OSTEOPROBE USER MANUAL

Patent 7,878,987
Patent 7,966,866
Patent 8,398,568
Patent 9,895,104
Patent 9,983,107
Additional Patents Pending

27 East Cota Street Suite 400
Santa Barbara, CA 93101
www.activelifescientific.com

Table of Contents

1.0 Safety Warnings & Precautions

Rx ONLY

1.1 Warnings

To avoid potential injury to the user and the patient and/or damage to the equipment, please note the following warnings:

1. Failure to follow the instructions, warnings, and precautions in this manual may lead to injury or damage to the equipment.
2. This equipment is only to be used by qualified personnel, who have complete knowledge of the use of the equipment.
3. To avoid the risk of electrical shock, only use the equipment with the provided Power Supply and AC Cable.
4. To avoid risk of electrical shock, equipment must be used on battery power or only be connected to a supply mains with protective earth.
5. To avoid the risk of electrical shock, do not contact the Stylus to a source of voltage other than the Stylus Cable and E-Box.
6. To avoid accidental detachment of the Stylus Cable and loss of connectivity, always hold the Stylus by the black Handle ABOVE the USB port on the Body during use.
7. There are no significant risks of reciprocal interference posed by the presence of the equipment during specific investigations or treatments.
8. There are no significant risks of potential electromagnetic or other interference between the equipment and other devices.
9. To electrically isolate circuits from supply mains on all poles simultaneously, disconnect the Power Supply from the Laptop.
10. The equipment is *unsterile* so it is not suitable for an operating room environment. Do not attempt to sterilize any part of the equipment, except the Tip Assemblies (see Section 3.7: Tip Assembly Sterilization), via any sterilization method.
11. Tip Assemblies are shipped *unsterile* and should be sterilized according to the procedure in Section 3.7: Tip Assembly Sterilization.
12. The Tip Assemblies are sharp and may be hazardous to the user. Use caution when handling, using, and disposing of Tip Assemblies.
13. No servicing, modification, or maintenance of the equipment should be conducted by end-users. Contact Active Life Scientific, Inc. if the device is not performing.

1.2 Precautions

To avoid improper use and/or damage to the equipment, please note the following precautions:

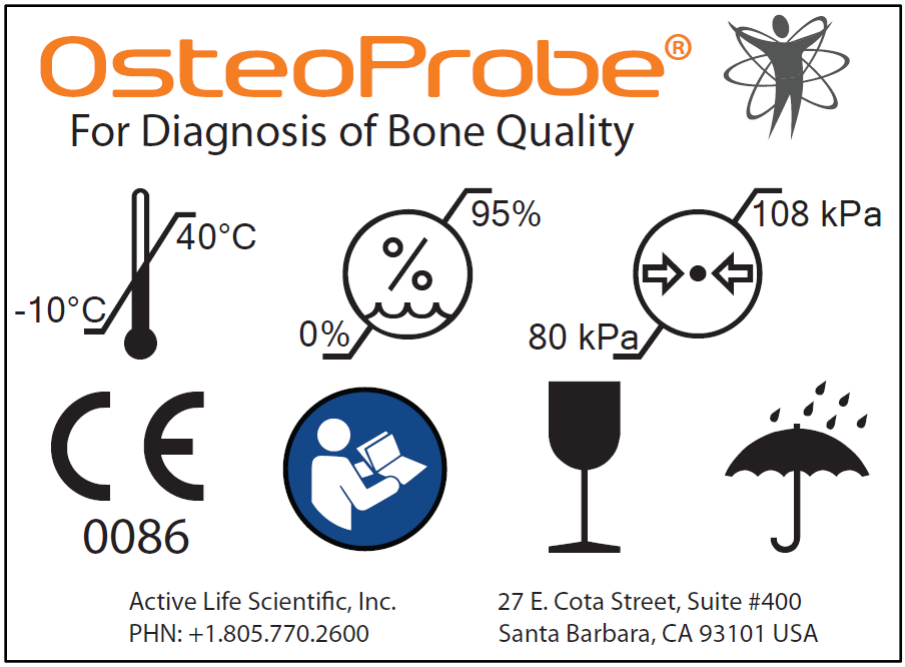
1. Carefully unpack the equipment and check for any damage that may have occurred during shipment. If damage is detected, refer to Section 10: Warranty and Return Policy.
2. Operation, transport, and storage of equipment is recommended in the following conditions:

Temperature: -10°C – 40°C
Relative Humidity: 0% – 95%
Atmospheric Pressure: 80 kPa – 108 kPa

3. To reduce the risk of damage to the equipment, avoid actuating the Stylus without a Tip Assembly attached.
4. To reduce the risk of damage to the equipment, only use the approved cleaning methods described in Section 5: Maintenance & Cleaning. Do not immerse the equipment in liquid.
5. Avoid rough handling or dropping of the equipment or any component of the equipment to prevent damage by mechanical shock.
6. All components of the equipment should be stored and transported in the provided Carrying Case.
7. To shut down the equipment, close the OsteoProbe Software and shutdown the Laptop. If the equipment is shut down during measurement, results may not be saved.

Note: The warranty is void if any of these warnings or precautions are disregarded.

1.3 Safety Labels



[On exterior of Carrying Case]

[On exterior of E-Box]

[On exterior of E-Box]

[On exterior of E-Box]

[On each individual Tip Assembly Tube]

REF OPD-900

LOT

20 UNITS
Patent Pending

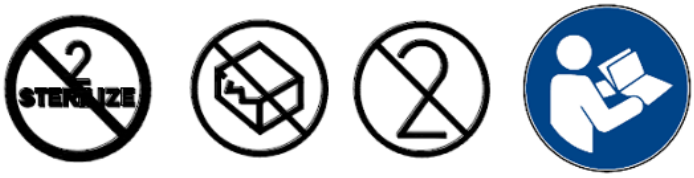
REF REFERENCE NUMBER
LOT LOT NUMBER
DO NOT RESTERILIZE
FOR SINGLE USE ONLY
CONSULT INSTRUCTIONS FOR USE
DO NOT USE IF PACKAGE IS DAMAGED

Active Life Scientific, Inc.
Santa Barbara, CA, USA
(805)770-2600

[On each pack of Tip Assemblies]

ACTIVE LIFE SCIENTIFIC
the bone quality company

OsteoProbe Probe Assembly Sterilization Instructions



Manufacturer: Active Life Scientific, Inc.
Method: Steam Sterilization (Autoclave) Device(s): OPD-900 OsteoProbe Probe Assembly

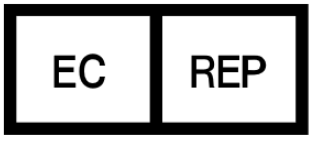
WARNING: The instructions provided on the reverse have been validated by Active Life Scientific, Inc. as being CAPABLE of preparing the device for use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials, and personnel in the processing facility achieves the desired result. This normally requires validation and routine monitoring of the process.

OPD-010 Rev B

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:	1. Carefully insert the Test Probe and Reference Guide into a 3" x 8" sterilization pouch suitable for steam sterilization.
Sterilization:	1. When sterilizing more than one pouch at a time, make sure the plastic side of pouch always faces paper side of adjacent pouch. 2. 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. 3. 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 #400 | Santa Barbara CA 93101 | USA +1.805.770.2600

OPD-010 Rev B

[Included inside each pack of Tip Assemblies]

Symbol	Definition
	MANUFACTURER
	DATE OF MANUFACTURE
	CE LOGO
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

Symbol	Definition
	CATALOG NUMBER
	SERIAL NUMBER
	REFER TO INSTRUCTION MANUAL/BOOKLET
	TYPE B APPLIED PART
Power Rating: 5V ⎓ 100 mA	POWER RATING (DIRECT CURRENT)
	TEMPERATURE LIMITS
	HUMIDITY LIMITS
	ATMOSPHERIC PRESSURE LIMITS
	FRAGILE, HANDLE WITH CARE

Symbol	Definition
	KEEP DRY
Rx ONLY	CAUTION: Federal law restricts this device to sale by or on the order of a medical professional.

2.0 Introduction

2.1 Overview

Welcome to the OsteoProbe®!

OsteoProbe® is a device that measures bone quality in patients without the need for surgery or radiographic imaging.

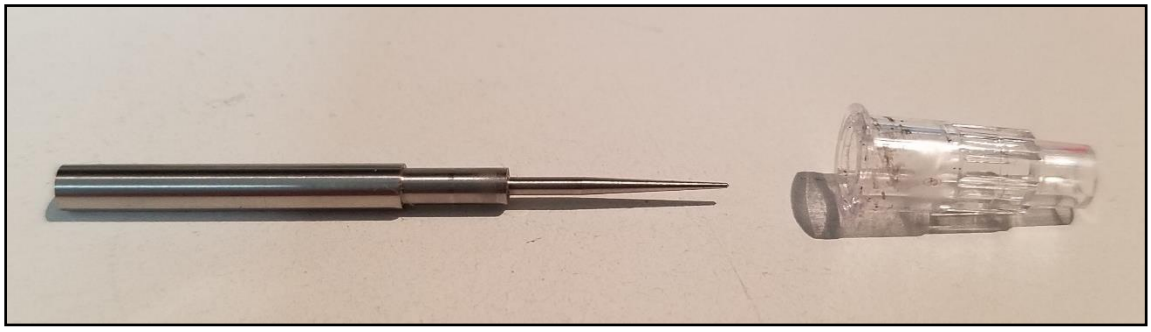
A single-use, precisely-engineered disposable needle is mated to the OsteoProbe® stylus to make subcutaneous measurements on a patient's left or right tibia without the need for an incision.

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.

2.2 Key Features

Complete OsteoProbe® system. Pictured here: (1) Stylus & Tip Assembly, (2) Holder & Reference Block, (3) E-Box, and (4) Laptop.

2.2.1 Tip Assembly (Unsterilized)



The Tip Assembly is a single-use disposable that comes with a Tip 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.

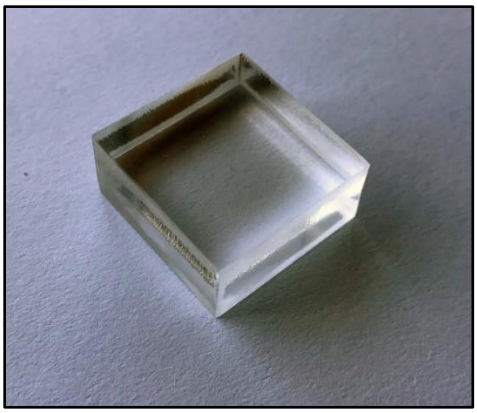
NOTE: The Tip Assemblies ship ***unsterilized***. See Section 3.7: Tip Assembly Sterilization for information on sterilization of Tip Assemblies.

2.2.2 Stylus

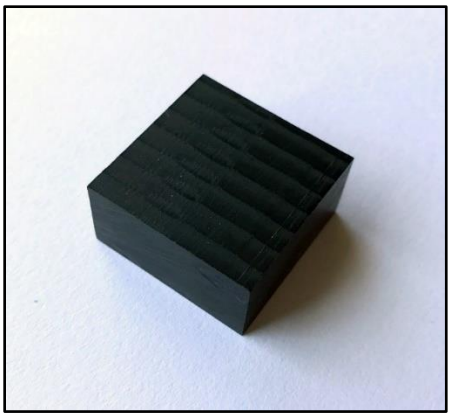
The Measurement Head Unit is the Stylus that the operator uses to make measurements. The Stylus consists of an outer Handle and an internal Body. The Tip Assembly is attached to the Stylus via a magnetic coupling. The Stylus delivers an impact to the Tip Assembly, and an internal sensor measures the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

2.2.3 Holder & Reference Materials

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



Reference Block

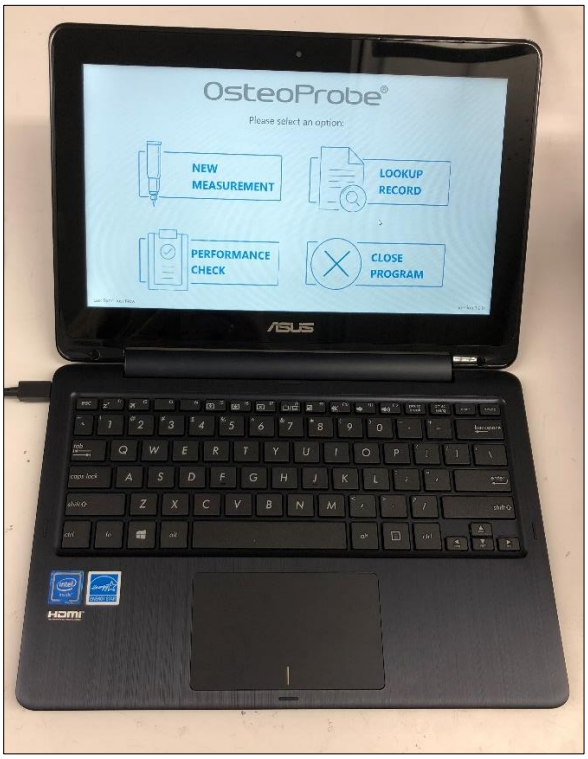


Performance Check Block

2.2.4 E-Box

The E-Box conditions and transmits the signal from the Stylus to the Laptop for further processing.

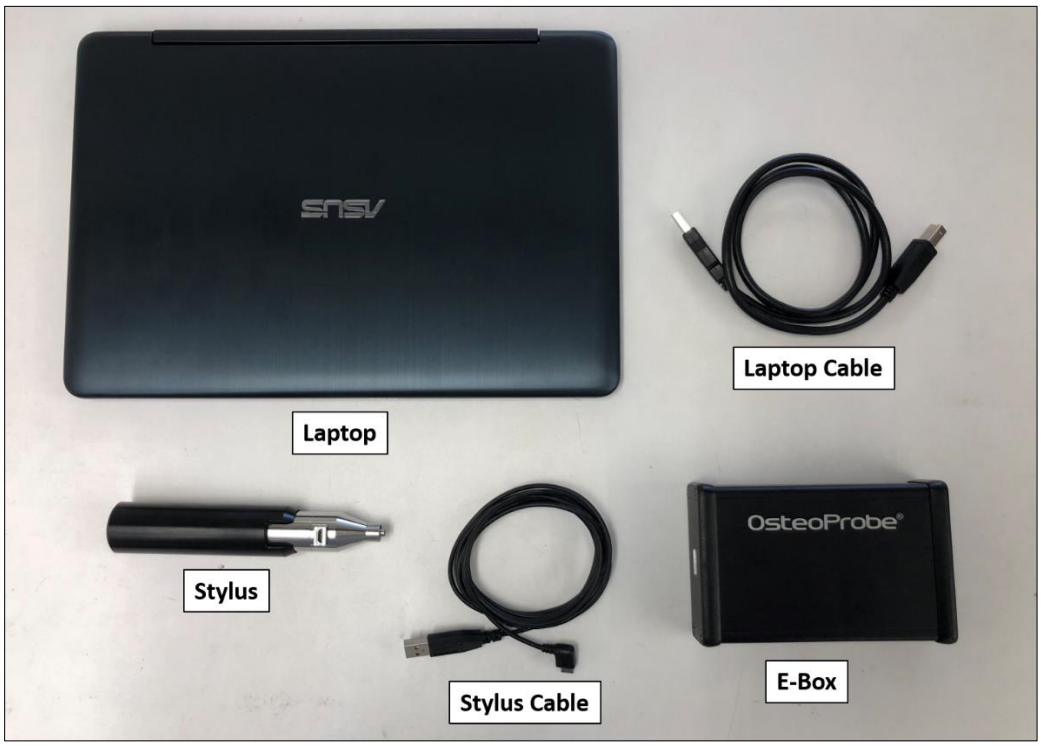
2.2.5 Laptop

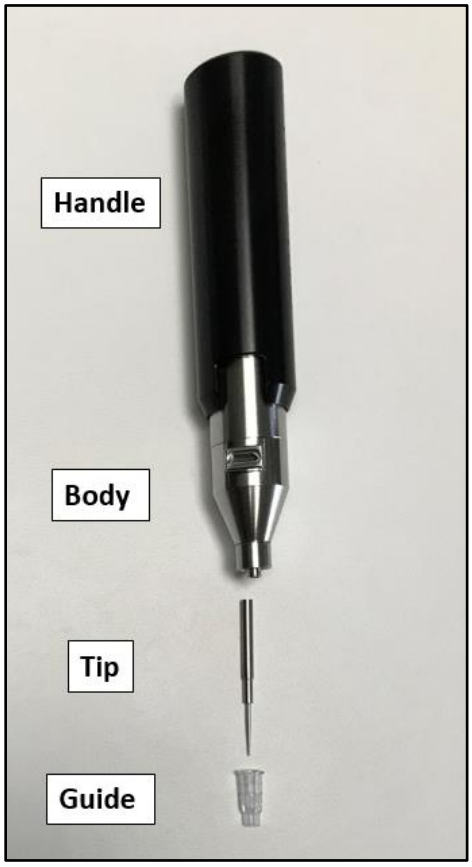


The Laptop runs the OsteoProbe Software, collects and stores measurement data, and transmits measurement data back to Active Life Scientific, Inc. for quality control purposes.

3.0 System Setup

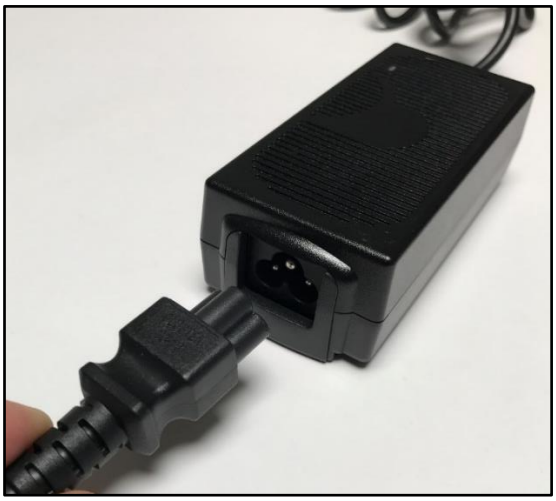
Getting started with the OsteoProbe is straight-forward. This section will go through the setup of the device to get ready to make measurements.





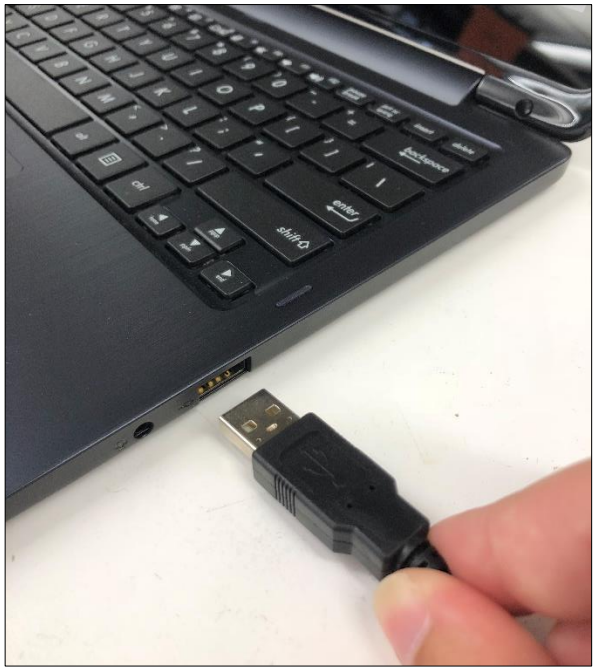
3.1 Connecting the System

3.1.1 Use the AC Cable to connect the Power Supply to an appropriate power outlet.



3.1.2 Plug the connector of the Power Supply into the Laptop. An orange LED will light up along the front edge of the Laptop to indicate that the Laptop is charging.

3.1.3 Plug the USB-B connector of the Laptop Cable into the E-Box and plug the USB-A connector into the Laptop.



3.1.4 Plug the USB-A connector of the Stylus Cable into the E-Box and plug the Micro-B connector into the Stylus.

3.2 Securing a Reference Block

3.2.1 Wipe down the pocket of the Holder to ensure that the pocket is free of debris that could prevent the Reference Block from sitting completely flat.

3.2.2 Lightly push down on the Reference Block while tightening down the Holder Screw to help ensure that the block sits completely flat in the Holder. Note that the Holder Screw does not need to be tightened down excessively to properly secure the Reference Block in place.

3.2.3 Select a flat, stable surface to place the Holder on. If needed, wipe down the bottom of the Holder and the surface to ensure that the RMH sits in a flat and stable position on the surface.

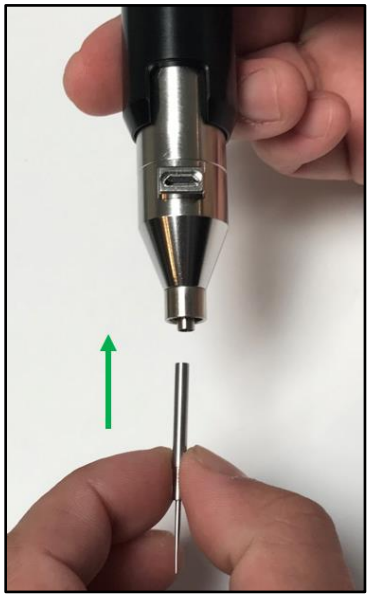
3.3 Handling Tip Assemblies

3.3.1 Tip Assemblies are extremely sharp and can blunt easily. Tips can get blunted by getting dropped or by touching the metal of the Holder.

3.3.2 Take care to avoid touching the Tip to anything except Samples, Performance Check Blocks, and Reference Blocks.

3.4 Loading Tip Assemblies

3.4.1 First, get a feel for the magnetic coupling of the Tip to the inside of the Body - take just the Tip, and insert it into the opening at the bottom of the Body. An audible click will sound when the Tip engages the magnetic coupling within the Body.



3.4.2 Now, pull the Test Probe out of the Body to get a feel for the pull strength of the magnetic coupling.

3.4.3 Attaching a Guide to the Body is similar to attaching a hypodermic needle to a syringe. To get a feel for attaching a Guide, take just the Guide, and attach it to the Body by gently pressing the Guide onto the bottom of the Body and rotating clockwise to engage the locking threads. Thread the Guide on until it does not come out or wiggle when gently pulled. Note how the Guide does not need to be tightened down with force to properly secure it to the Body.

3.4.4 To load a Tip Assembly onto the Stylus:

i. To help prevent the Guide from catching on the Tip, hold the Stylus in a vertical position while loading a Tip Assembly.

ii. Hold the Tip Assembly by the Guide and carefully begin bringing the Tip into the opening at the bottom of the Body.

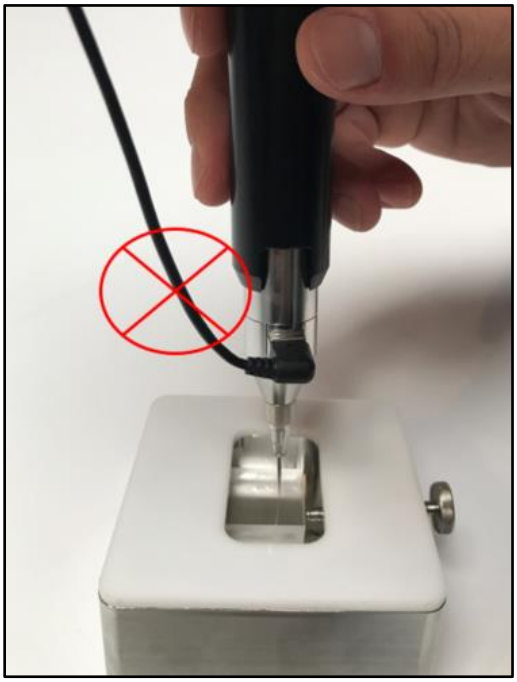
iii. As the Guide begins to engage the bottom of the Body, rotate the Guide to thread it onto the bottom of the Body.

iv. Tighten down the Guide until it is secured to the bottom of the Body. The Guide should not wiggle or feel loose when properly loaded onto the bottom of the Body.

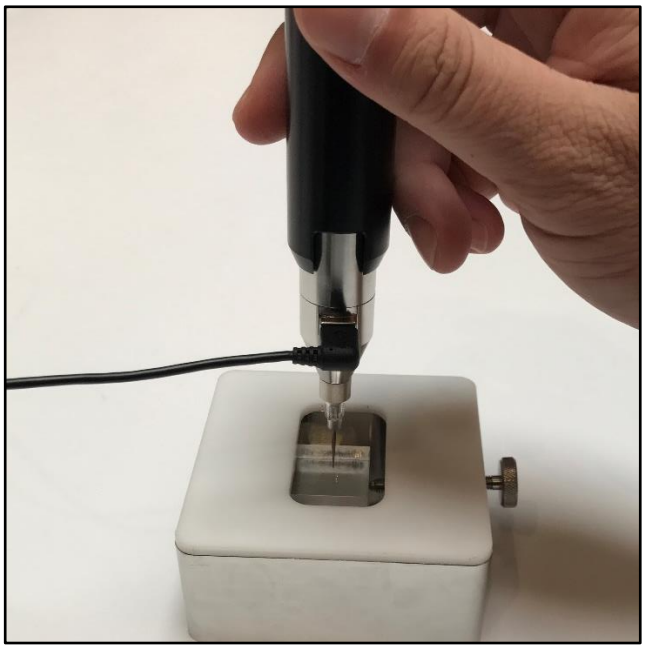
3.5 Handling the Stylus Cable

3.5.1 Treat the Stylus Cable with care, as it can get damaged by coiling it up too tightly or by getting pinched. Always store the Stylus Cable in the cutout in the foam of the Carrying Case.

3.5.2 During an actuation, tension on the Stylus Cable can lead to inaccurate results.



3.5.3 Place the E-Box in a secure position to ensure that the Stylus Cable is slack during actuations.



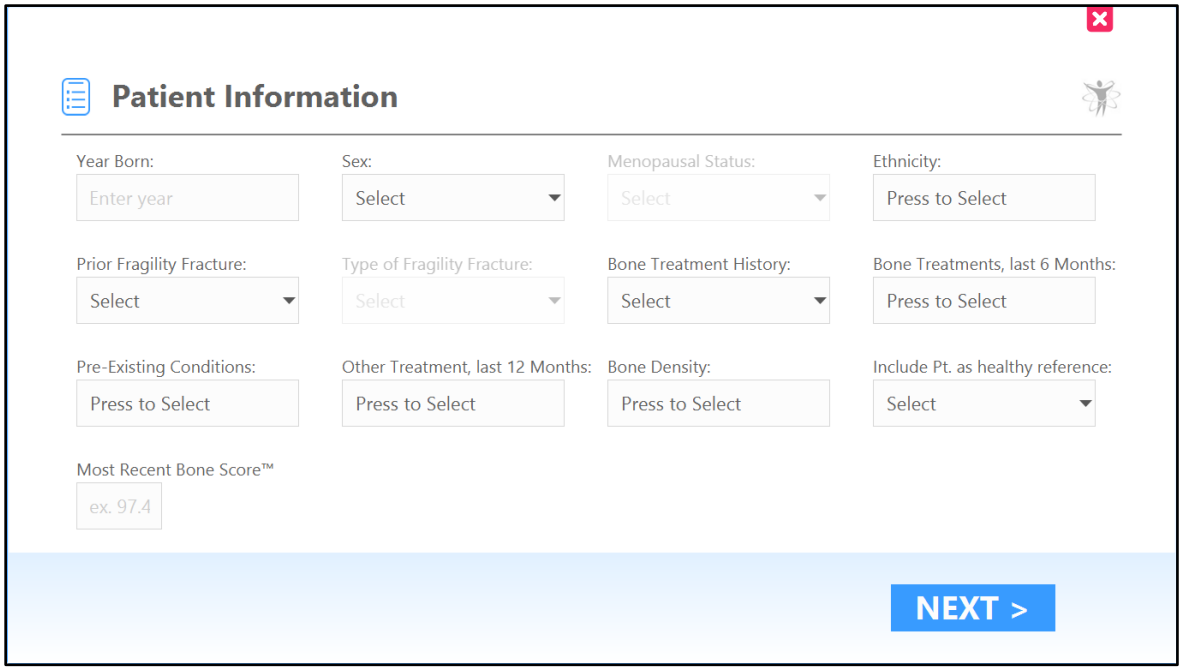
3.6 Software Setup

3.6.1 Main Menu Screen

Select “NEW MEASUREMENT” on the Main Menu Screen to begin a new measurement.

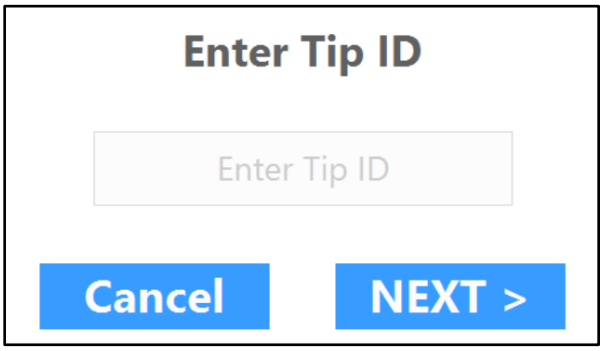
3.6.2 Patient Information Screen

Fill out the patient information fields, then select “NEXT” to proceed to the Tip ID prompt.

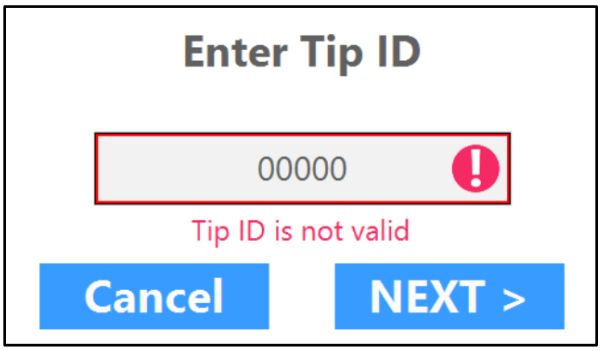


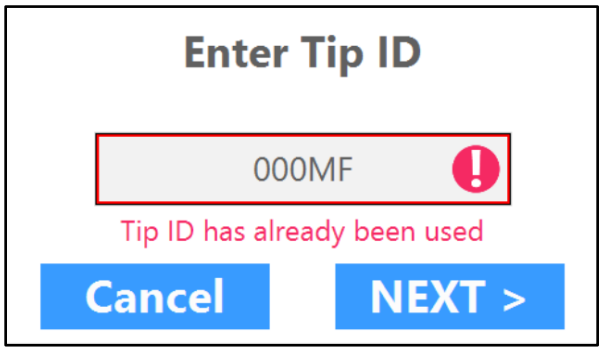
3.6.3 Tip ID Prompt

Enter in the Tip ID of the Tip Assembly to be used, then select “NEXT” to proceed to the Patient Indentations Screen and begin performing indentations.



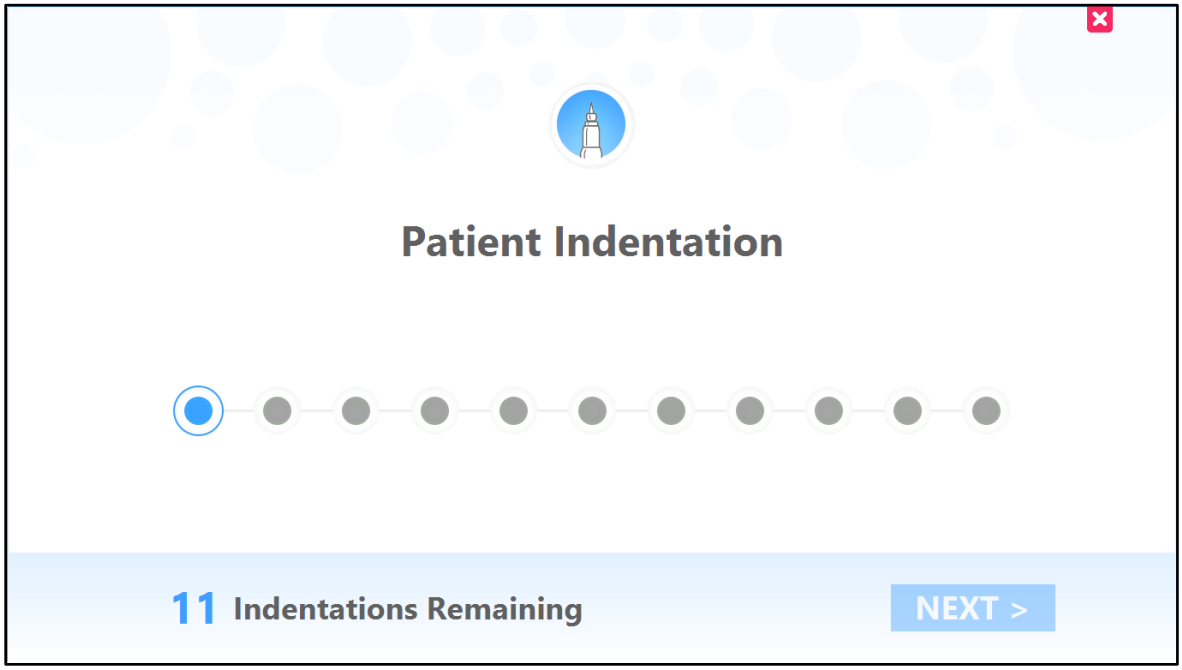
Red text will indicate if the Tip ID is not valid or has already been used.



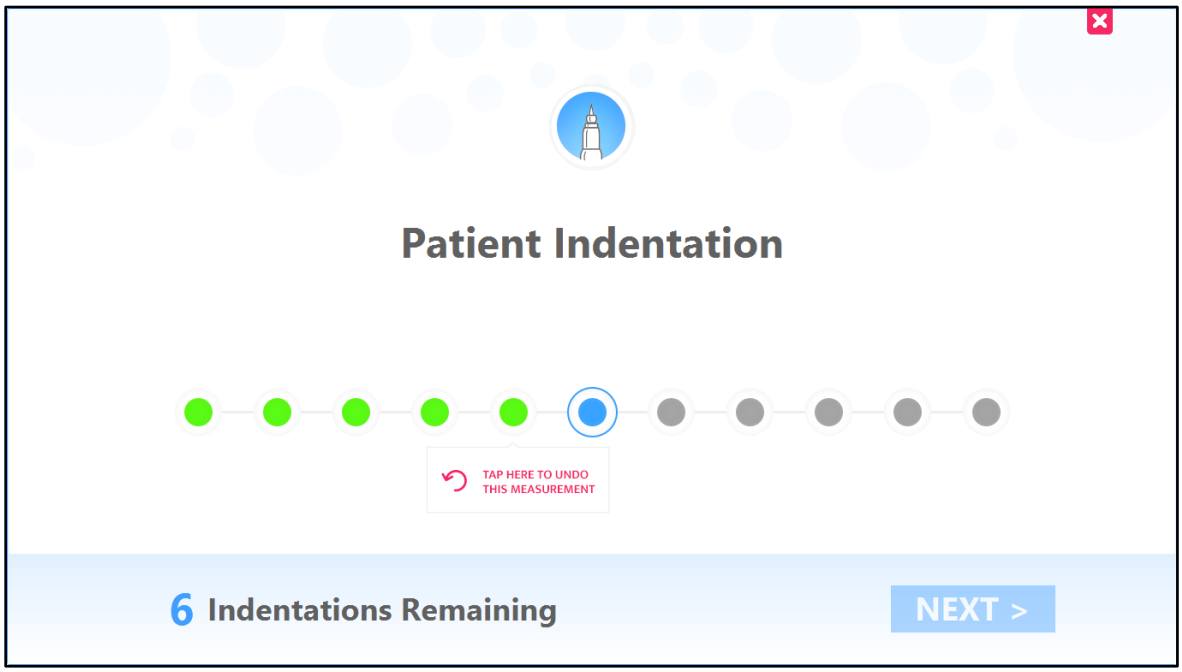


3.6.4 Patient Indentation Screen

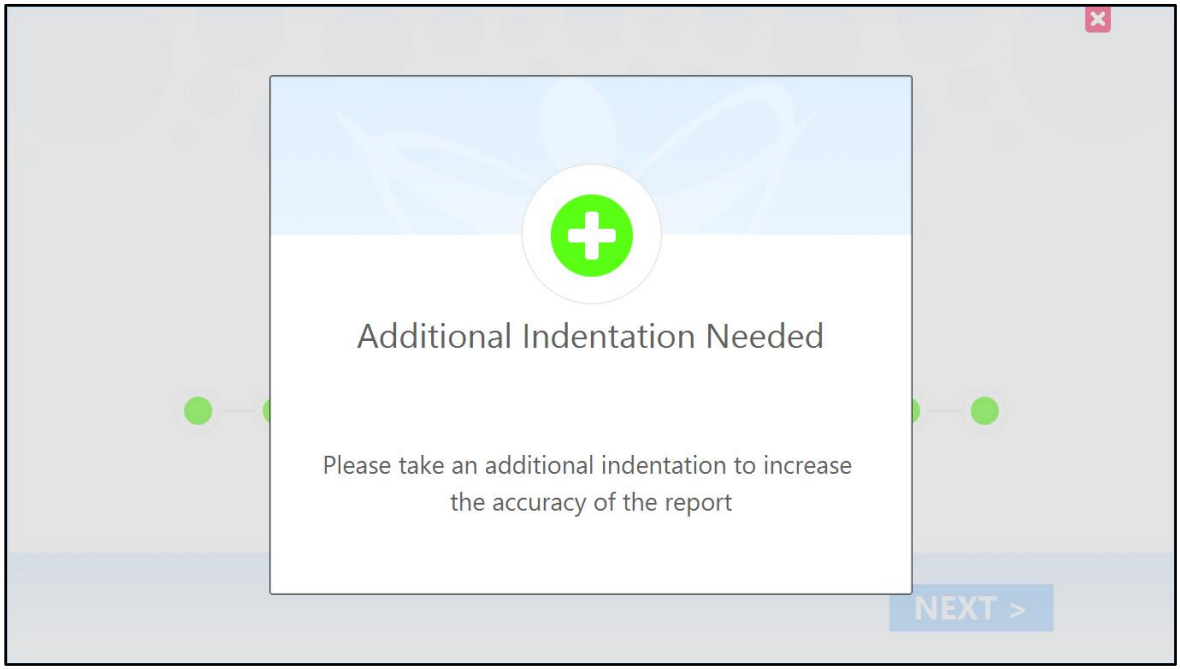
The indentation count will be displayed on the screen as indentations are performed.



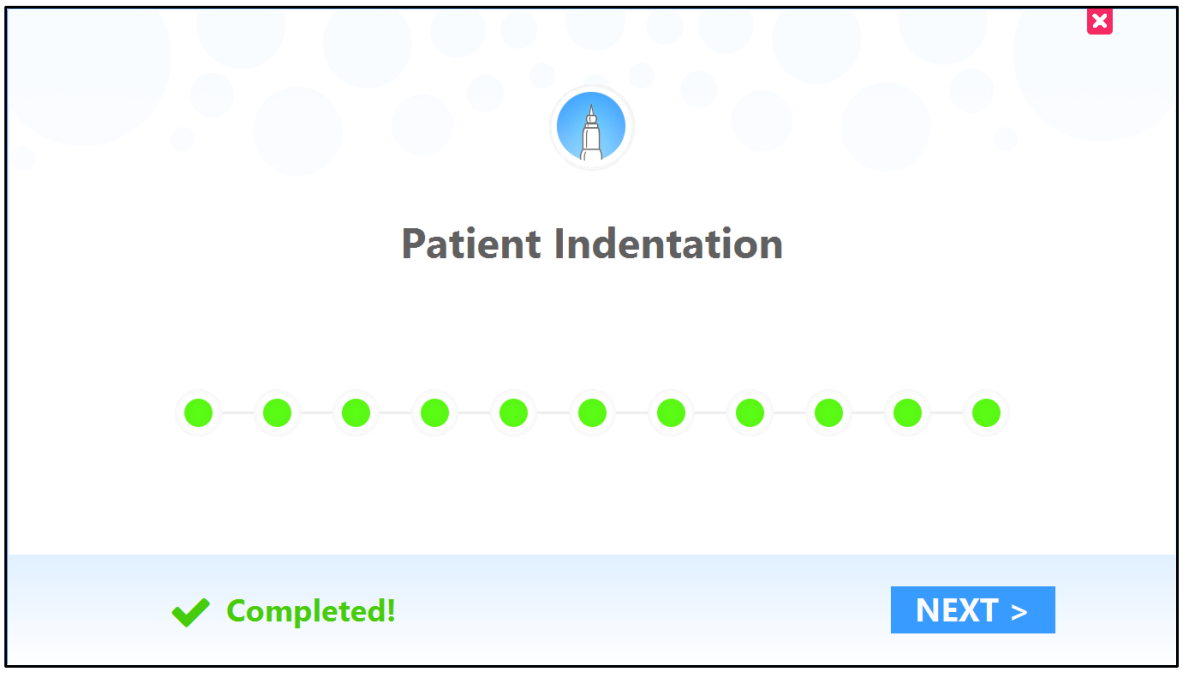
If necessary, select “TAP HERE TO UNDO THIS MEASUREMENT” to remove the last indentation performed.



If necessary, perform additional indentations as indicated by the Software prompt.

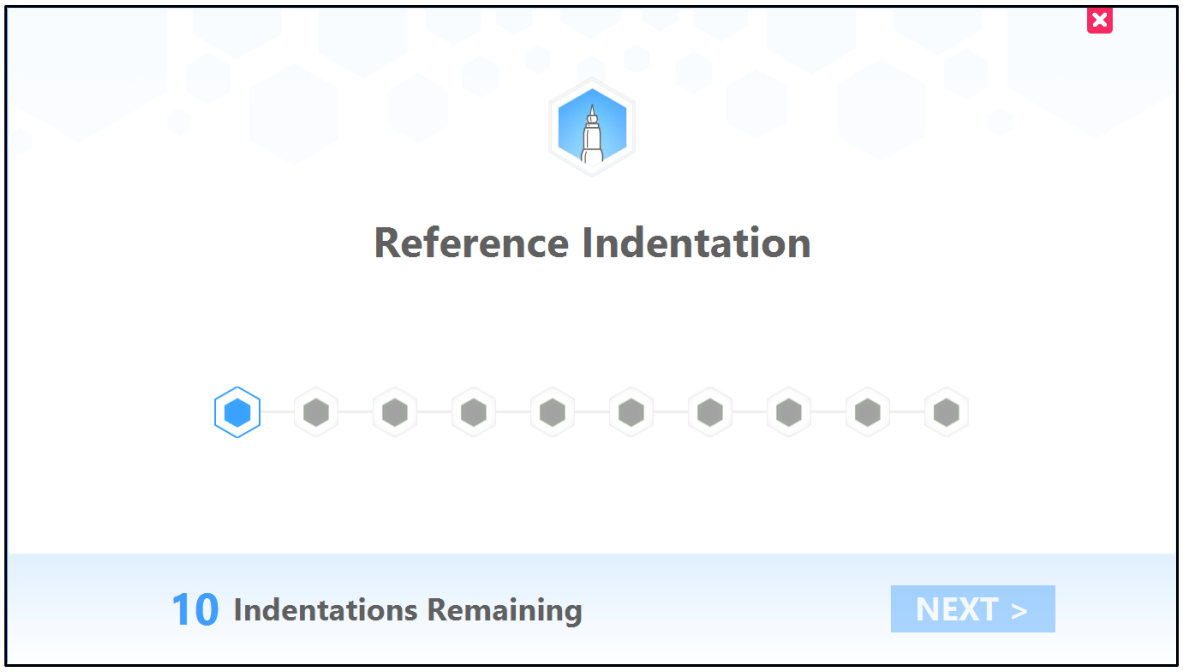


After the patient indentations are completed, select “NEXT” to proceed to the Reference Indentation Screen.

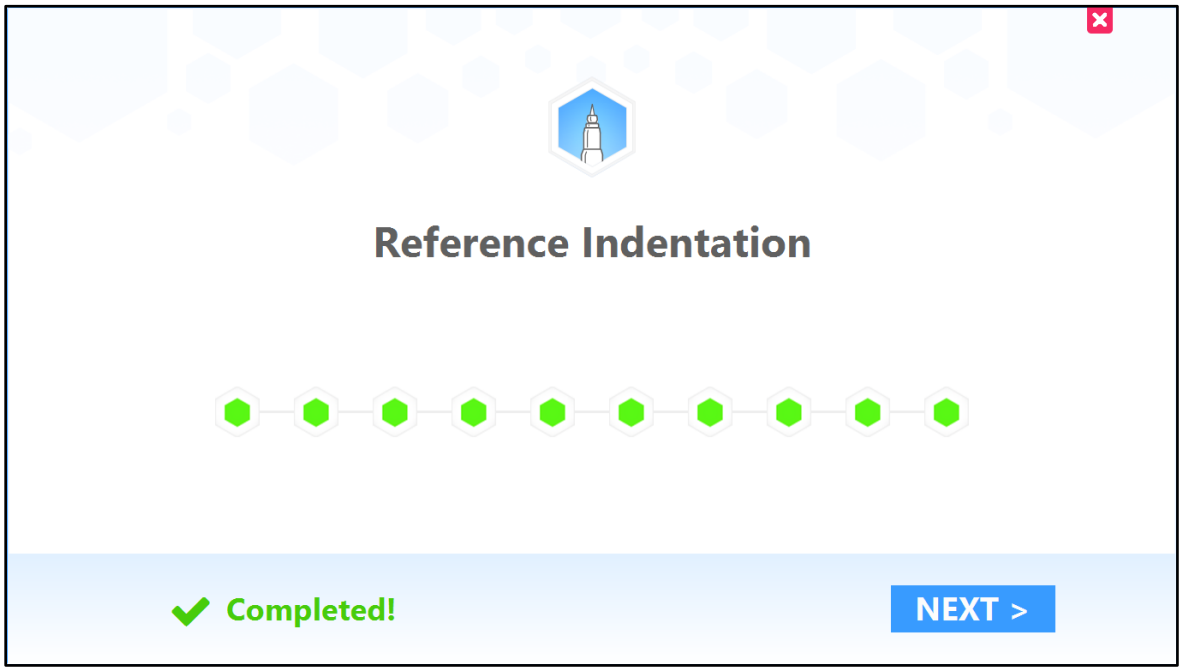


3.6.5 Reference Indentation Screen

Similar to the Patient Indentation Screen, the indentation count will be displayed on the screen as indentations are performed.

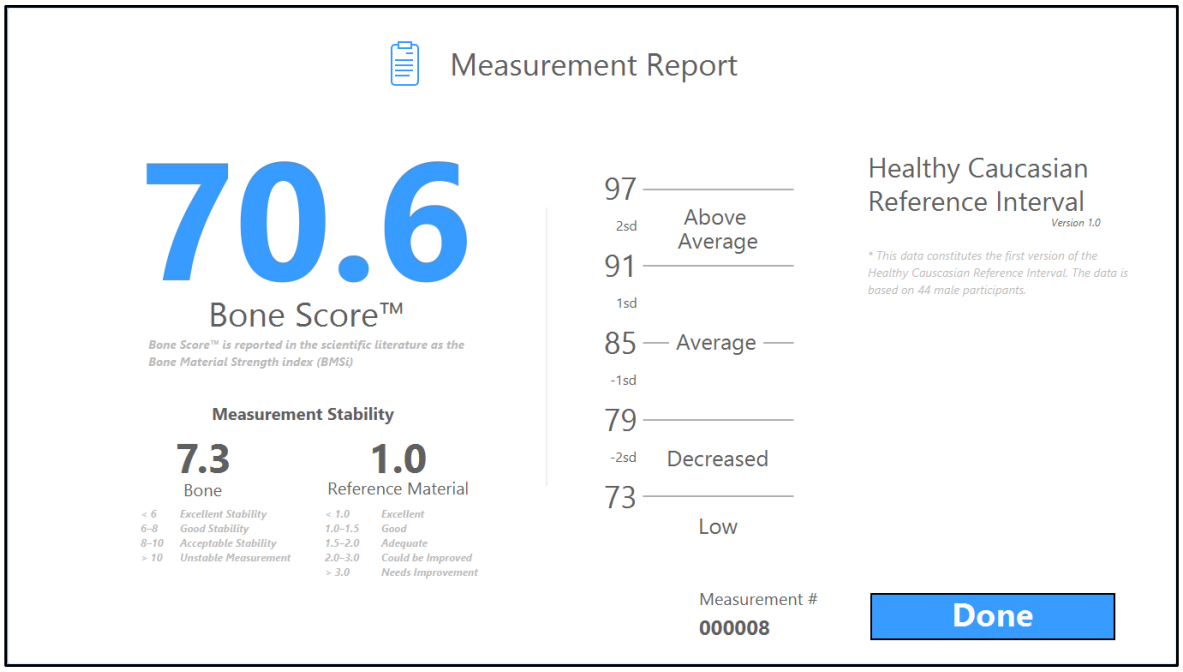


After the reference indentations are completed, select “NEXT” to proceed to the Report Screen.



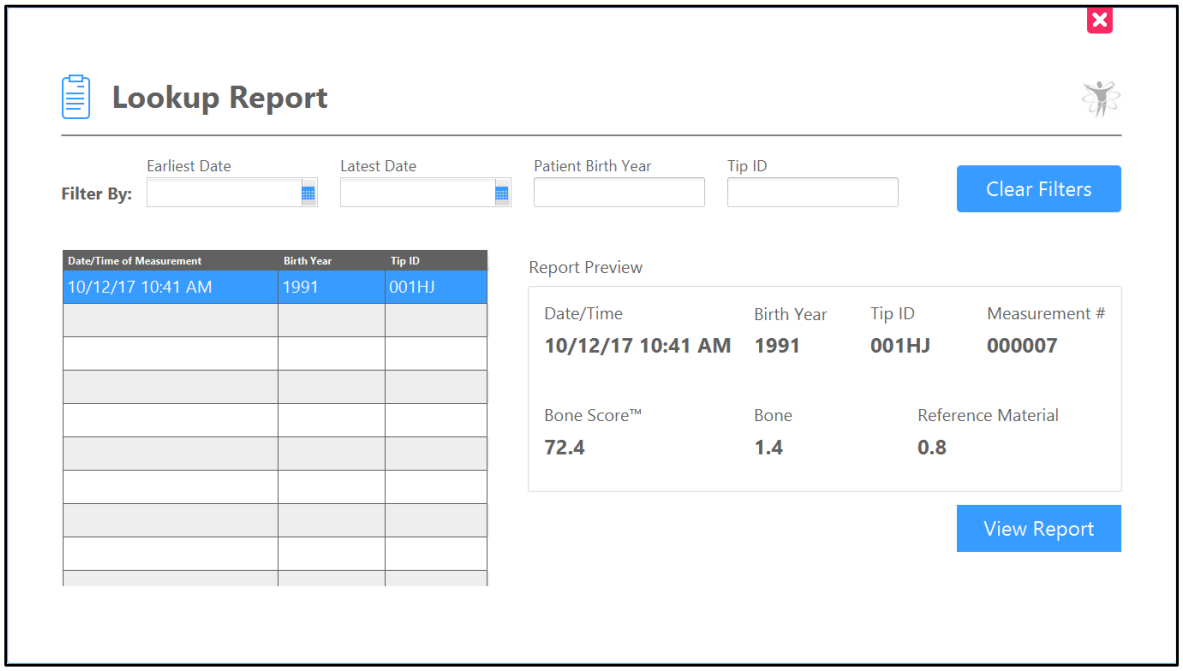
3.6.6 Measurement Report Screen

The Measurement Report Screen will display the results of the Bone Score™ procedure. This Report can be accessed at a later point through the “LOOKUP RECORD” button on the Main Menu of the Software.

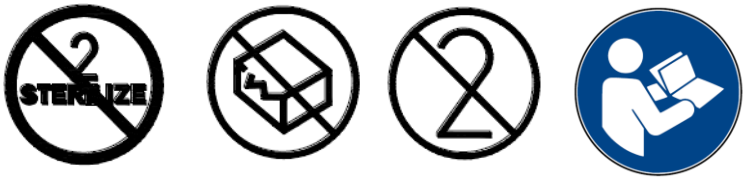


3.6.7 Lookup Report

Bone Score™ Reports can be accessed at any time by selecting “LOOKUP RECORD” in the Main Menu of the Software.



3.7 Tip Assembly Sterilization



Manufacturer: Active Life Scientific, Inc.
Device(s): OPD-900 OsteoProbe Tip Assembly

Method: Steam Sterilization (Autoclave)

WARNINGS	The Tip Assembly is sharp and may be hazardous to the user. Use caution when handling, using, and disposing of Tip Assemblies.
Limitations on reprocessing	Tip Assemblies are single use and may only be processed once.
INSTRUCTIONS	
Point of use:	N/A – Tip Assemblies are to be disposed after one use
Preparation for decontamination:	N/A – Tip Assemblies are to be disposed after one use
Cleaning: Automated	N/A – Tip Assemblies are to be disposed after one use
Cleaning: Manual	N/A – Tip Assemblies are to be disposed after one use
Disinfection:	N/A – Tip Assemblies are to be disposed after one use
Drying:	N/A – Tip Assemblies are to be disposed after one use
Maintenance, Inspection and Testing:	N/A – Tip Assemblies are to be disposed after one use
Packaging:	1. Carefully insert the Tip and Guide into a 3” x 8” sterilization pouch suitable for steam sterilization.
Sterilization:	1. When sterilizing more than one pouch at a time, make sure the plastic side of pouch always faces paper side of adjacent pouch. 2. 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. 3. Gravity Steam Sterilization Cycle - 60 minutes at 121° C, 30 minutes drying time. Do not exceed 130° C.
Storage:	Store in a dry place.
Manufacturer contact:	27 E. Cota Street Suite #400 | 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.

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

4.0 Measurement Technique

4.1 Learning Proper Measurement Technique

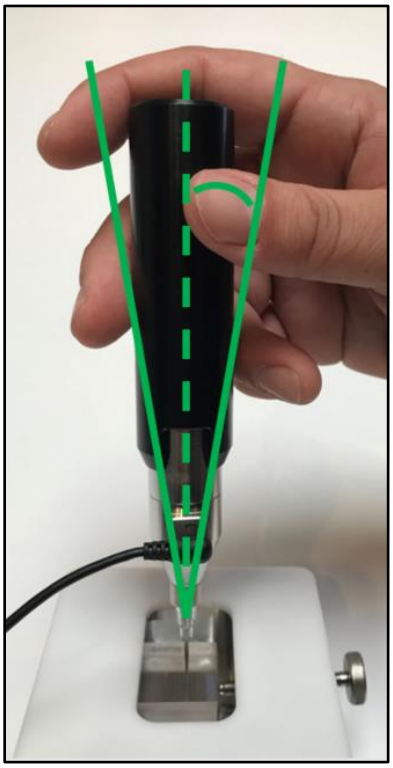
4.1.1 Holding the Stylus

Hold the Stylus by the Handle with one hand in as comfortable and natural a position as possible. It is important to hold the Stylus in a manner so as to avoid touching any part of the Body during actuation, while taking into account that the hand position relative to the Body changes during the compression of an actuation.

Contacting any part of the Stylus **EXCEPT** the Handle during actuation can lead to inaccurate results.

4.1.2 Actuating the Stylus

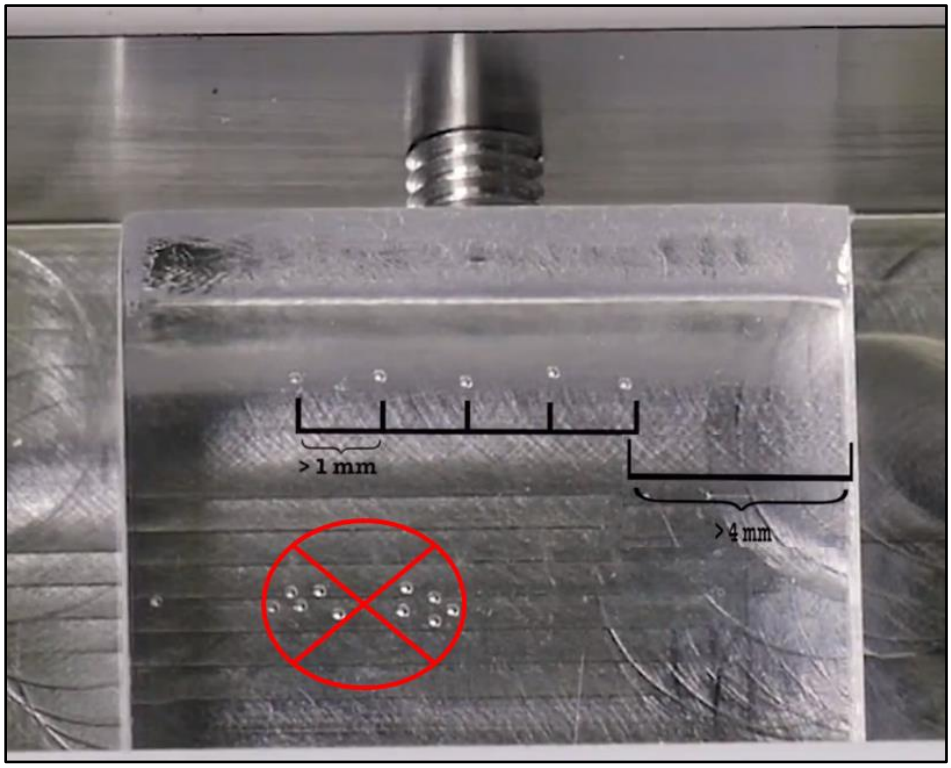
Hold the Stylus by the Keep the Stylus perpendicular to the surface of the material being measured [during actuation.] while actuating the Stylus. Actuating the Stylus at angles greater than 10° can lead to inaccurate results.



Slowly compress the Handle until the Stylus actuates. The time from starting the compression to the actuation should be 1 ½ to 3 seconds. Actuating the Stylus faster than 1 second can lead to inaccurate results.

4.1.3 Indentation Sites

Hold the Indent in a new location on the Reference Block for every indentation. Ensure that each indentation site is at least 1 mm away from other indentation sites and at least 4 mm away from any edge of the Reference Block.



IN BETWEEN ACTUATIONS, the opposite hand can be used to hold the Guide to help move to a new location in a controlled manner. Remember that nothing should be touching the Body, the Guide, or the Tip during an actuation.

5.0 Instructions for Use

5.1 Indications for Use

OsteoProbe® is indicated to measure bone material quality on skeletally mature adults on the mid-shaft of the left or right tibia.

OsteoProbe® should be used on skeletally mature patients, male or female, to measure bone material quality on the left or right tibia when additional information about skeletal health is needed or desired by a physician. Patients with the following indications are appropriate for measurement with OsteoProbe®:

1. Patients with any disorders associated with altered skeletal structure or function including:
    a. Chronic renal impairment (chronic kidney disease [CKD] stage IV or V)
    b. Acromegaly
    c. Type I or Type II diabetes
    d. Gaucher's disease
    e. Any hereditary/genetic diseases that affect the skeleton.
2. Patients undergoing treatments with any of the bone modifying drugs including:
    a. Corticosteroids
    b. Bisphosphonates
    c. Denosumab
    d. Teriparatide
    e. Any therapies that affect the skeleton.

5.1.1 Details

The device utilizes both a reusable, non-invasive component and a single-use, transient invasive component. The Tip 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 and quality 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 bone material 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 as well as application of local anesthetic.

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 metastic 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

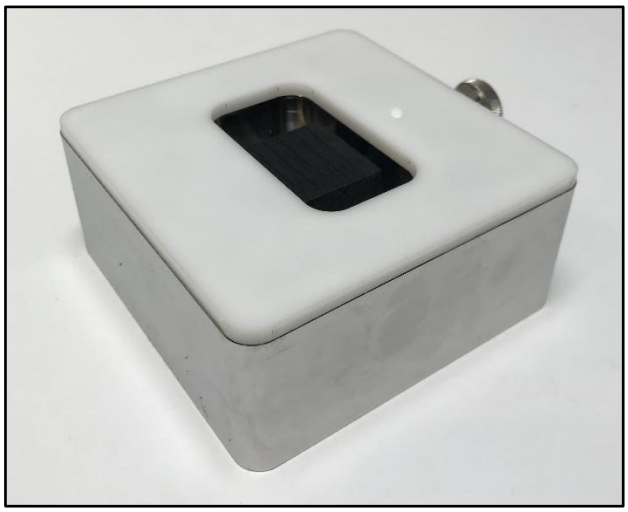
The Bone Score™ procedure takes place at the mid-diaphysis of the tibia (either leg). The Bone Score™ consists of the following steps:

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, 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 Reference Block, secured within the Holder, on a firm, stable 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.
8. Insert a sterile Tip Assembly 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 Tip 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 Handle of the device toward the patient's leg to initiate an indentation (see below for details).
11. For every indentation, the Handle of the device is pulled down slowly and smoothly for a 2 to 3 second period.
12. The first indentation should be systematically disregarded since there is often inadequate penetration of the Tip through the periosteum.
13. After each indentation, slide the Tip 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 10 indentations are obtained without pulling the Tip out of the skin. If additional indentations are required, the software will prompt the operator.
14. After the set of indentations in the bone have been completed, the normalization phase starts. Following the software indications, perform 10 indentations on the Reference Block (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 Block. After the measurement is complete, both the Tip Assembly and Reference Block should be considered contaminated and should be disposed of (see Section 7.0: Cleaning & Disposal).
15. The screen will then display the result of the Bone Score™

6.0 Performance Check

A Performance Check is required every 30 days to determine whether the device is functioning properly.

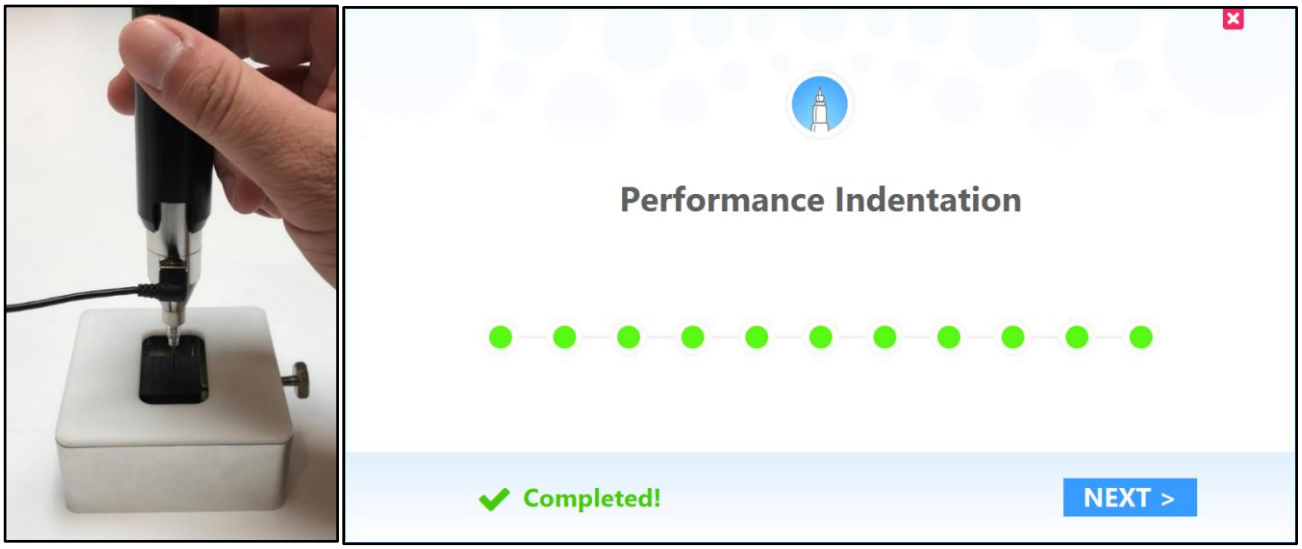
i. Secure a Performance Check Block in the Holder.



ii. Load a Tip Assembly onto the Stylus.

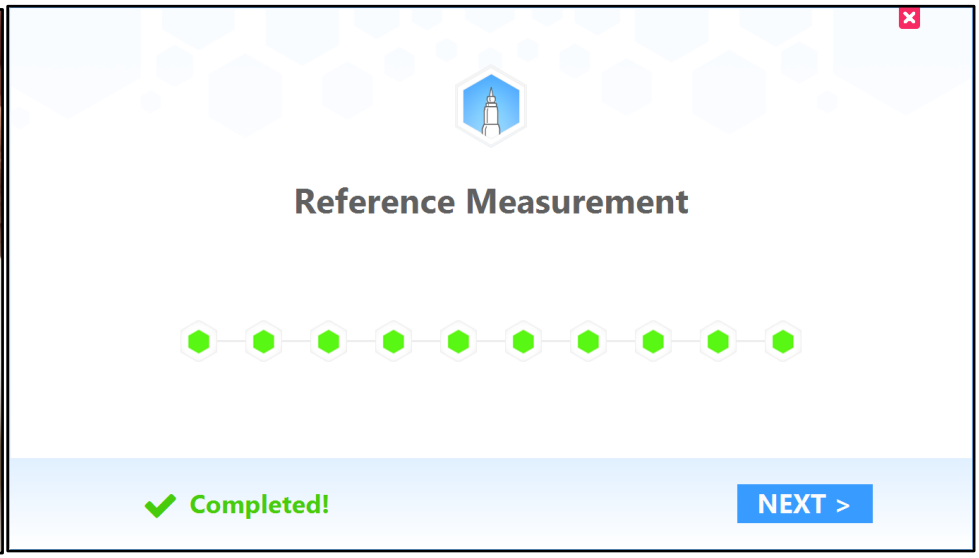
iii. Select “PERFORMANCE CHECK” on the Main Menu of the OsteoProbe Software to enter the Performance Check Mode.

iv. Perform 10 indentations on the Performance Check Block.

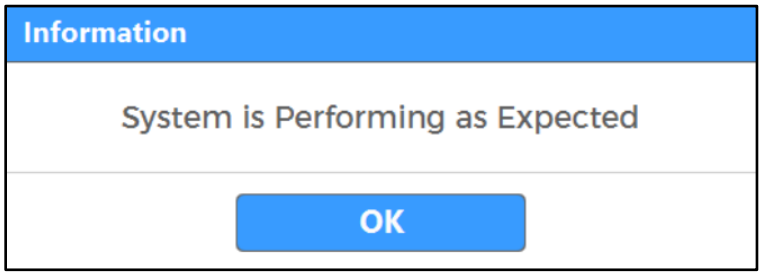


v. Remove the Performance Check Block and secure a Reference Block in the Holder.

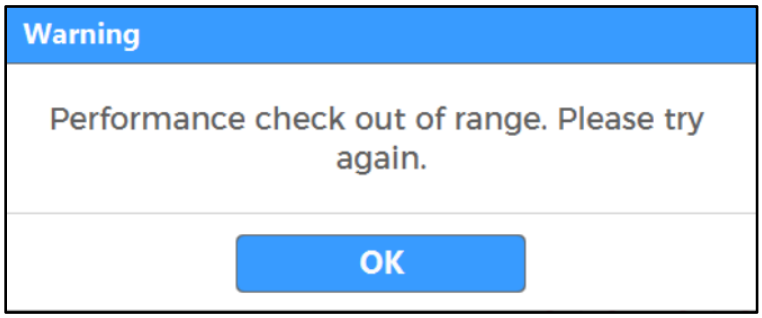
vi. Perform 10 indentations on the Reference Block.



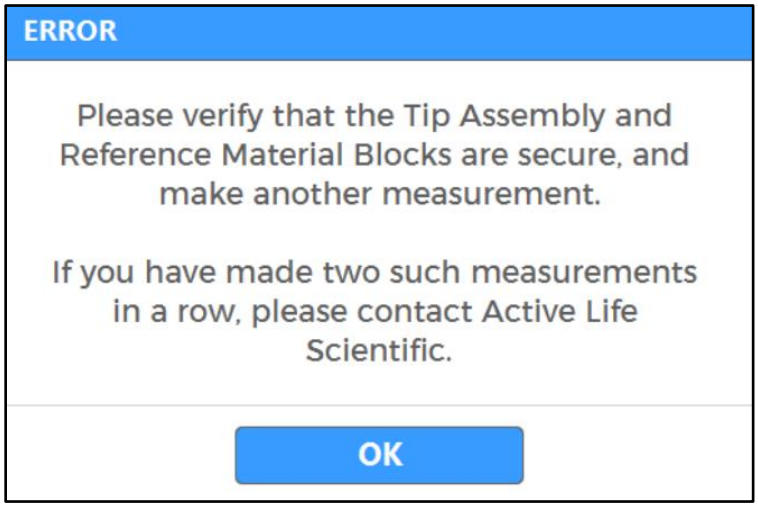
vii. The software will automatically determine whether the device is functioning properly.



viii. If the Performance Check indicates that the device is not functioning properly, perform another Performance Check.



ix. If the second Performance Check also indicates that the device is not functioning properly, contact Active Life Scientific, Inc.



7.0 Cleaning & Disposal

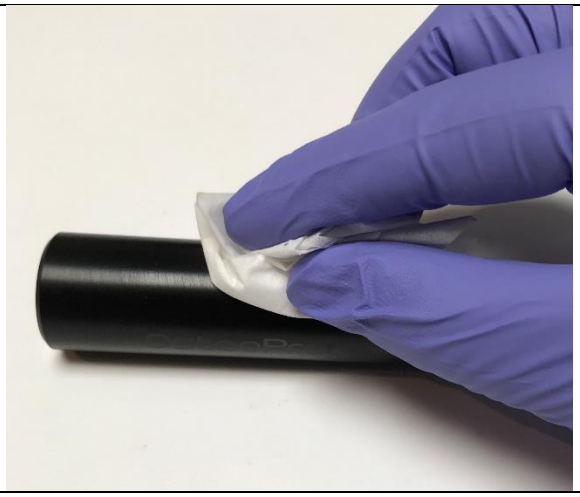
7.1 Cleaning

To help prevent dirt contamination of the equipment, clean on a regular basis. If the device is used frequently (>5 times a day), clean on a daily basis. This cleaning procedure does not apply to the Tip Assemblies. See Section 3.7: Tip Assembly Sterilization for information on sterilization of Tip Assemblies.

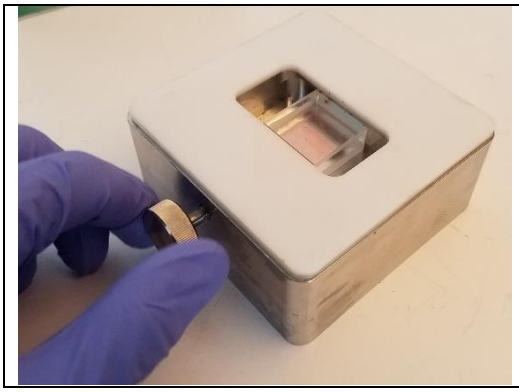
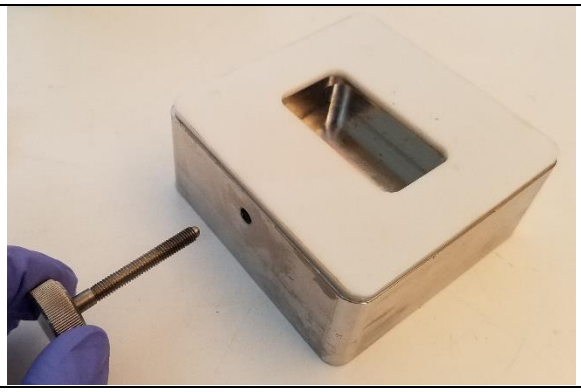
7.1.1 Cleaning Supplies

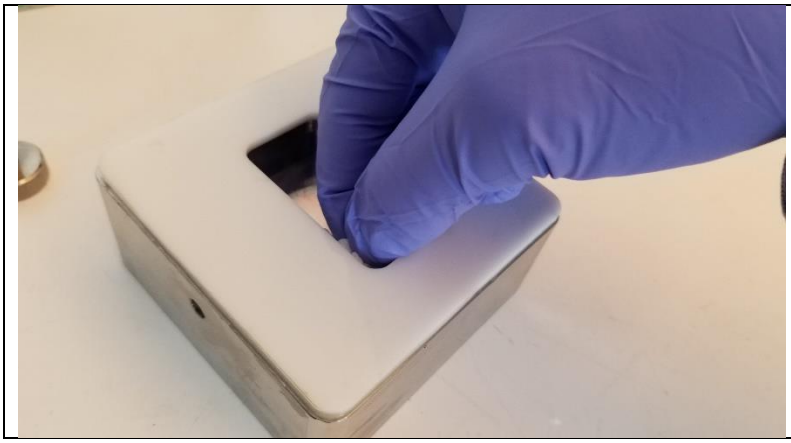
		Including gloves, the only materials needed to clean the device include: • Isopropyl Alcohol (IPA) • Kimwipes

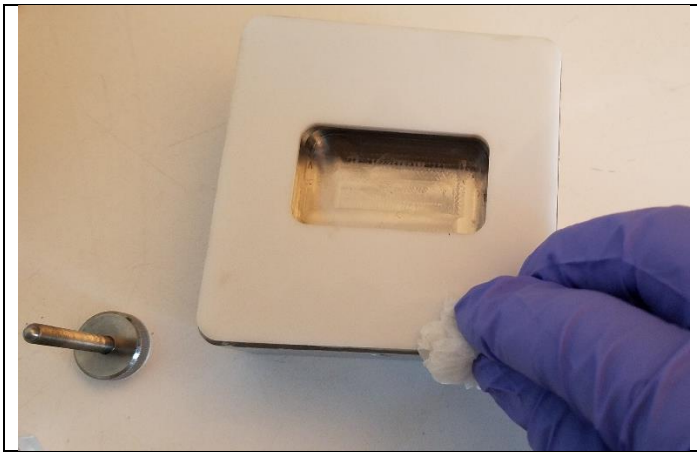
7.1.2 Cleaning the Stylus

Lightly wet a Kimwipe with IPA. Clean the exterior of the Handle and Body of the Stylus.		

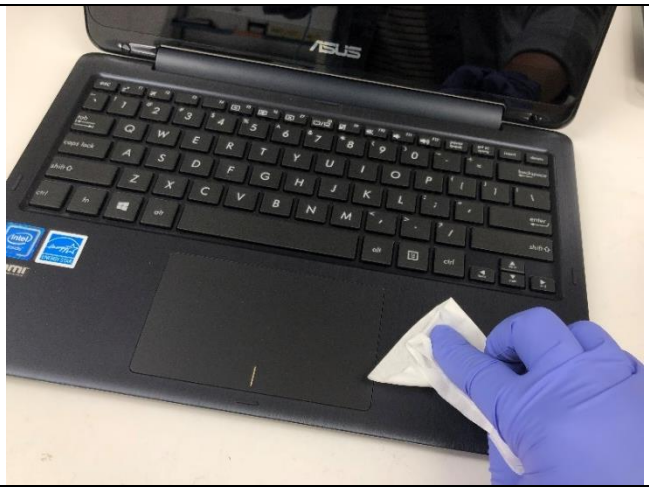
7.1.3 Cleaning the Holder

		Unscrew and remove the Holder Screw. Wet a Kimwipe with IPA and wipe down the Holder Screw.

	Wet a Kimwipe with IPA and clean the pocket of the Holder. NOTE: the most critical areas to clean are along the edges. Dirt can accumulate in these areas which can introduce measurement error.

	Wet a new Kimwipe with IPA and wipe down the exterior surfaces of the Holder. Let the Holder and Holder Screw dry, then re-attach the Holder Screw.

7.1.4 Cleaning the Laptop

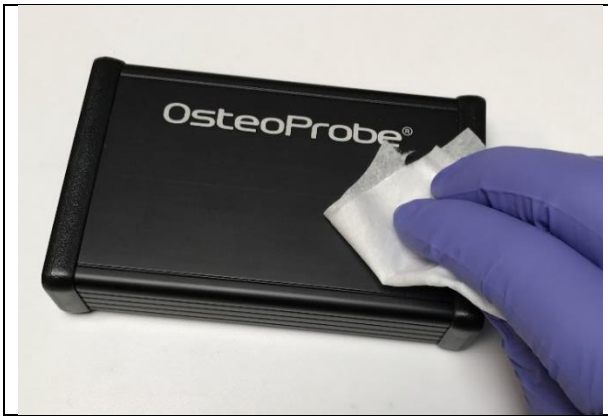


Ensure that the Laptop is disconnected from the Power Supply and completely shut down.

Use a dry, new Kimwipe to 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 slightly wetted with IPA.

7.1.5 Cleaning the E-Box



Wet a 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 E-Box dry completely prior to connecting.

7.2 Disposal

7.2.1 Disposal of OsteoProbe Equipment

OsteoProbe should be returned to Active Life Scientific, Inc. for disposal. See Section 10.2: Return Policy for information on how to return products.

7.2.2 Disposal of Tip Assemblies

Used Tip Assemblies should be considered contaminated ‘sharps’ and disposed of accordingly.

7.2.2 Disposal of Reference Blocks

Used Reference Blocks should be considered contaminated and disposed of accordingly.

8.0 Technical Specifications

8.1 System Information

Parameter	**Parameter Value**	
System Classification	EU Class:	Class IIa
Safety Certifications	EU Certification:	IEC 60601-1: 2012
	EMC Certification:	IEC 60601-1-2:2014 (4TH EDITION)
CE Marking	CE Marking for MDD 93/42/EEC	
Type of Equipment	Medical Device	
Classification of Use	Type B Applied Part	
Intended Use	See Section 5.1: Indications for Use	

8.2 Specifications

Parameter	**Parameter Value**	
Power Input Requirements	Voltage: Frequency: Current:	100 – 240 V~ 50 – 60 Hz 1.5 A
Stylus Dimensions	Approximately:	⌀2.7 x 14.0 cm
Stylus Weight	Approximately:	240 g
Case Dimensions	Approximately:	46 x 34 x 17 cm
Case Weight	Approximately:	8 kg
Internet Connectivity	Wireless: Ethernet:	802.11b/g/n RJ-45 (100/1000 Mbps)

9.0 Troubleshooting

9.1 Laptop Power

If the Laptop is not turning on, check the following:

1. Check to ensure that the AC Cable is properly connecting the Power Supply to an appropriate power outlet.
2. Check to ensure that the connector of the Power Supply is properly connected to the Laptop.
3. Check to ensure that the power outlet the Power Supply is plugged into has power by plugging in another device that draws power (such as a phone charger).
4. If the Laptop is still not turning on, contact Active Life Scientific, Inc.

9.2 Software Communication

If the Software is not registering a connection to the Stylus, check the following:

1. Check to ensure that the USB-B connector of the Laptop Cable is properly connected to the E-Box and that the USB-A connector is properly connected to the Laptop.
2. Check to ensure that the USB-A connector of the Stylus Cable is properly connected to the E-Box and that the Micro-B connector is properly connected to the Stylus.
3. If the Software is still not registering a connection to the Stylus, contact Active Life Scientific, Inc.

10.0 Warranty & Return Policy

10.1 Product Warranty

Active Life Scientific, Inc. ("Company") warrants that each new OsteoProbe® System("OsteoProbe®"), single use Tip Assemblies for OsteoProbe® ("Components"), and software for OsteoProbe® ("Software") hereinafter the Products ("Products"), shall be free from defects in materials and workmanship under normal use and service and when correctly maintained for two years from the date of shipment ("Warranty Period").

Procurer agrees that before this limited warranty shall become effective, Procurer shall fully inspect each Product within five (5) days of delivery and before such Product is put to use. Further, before this limited warranty shall become effective, Procurer shall complete training. Procurer also agrees to operate the Product in accordance with Product's User Manual as provided and that failure to do so shall void this limited warranty. Procurer further agrees that any claim for breach of warranty must be made in writing promptly following the discovery of a purported defect and within the Warranty Period. Company will not be responsible for any alleged breach of warranty, which, as a result of Company's inspection, Company determines to have arisen from a cause not covered by this limited warranty. Warranties are granted to the original Procurer of the Products only, and are nontransferable without the express written consent of Company. If a valid warranty claim is received within the Warranty Period, Company will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product, or (2) refund the amount paid for the product on a prorated basis. In any event, Company's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

This limited warranty does not apply to: (A) replacement of Products necessitated by misuse, abuse, accident, neglect, modification, alteration, adjustment, tampering, improper installation or repairs made by persons other than Company or persons expressly authorized by Company to perform repairs; (B) use of Components or Software with OsteoProbe® other than those expressly approved by Company; (C) the subjugation of the Products to unusual stress or environmental conditions; (D) Acts of God, or other causes not within the control of Company; (E) Products on which any original serial numbers or other identification marks have been removed or destroyed.

If Company determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of replacement of the Product. In such an event, any replacement would be performed at Company's standard rates.

Products replaced under this warranty continue to be warranted as described herein during the initial Warranty Period or, if the initial Warranty Period has expired by the time the Product is replaced, for thirty (30) days after delivery of the replaced product. When a Product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Company's property. If a refund is provided by Company, the Product for which the refund is provided must be returned to Company and will become Company's property.

If Procurer believes that a Product does not comply with the limited warranty stated above, Procurer should contact Company at the address stated at the beginning of this manual or by email at customer.care@activelifescientific.com, describing the problem and providing Serial Number(s) of Products. The Company will then schedule a mandatory remote diagnosis session. If directed by Company, Procurer shall return the Products, at the customer's expense unless Company specifically agrees otherwise in writing, properly packaged in an Company approved shipping container and properly

identified by a Return Material Authorization Form issued by Company. Company does not accept any COD returns. Products returned without a Return Material Authorization Form will be refused and returned at Procurer's expense.

THIS LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES OR REPRESENTATIONS, EXPRESSED, OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. NO REPRESENTATION OR STATEMENT OF COMPANY MAY CHANGE OR ALTER THIS LIMITED WARRANTY.

COMPANY SHALL HAVE NO FURTHER LIABILITY FOR DAMAGES, LOSSES, COST OR FEES OF ANY KIND OR NATURE, WHETHER FORESEEABLE OR NOT, INCLUDING BUT NOT LIMITED TO ATTORNEY'S FEES AND CONSEQUENTIAL, GENERAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, REGARDLESS OF THE FORM OF ANY CLAIM, WHETHER IN CONTRACT, TORT OR OTHERWISE, ARISING OUT OF OR RELATED TO THE USE OF COMPANY PRODUCTS EVEN IF COMPANY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, LOSSES, COST OR FEES.

Any claims for breach of this limited warranty shall be governed by California law and must be brought in a State or Federal court in California.

COMPANY EXPRESSLY DISCLAIMS ANY AND ALL RESPONSIBILITY FOR ANY UNAPPROVED USE OF THE PRODUCTS.

10.2 Return Policy

A Returned Merchandise Authorization (RMA) Form must be obtained from Company before returning product. To obtain an RMA Form, please contact Company Customer Service at 805.770.2660 or email:

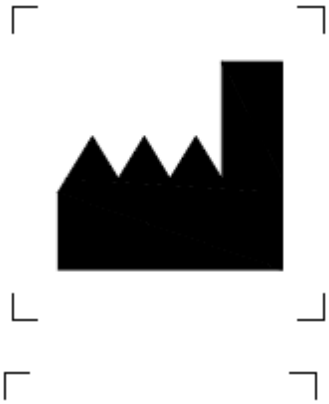
customer.care@activelifescientific.com

Upon issuing an RMA Form, Company will provide further instruction for returning OsteoProbe System. Please include the completed RMA Form with the return.

Please follow instructions provided by Company to clean all potentially contaminated products prior to returning them to Company. It is unlawful to transport bio-contaminated products through interstate commerce, unless they are properly packaged and labeled as such.

If a return does not comply with these terms, Company reserves the right to destroy the product at the customer's expense. Any replacement would be at the customer's expense.

11.0 Contact Information



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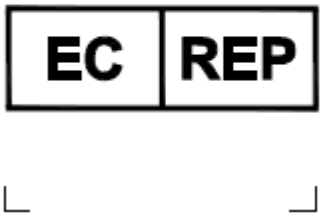

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