifies a patient's bone quality.

This manual provides all the details you will need to get up and running with the OsteoProbe®, including:

1. Getting started
2. Key Features
3. Software Guide
4. Instructions for Use
5. Training
6. Probe Sterilization and Disposal
7. Maintenance and Cleaning

Additional information is available at www.activelifescientific.com.

2.0 Getting Started

Getting started with the OsteoProbe is straight forward. This section will go through the setup of the device to get ready to make measurements.

All components required to begin using the OsteoProbe are included in the storage case. Inside you will find the following:

- Laptop Computer
- Laptop Power Cable
- 10 unsterile probe assemblies
- 5 blocks of BMSi-100 Reference Material
- 5 blocks of BMSi-73 Reference Material
- microUSB-A to Measurement Head Unit Cable
- USB A-B to Laptop Cable
- Electronics Box
- Reference Material Holder (RMH)
- Measurement Head Unit (MHU)

2.1 Charging the Laptop

2.1.1 Connect the Laptop Power Cable to the Laptop Computer.



2.1.2 Connect the Laptop Power Adapter

Find an appropriate power outlet and plug in the Laptop Power Cable Adapter.



USA, Canada, Mexico & Japan.

100 - 127 V

socket compatible with plug types A & B



Europe & Russia, except for the UK & Ireland

220-240 V

socket compatible with plug types C, E & F

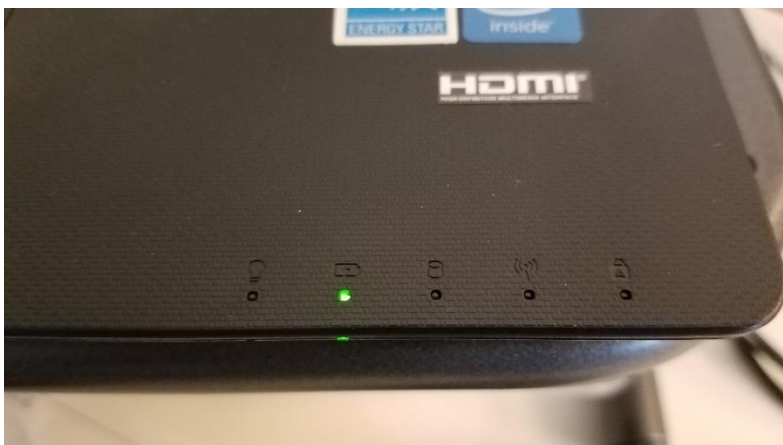


United Kingdom, Ireland, Malta, Malaysia & Singapore

220-240 V

socket compatible with plug type G

2.1.3 Check the Laptop Computer and verify that the green LED is shining, indicating that the Laptop Computer is being charged.



2.2 Connect the Electronics

2.2.1 Connect the USB A-B to Laptop Cable to the Electronics Box.



2.2.2 Connect the other end of the USB A-B to Laptop Cable to the Laptop Computer.



2.3 Connect the Stylus

2.3.1 Connect the microUSB-A to Measurement Head Unit Cable to the Electronics Box.

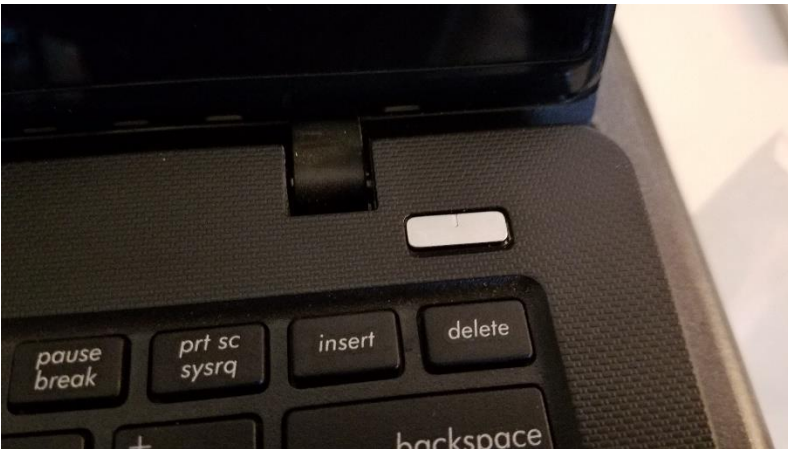


2.3.2 Connect the other end of the microUSB-A to Measurement Head Unit Cable to the stylus.



2.4 Open Measurement Software

2.4.1 Turn on the Laptop Computer by pressing the power button located to the top right of the keyboard.

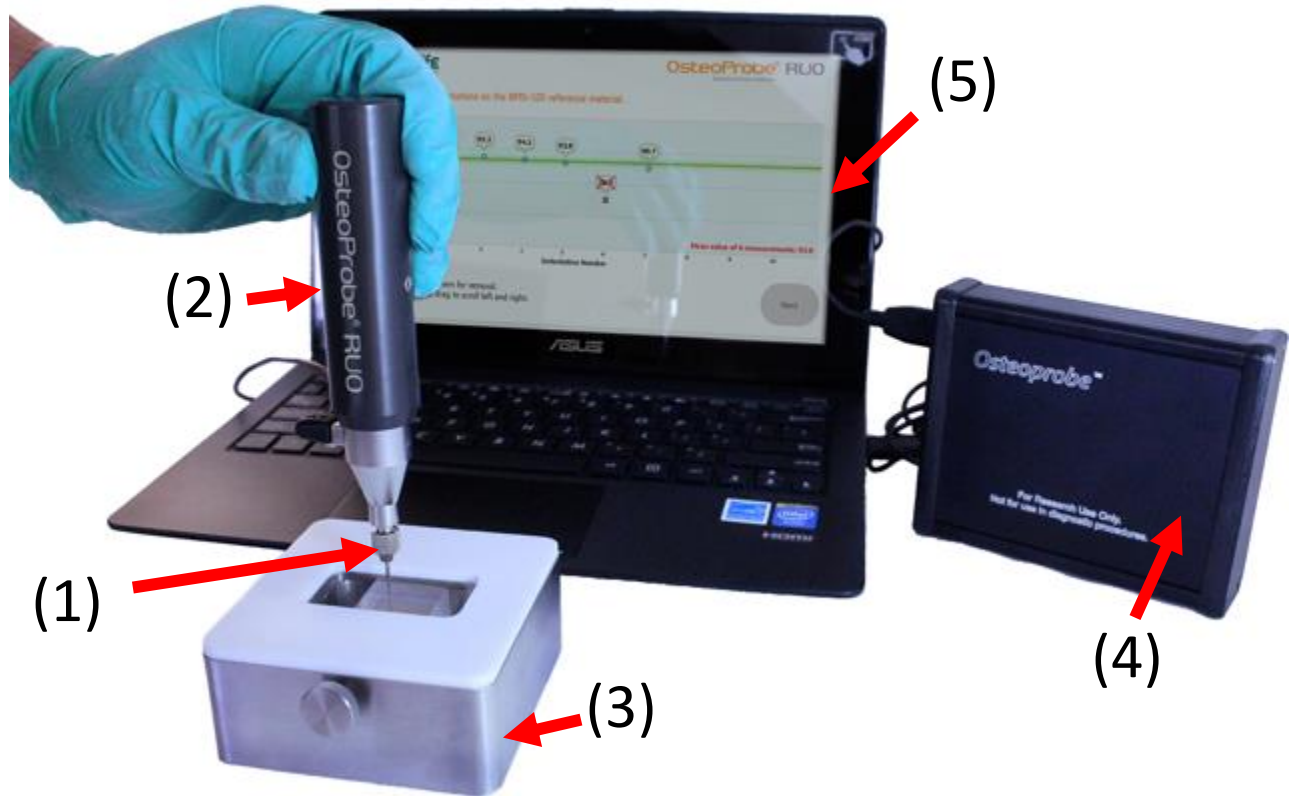


2.4.2 Open Measurement Software

Once the Laptop Computer has booted up, double click on the OsteoProbe® Clinical Software icon on the desktop.

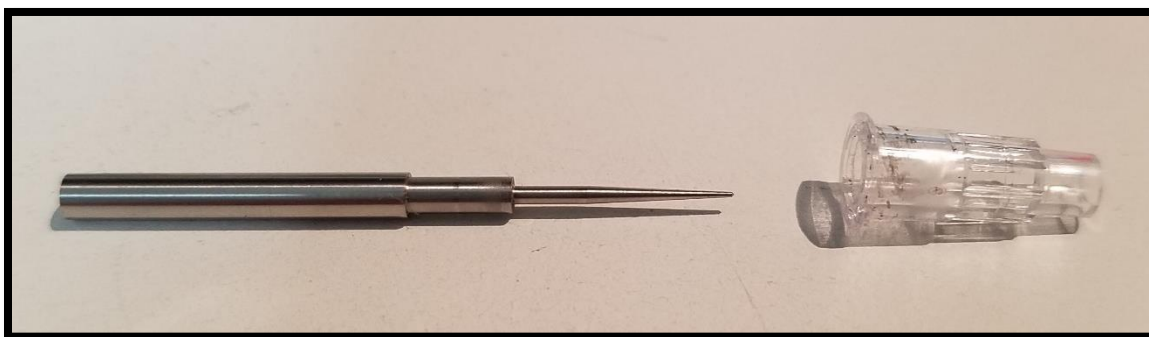
3.0 Key Features

Now that the system is setup, let's review the Key Features of OsteoProbe®.



Complete OsteoProbe® system. Pictured here: Probe Assembly (1), Stylus (2), Reference Material Holder and BMSi-100 Reference Material (3), Electronics Box (4), Laptop Computer, software, and cables (5)

3.1 Probe Assembly (Unsterilized)



The Probe Assembly is a single-use disposable that comes with a Probe ID that must be entered into the software prior to beginning measurement on a patient. These are sharp needles and should be handled with care.

NOTE: The Probe Assemblies ship unsterilized. Refer to Section 6.0 for more information on sterilization and disposal of used Probe Assemblies.

3.2 Stylus

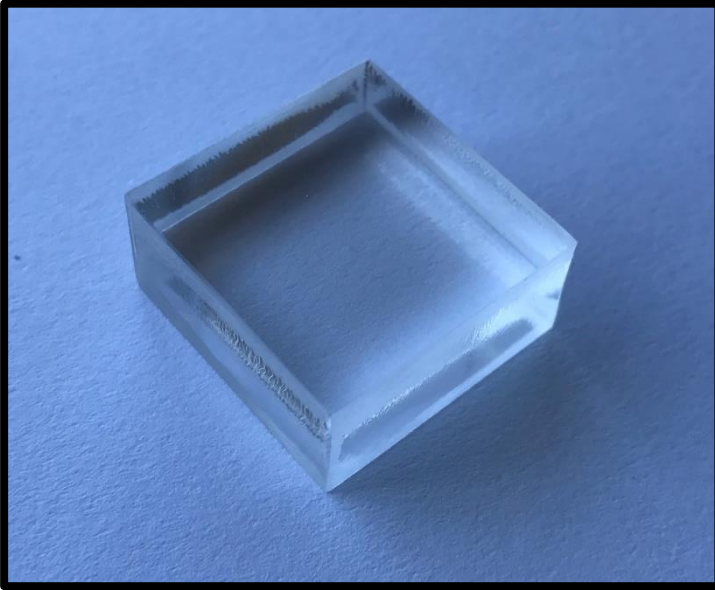


The Measurement Head Unit is the Stylus that the operator uses to make measurements. The Probe Assembly is attached to the Stylus via a magnetic coupling. The Stylus delivers an impact to the Probe Assembly, and an internal sensor measures the indentation depth.

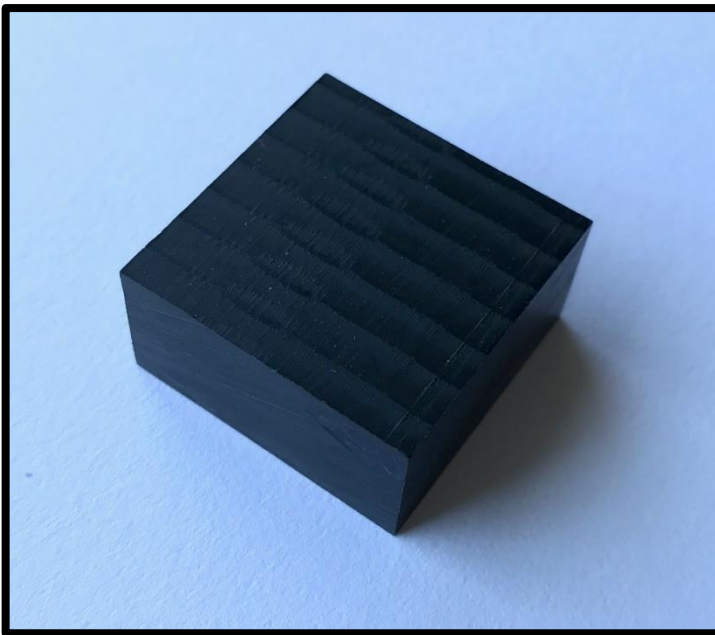
3.3 Reference Material Holder



The Reference Material Holder provides sufficient mass and secures Reference Materials in a stable position for making consistent measurements.



BMSi-100 Reference Material



BMSi-73 Reference Material

3.4 Electronics Box

The Electronics Box conditions and transmits the signal from the Stylus to the Laptop Computer for further processing.

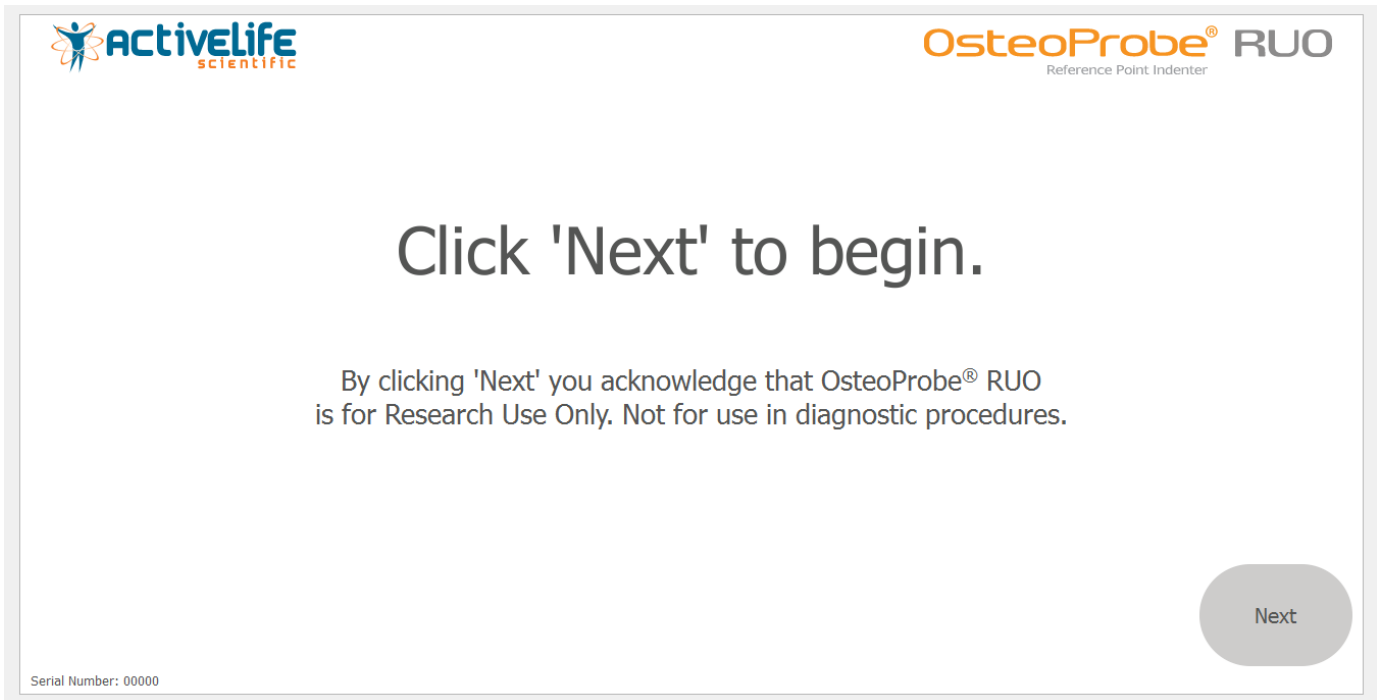
3.5 Laptop Computer

The Laptop Computer runs the OsteoProbe software, collects and stores measurement data, and transmits measurement data back to Active Life for quality control purposes.

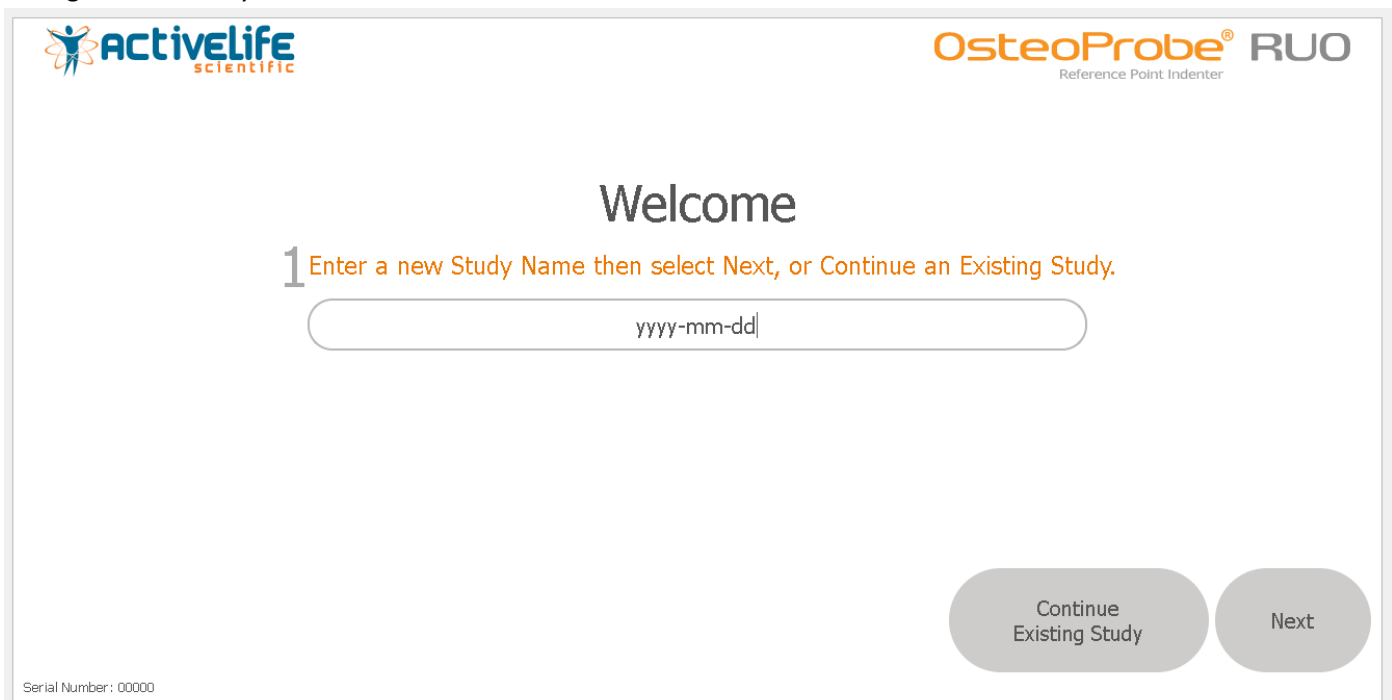
4.0 Software Guide

4.1 Study Setup

Select next on the start screen to begin.



Select “Continue Existing Study” to load and continue an existing study, or enter in a new study name and select “Next” to begin a new study.



4.2 Measurement Setup

Enter in the Sample ID of the sample that is going to be measured and the Operator's Initials.



Existing Sample IDs

Sample ID
Sample

Operator Initials
OP

Probe ID
Please enter a valid Probe ID.

Back

Next

Serial Number: 00000

Enter in the Probe ID of the probe assembly that is going to be used. If the Probe ID has not been used before, the software will say "Probe ID is unused." Then select "Next" to go to the Measurement Screen and begin making indentations.



Existing Sample IDs

Sample ID
Sample

Operator Initials
ABC

Probe ID
Ø27wd
Probe ID is unused.

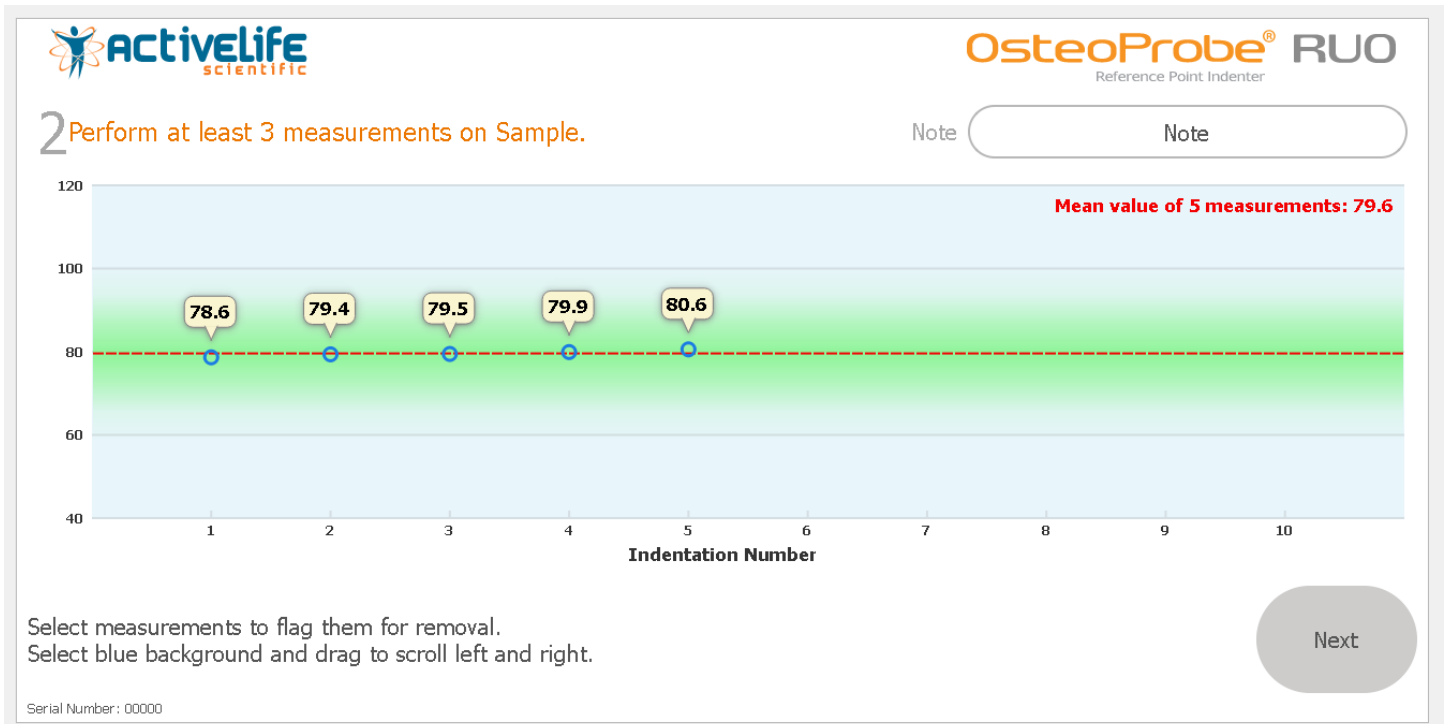
Back

Next

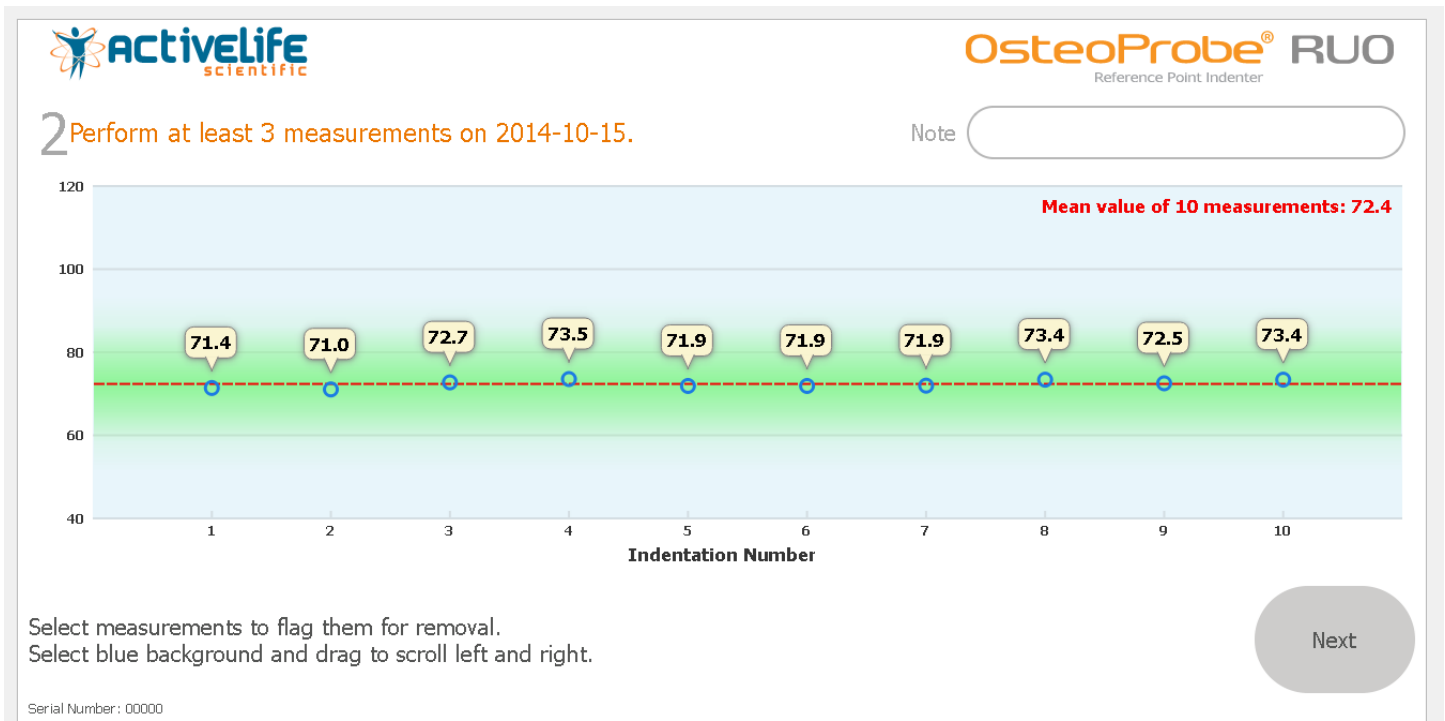
Serial Number: 00000

4.3 Measurement



Measurements will appear on the screen as indentations are made.



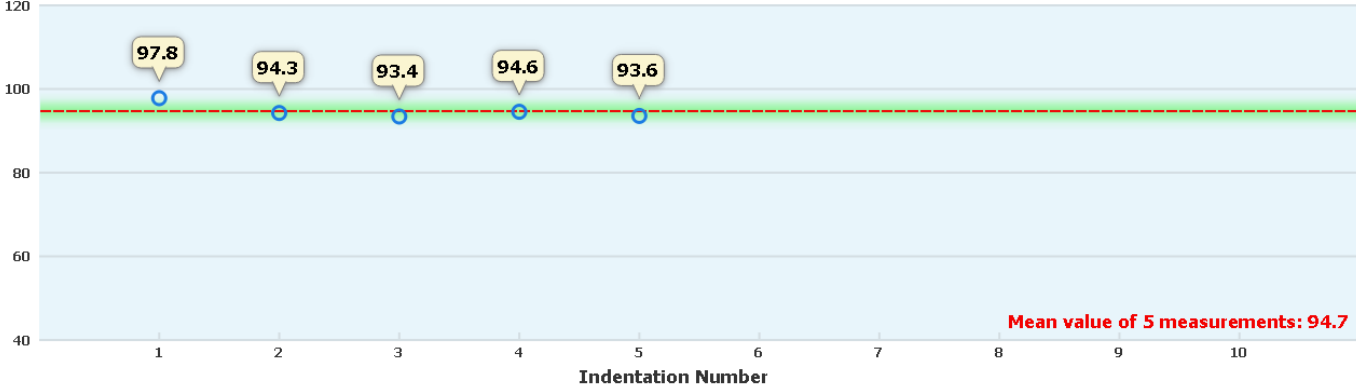
Once an adequate number of measurements have been made, select “Next” to proceed to the BMSi-100 Reference Material Measurement Screen.



Perform at least 5 indentations on the BMSi-100 Reference Material. It is recommended that 8 indentations are performed on the BMSi-100 Reference Material. Then select "Next" to proceed to the Sample Report Screen.

3 Perform 5 or more indentations on the BMSi-100 reference material.





Indentation Number	Value
1	97.8
2	94.3
3	93.4
4	94.6
5	93.6
Mean value of 5 measurements: 94.7	

Select measurements to flag them for removal.
Select blue background and drag to scroll left and right.

Next

Serial Number: 00000

BMSi score and measurement consistency will be displayed on the Sample Report Screen.

OsteoProbe RUO Report - For Research Use Only - ActiveLife

Data taken with instrument SN00000.

<p style="font-size: 2em; font-weight: bold;">72.2</p> <p><small>Mean BMSi</small></p> <p style="font-size: 1.5em; font-weight: bold;">0.26</p> <p><small>Standard Error</small></p> <p style="font-size: 1.5em; font-weight: bold;">0.82</p> <p><small>Standard Deviation</small></p>	<p style="font-size: 1.2em; font-weight: bold;">2014-10-15</p> <p><small>Operator: ABC, Number of Indents: 10</small> Any sample notes can be found in the Summary Data file.</p> <p style="color: green; font-weight: bold;">VERY CONSISTENT MEASUREMENTS</p> <p><small>Suggesting excellent technique.</small></p> <p>BMSi-100 Measurements <small>BMSi-100 Bone Material Strength Standard Deviation: 0.6</small> <small>The BMSi-100 measurements were excellent!</small></p> <p>Probe ID 000MF <small>Warning Probe ID has been used more than once.</small></p>
--	--

Next Sample

Finish

Serial Number: 00000

5.0 Instructions for Use

5.1 Indications for Use

The OsteoProbe® is intended to measure material aspects of bone quality by percutaneous micro-indentation on the medial surface of either the left or right tibia in living humans.

The device utilizes both a reusable, non-invasive component and a single-use, transient invasive component. The Probe Assembly is the single-use, transient invasive component. The duration of a measurement, and therefore contact with the body, is typically 1-5 minutes.

OsteoProbe® is intended to provide physicians, medical professionals, and researchers with information about the mechanical characteristics of a patient's bone tissue without surgery or removing any tissue from the body.

Micro-indentation has been demonstrated to be a reliable measure of material aspects of bone quality in both pre-clinical and clinical studies. The OsteoProbe® should be used by trained technicians, nurses or physicians with experience handling sterile needles and sharps.

5.2 Contraindications for Use

Patients with the following conditions should not be measured with the OsteoProbe®:

- Local edema ^a
- Local skin infection or cellulitis ^a
- Prior clinical or stress fracture in the tibia diaphysis ^a
- Dermatological lesions in the area of measurement ^a
- Focal tibial lesions like in primary or metastatic tumor, Paget's disease, Gaucher, etc. ^a
- Osteomyelitis of the tibia ^a
- Systemic infection or fever (unless unrelated to infection)
- Severe obesity
- Allergy to lidocaine or alternative local anesthetic used

^a In the event that a patient has one of these conditions, the opposite tibia may be used.

5.3 Instructions for Use

5.3.1 Patient Measurement

Measurements are taken at the mid-diaphysis of the tibia (either leg). A Measurement consists of the following steps:

1. Position the patient in decubitus supine position for improved comfort. The non-dominant tibia is selected for the measurement unless some local contraindication is present (see Indented Patient Population), in which case the contralateral side can be used.
2. Position the leg in external rotation to orient the flat surface of the medial tibia diaphysis horizontal (i.e., parallel to the exam table).
3. Mark the mid distance between the medial border of the tibia plateau and the medial malleolus using a measuring tape.

4. Perform a careful disinfection of a wide area of the anterior mid tibia region using a chlorhexidine solution or any other local disinfectant.
5. Perform local anesthesia infiltration by inserting a thin syringe needle both subcutaneously and in the periosteal surface. Lidocaine 2%, mepivacaine 2% or equivalent, with or without adrenaline, can be used.
6. Place the BMSi-100 Reference Material, secured within the Reference Material Holder (RMH), on a firm surface.
7. While local anesthesia is taking over, the operator, ideally assisted by another person that operates the computer, wears sterile gloves after handwashing or disinfecting with a topical solution. The operator, for an optimal procedure, remains blinded to the computer screen.
8. Insert a sterile probe into the Osteoprobe®.
9. Pierce the skin and periosteum at the marked mid diaphysis point of the medial tibia, until reaching the bone cortex.
10. Without losing probe contact with the bone surface, adjust the angle of the device to become perpendicular to the tibia surface, with a variation degree inferior to 10°, and slide the outer housing of the device toward the patient's leg to initiate a measurement (see below for details).
11. For every indentation, the body of the device is pulled down slowly and smoothly for a 2 to 3 s period.
12. The first indentation should be systematically disregarded since there is often inadequate penetration of the probe through the periosteum.
13. After each indentation, slide the probe to a new location at least 2 mm away from the previous indentation, re-adjust the angulation of the device, and perform another indentation. Do this until 8–10 measurements are obtained without pulling the probe out of the skin.
14. After the set of measurements in the bone have been completed, the normalization phase starts. Following the software indications, make eight indentations on the BMSi-100 Reference Material (maintaining perpendicularity to the surface and at the same speed as in the tibia). The same focus and precision used for a patient should be used for the reference material. After the measurement is complete, both the Probe Assembly and reference material should be considered contaminated and should be disposed of.
15. The screen will then display the result as the Bone Material Strength index (BMSi).



(1) Infiltration with subcutaneous local anesthesia; (2,3) Piercing with the test probe until reaching the periosteum. Then the probe must be placed perpendicular to the bone surface; (4) Indentation in the BMSi-100 Reference Material, also keeping perpendicularity to the surface and at the same speed as in the tibia.

5.3.2 Device Performance Check

Performance Checks should be made to determine whether the instrument is functioning properly. Use the BMSi-73 Reference Material as the sample for the Performance Check.

1. Begin a study titled “Performance Check”, or continue the “Performance Check” study if already created. Enter in the date for the Sample ID and the Probe ID that will be used for the Performance Check.
2. Secure the BMSi-73 Reference Material in the Reference Material Holder as outlined in Section 3.3.
3. Proceed to the Sample Measurement Screen, perform 1 indentation to settle the Test Probe into the MHU, and then make 10 indentations on the BMSi-73 Reference Material.
4. Remove the BMSi-73 Reference Material and secure the BMSi-100 Reference Material in the Reference Material Holder as outlined in Section 3.3.
5. Proceed to the BMSi-100 Reference Material Measurement Screen and perform 10 indentations on the BMSi-100 Reference Material.
6. Perform 3 Performance Check measurements. An average BMSi of 73.0 ± 2.0 indicates that the instrument is performing as expected.

Contact Active Life Scientific, Inc. for options regarding data back-up and device performance monitoring.

6.0 Training Procedure

OsteoProbe training is a critical aspect of ensuring that indentations are accurate. A Training Checklist has been developed to help operators hone their technique.

6.1 Training on Reference Materials

Initially, users should hone their technique on reference materials (steps 1 & 2). For best results on reference materials, users should perform measurements on a stable surface. Ten Probe Assemblies are provided for training. If all training Probe Assemblies have been used, contact Active Life Scientific for replacements.

1. Start by practicing a consistent and smooth actuation by indenting the BMSi-100 Reference Material as BOTH the sample and reference material. Follow this standard training protocol using the training probe assemblies and associated Probe IDs provided with the device:
 - a. Begin a study titled “Consistency Training”, or continue the “Consistency Training” study if already created.
 - b. Enter in the Sample ID as “BMSi-100” and the Probe ID that will be used for Training.
 - c. Secure the BMSi-100 Reference Material in the Reference Material Holder (RMH) and place on a stable surface.
 - d. Proceed to the Sample Measurement Screen, perform 1 indentation to settle the Test Probe into the MHU, and then make 10 indentations on the BMSi-100 Reference Material, ensuring that each indentation is at least 1mm away from other indentation sites and at least 4mm away from any edge of the BMSi-100 Reference Material.
 - e. Once complete, proceed to the next measurement screen.
 - f. Perform 10 additional indentations on the BMSi-100 Reference Material, again ensuring that each indentation is at least 1mm away from other indentation sites and at least 4mm away from any edge of the BMSi-100 Reference Material.
 - g. Click “Finish”, record the results of the measurement on the Training Checklist, and then click “Next Sample”.
 - h. Repeat protocol until 3 measurements have been completed, then click “Finish”.

By performing a BMSi measurement in this manner, users can practice measurement consistency and precision since the ratio of indentation depths should be equal to 1 and thus provide a BMSi of 100. Practice this technique until the user achieves a BMSi of 100.0 ± 1.5 three times in a row - *only then should a user move on to step 2*. Smooth, consistent, and repeatable actuations are a vital aspect of OsteoProbe success.

2. The next exercise aims at ensuring a user’s technique is accurate. Obtaining accurate indentations depends primarily on actuation rate and perpendicularity. Users can practice accuracy by indenting the BMSi73 Reference Material as the sample and indenting the BMSi-100 Reference Material as the reference. Follow this standard training protocol using the training probe assemblies and associated Probe IDs provided with the device:
 - a. Begin a study titled “Accuracy Training”, or continue the “Accuracy Training” study if already created.
 - b. Enter in the Sample ID as “BMSi-73” and the Probe ID that will be used for Training.
 - c. Secure the BMSi-73 Reference Material in the Reference Material Holder (RMH) and place on a stable surface.
 - d. Proceed to the Sample Measurement Screen, perform 1 indentation to settle the Test Probe into the MHU, and then make 10 indentations on the BMSi-73 Reference Material, ensuring that each indentation is at least

1mm away from other indentation sites and at least 4mm away from any edge of the BMSi-100 Reference Material.

- e. Once complete, remove the BMSi-73 Reference Material from the Reference Material Holder (RMH) and secure the BMSi-100 Reference Material into the Reference Material Holder (RMH).
- f. Proceed to the next measurement screen.
- g. Perform 10 additional indentations on the BMSi-100 Reference Material, again ensuring that each indentation is at least 1mm away from other indentation sites and at least 4mm away from any edge of the BMSi-100 Reference Material.
- h. Click “Finish”, record the results of the measurement on the Training Checklist, and then click “Next Sample”.
- i. Repeat protocol until 3 measurements have been completed, then click “Finish”.

Practice this technique until the user achieves a BMSi of 73 ± 2.0 three times in a row – *only then should a user move on to step 4.2*. Only after mastering the technique on reference materials in a controlled environment should users progress to practicing technique on cadaveric tissue.

6.2 Training on Cadaveric Tissue.

Ideally, the tibia of a full body cadaver would be used for training, however this can be accomplished with an incomplete tibial cadaver as well. Users should practice their technique in phases (A-C).

- A. First, practice piercing the skin and soft tissue down to the periosteum as well as through the periosteum to the bone surface, and feeling the difference between the two. This helps to commit to memory the difference between the rougher feeling of bone versus the smoother feeling of the periosteum. Feeling the probe assembly penetrate the soft tissue and the periosteum down to the bone surface is important for ensuring indentation consistency.
- B. Second, practice moving the probe assembly in a controlled manner under the skin and soft tissue. To practice consistent measurements with other users, the probe assembly should be moved incrementally in the pattern described in the official protocol without actually performing indentations. Confidence in moving the probe assembly between indentations in the described pattern is another important element to commit to memory. Sometimes the skin can feel very taught. If this is the case, a second penetration may be required.
- C. Third, bring all the above elements of training together and perform three BMSi measurements on the cadaver and practice technique until indentations consistently appear within the Green Zone in the software. Follow this standard training protocol for cadaveric measurement:
 1. Begin a study titled “Cadaver Training”, or continue the “Cadaver Training” study if already created.
 2. Enter in the Sample ID as “Cadaver” and the Probe ID that will be used for Training.
 3. Position the leg in external rotation to orient the flat surface of the medial tibia diaphysis horizontal (i.e., parallel to the exam table).
 4. Mark the mid distance between the medial border of the tibia plateau and the medial malleolus using a measuring tape.
 5. Pierce the skin and periosteum at the marked mid diaphysis point of the medial tibia, until reaching the bone cortex.

6. Without losing probe contact with the bone surface, adjust the angle of the device to become perpendicular to the tibia surface, with a variation degree inferior to 10°, and slide the outer housing of the device toward the cadaver's leg to initiate a measurement (see below for details).
7. For every indentation, the body of the device is pulled down slowly and smoothly for a 2 to 3 s period.
8. The first measurement should be systematically disregarded since there is often inadequate penetration of the probe through the periosteum.
9. After the measurement, slide the probe to a new location at least 2 mm away from the prior measurement, re-adjust the angulation of the device, and perform another measurement. Do this until 10 measurements are obtained without pulling the probe out of the skin.
10. Proceed to the BMSi-100 Measurement screen.
11. Perform 10 additional indentations on the BMSi-100 Reference Material.
12. Click "Finish", record the results of the measurement on the Training Checklist, and then click "Next Sample".
13. Repeat protocol until 3 measurements have been completed, then click "Finish".

Note: it has been observed that cadaveric measurements can often be more variable than in vivo measurements depending on the type (full body or partial) and condition (fixed or fresh) of the cadaver, therefore mastering technique under these conditions will most likely translate into better results in vivo.

6.3 Using the Green Zone

All OsteoProbes in use around the world provide the user with a visualization of individual indentation consistency by displaying a "Green Zone" that is ± 7 BMS units from the running average. This window was experimentally determined by analyzing data on living human patients and cadaveric bone to be representative of 'excellent in vivo device technique'. Its purpose is to provide users with live feedback relative to an excellent user.

However, it is conceivable that certain diseases or conditions could lead to heterogeneous bone that results in measurements outside the Green Zone that are not necessarily 'outliers'. Outliers are automatically removed by a validated algorithm once all measurements are complete.

6.4 In Vivo Measurement

After an operator has completed the Training Checklist with results consistent to other expert operators, on both reference materials and a cadaver, they should measure a healthy living subject using the following standard protocol:

Measurements are taken at the mid-diaphysis of the tibia (either leg). A Measurement consists of the following steps:

1. Position the patient in decubitus supine position for better comfort. The non-dominant tibia is selected for the measurement unless some local contraindication is present (see Indented Patient Population), in which case the contralateral side can be used.
2. Position the leg in external rotation to orient the flat surface of the medial tibia diaphysis horizontal (i.e., parallel to the exam table).
3. Mark the mid distance between the medial border of the tibia plateau and the medial malleolus using a measuring tape.
4. Perform a careful disinfection of a wide area of the anterior mid tibia region using a chlorhexidine solution or any other local disinfectant.

5. Perform local anesthesia infiltration by inserting a thin syringe needle both subcutaneously and in the periosteal surface. Lidocaine 2%, mepivacaine 2% or equivalent, with or without adrenaline, can be used.
6. Place the BMSi-100 Reference Material, secured in the Reference Material Holder (RMH), on a firm surface.
7. While local anesthesia is taking over, the operator, ideally assisted by another person that operates the computer, wears sterile gloves after handwashing or disinfecting with a topical solution. The operator, for an optimal procedure, remains blinded to the computer screen.
8. Insert a sterile probe into the Osteoprobe.
9. Pierce the skin and periosteum at the marked mid diaphysis point of the medial tibia, until reaching the bone cortex.
10. Without losing probe contact with the bone surface, adjust the angle of the device to become perpendicular to the tibia surface, with a variation degree inferior to 10° , and slide the outer housing of the device toward the patient's leg to initiate a measurement (see below for details).
11. For every indentation, the body of the device is pulled down slowly and smoothly for a 2 to 3 s period.
12. The first indentation should be systematically disregarded since there is often inadequate penetration of the probe through the periosteum.
13. After each indentation, slide the probe to a new location at least 2 mm away from the previous indentation, re-adjust the angulation of the device, and perform another indentation. Do this until 8–10 measurements are obtained without pulling the probe out of the skin.
14. After the set of measurements in the bone have been completed, the normalization phase starts. Following the software indications, make eight indentations on the BMSi-100 Reference Material (maintaining perpendicularity to the surface and at the same speed as in the tibia). The same focus and precision used for a patient should be used for the reference material. After the measurement is complete, both the Probe Assembly and reference material should be considered contaminated and should be disposed of accordingly.
15. The screen will then display the result as the Bone Material Strength index (BMSi).



(1) Apply local



**(2) Insert through
skin to tibia**



(3) Measure Bone



**(4) Measure
reference material**

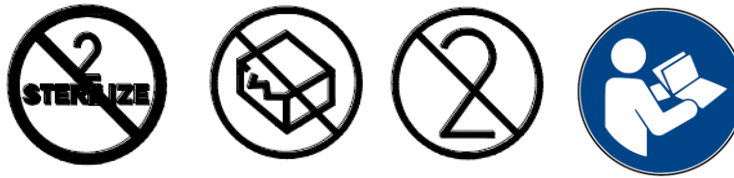
(1) Infiltration with subcutaneous local anesthesia; (2,3) Piercing with the test probe until reaching the periosteum. Then the probe must be placed perpendicular to the bone surface; (4) Indentation in the BMSi-100 Reference Material, also keeping perpendicularity to the surface and at the same speed as in the tibia.

6.5 Training Report

After successfully measuring a healthy living subject with acceptable consistency, an operator is ready to begin measuring more living subjects. It is recommended that an operator practice on several volunteer healthy subjects prior to measuring any patients. Use the Training Report below as a template:

Operator		Date	
Step 1: BMSi-100 (11 indents each, discarding the first)			
PMMA 1		PMMA 1	
PMMA 2		PMMA 2	
PMMA 3		PMMA 3	
Step 2: BMSi-73 (11 indents each, discarding the first)			
BMSi 1		Noryl 1	PMMA 1
BMSi 2		Noryl 2	PMMA 2
BMSi 3		Noryl 3	PMMA 3
Cadaver Leg(s) (11-12 indents on cadaver leg, discarding the first, 10 indents on PMMA)			
Test 1		PMMA 1	
Test 2		PMMA 2	
Test 3		PMMA 3	
Final Test: Healthy Patient (11-12 indents on patient, discarding the first, 10 indents on PMMA)			
BMSi			
StD			
PMMA StD			

7.0 Probe Sterilization



Manufacturer: Active Life Scientific, Inc.

Method : Steam Sterilization (Autoclave)





Device(s): OPD-900 OsteoProbe Probe Assembly

WARNINGS	The Probe Assembly is sharp and may be hazardous to the user. Use caution when handling, using, and disposing of Probe Assemblies.
Limitations on reprocessing	Probe Assemblies are single use and may only be processed once.
INSTRUCTIONS	
Point of use:	N/A – Probe Assemblies are to be disposed after one use
Preparation for decontamination:	N/A – Probe Assemblies are to be disposed after one use
Cleaning: Automated	N/A – Probe Assemblies are to be disposed after one use
Cleaning: Manual	N/A – Probe Assemblies are to be disposed after one use
Disinfection:	N/A – Probe Assemblies are to be disposed after one use
Drying:	N/A – Probe Assemblies are to be disposed after one use
Maintenance, Inspection and Testing:	N/A – Probe Assemblies are to be disposed after one use
Packaging:	<ol style="list-style-type: none"> Carefully insert the Test Probe and Reference Guide into a 3” x 8” sterilization pouch suitable for steam sterilization.
Sterilization:	<ol style="list-style-type: none"> When sterilizing more than one pouch at a time, make sure the plastic side of pouch always faces paper side of adjacent pouch. Up to 25 pouches can be placed into the same sterilization basket and up to 2 sterilization baskets can be used for a single sterilization cycle. Gravity Steam Sterilization Cycle - 60 minutes at 121° C, 30 minutes drying time. Do not exceed 130° C.
Storage:	Store in a dry place.
Additional Information:	No particular requirements.
Manufacturer contact:	27 E. Cota Street Suite #503 Santa Barbara CA 93101 USA +1.805.770.2600

WARNING: The instructions provided above have been validated by Active Life Scientific, Inc. as being CAPABLE of preparing the device for use. It remains the responsibility of the processor to ensure that the processing as actually

performed using equipment, materials, and personnel in the processing facility achieves the desired result. This normally requires validation and routine monitoring of the process.

Key:

	DO NOT RESTERILIZE
	DO NOT USE IF PACKAGE IS DAMAGED
	DO NOT REUSE
	REFER TO INSTRUCTION MANUAL/BOOKLET

8.0 Maintenance and Cleaning

8.1 End User Maintenance

To maintain the performance of the OsteoProbe®, always store all components in the provided case and clean on a regular basis. If the device is used frequently (> 5x per day), clean daily.



There is no recommended regular maintenance for end-users. If the OsteoProbe® requires maintenance, please contact Active Life Scientific, Inc. @ +1.805.770.2600 or visit www.activelifescientific.com.

8.2 Recommended Cleaning


OsteoProbe® is shipped unsterile and should not be autoclaved. Probe Assemblies are shipped unsterile and should be sterilized according to the procedure in Section 6.0. This cleaning procedure does not apply to the Probe Assembly.


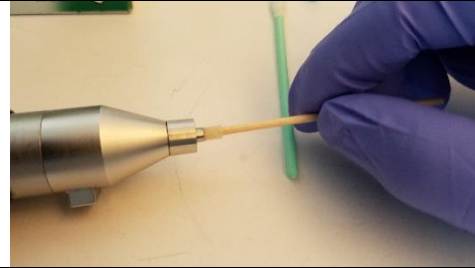


Even though the device is non-sterile, it is important to clean on a regular basis to avoid dirt contamination that could affect device performance. The following cleaning procedure is recommended:

8.2.1 Cleaning Supplies

		<p>Including gloves, the only materials you will need to clean the device include:</p> <ul style="list-style-type: none"> • Isopropyl Alcohol (IPA) • Kimwipes • Q-Tips
--	--	--


8.2.2 Cleaning the Stylus

<p>Wet a Kimwipe with IPA.</p> <p>Clean the Inner Housing and Nose Cone (shiny silver part) of the Stylus.</p>		
--	---	--

		<p>Wet a Q-tip with IPA.</p> <p>Carefully clean the <i>inner</i> hole, through which you connect the Probe Assembly to the Stylus.</p> <p>Next, wet a separate Q-tip with IPA.</p>
		<p>Carefully clean the <i>outer</i> threads that secure the Probe Lock to the Stylus.</p> <p>Replace the Dust Cap on the Stylus and return to the storage case.</p>

8.2.4 Cleaning the Reference Material Holder (RMH)

		<p>Unscrew the thumbscrew that secures the Reference Materials.</p>
---	---	---

	<p>Wet a new Kimwipe with IPA and clean the inside chamber of the RMH.</p> <p>NOTE: the most critical areas are along the edges. Dirt can accumulate which can introduce measurement error.</p>
--	--



Wet a new Kimwipe with IPA and wipe down the white plastic surface.

Once complete, replace the set screw and return to the storage case.

8.2.5 Cleaning the Laptop Computer



Shut down the Laptop Computer.

Using a new dry Kimwipe, gently wipe down the surface of the keyboard and monitor screen.

NOTE: If you have significant dirt or smudges on the keyboard or monitor screen, it is appropriate to use a Kimwipe that has been wetted with IPA.

8.2.6 Cleaning the Electronics



Wet a new Kimwipe with IPA and wipe down all exterior surfaces.

NOTE: use caution when cleaning near the USB ports to avoid saturation with IPA. If the ports do get wet, let the Electronics dry completely prior to connecting.

9.0 Technical & Performance Specifications

Impact Force:	41.0 ± 3.0N
Pre-Load Force:	10.5 ± 2.0N
BMSi (instrument) Resolution:	±0.1 BMSi
Case dimensions (exterior):	46.2 x 34 x 17 cm
Case weight:	10 kg
Measurement (raw) data file format:	CSV
USB connectivity:	2.0
Ethernet connectivity:	Wireless

10.0 Troubleshooting

TECHNICAL ASSISTANCE

If measurements on BMSi+73 Reference Material are outside of 73.0 ± 2.0 BMSi, or the device is not functioning, please contact:

Active Life Scientific, Inc.

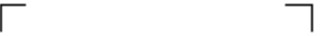
PHN: +1.805.770.2600 – FAX: +1.805.770.2606

support@activelifescientific.com

11.0 Contact Information



Active Life Scientific, Inc.
27 E Cota Street, Suite 503
Santa Barbara, CA 93101
PHN: +1.805.770.2600
www.activelifescientific.com



EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

