OSTEOPROBE USER MANUAL

0.1 Revision History

Revision	Release Date	Reason
D	10-OCT-2020	Updated as part of Technical File assessment - added revision history - simplified IFU - defined tip as an accessory - updated warning and cautions - updated labels - added specifications for device accuracy and resolution

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

CE
2797

The device meets e-IFU requirements of e-IFU regulation 207/2012 and directive 95/46/EC for protection of personal data.

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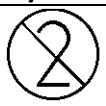
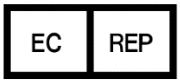
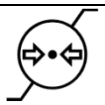
1.0 Glossary

Symbol	Definition	Symbol	Definition
	MANUFACTURER		DO NOT REUSE
	DATE OF MANUFACTURE		CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
	CE LOGO		SOURCE OF INTERFERENCE
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		DO NOT RESTERILIZE
	CATALOG NUMBER		DO NOT USE IF PACKAGE IS DAMAGED
	SERIAL NUMBER		HUMIDITY LIMITS
	REFER TO INSTRUCTION MANUAL		ATMOSPHERIC PRESSURE LIMITS
	TYPE B APPLIED PART		FRAGILE, HANDLE WITH CARE
Power Rating: 5V ⎓ 100 mA	POWER RATING (DIRECT CURRENT)		KEEP DRY
	TEMPERATURE LIMITS		

2.0 Descriptive Information

2.1 Intended Use

The OsteoProbe® system is to be used when performing an assessment of bone tissue's resistance to microindentation. The OsteoProbe® system incorporates a sterilized single-use disposable Tip that connects to a reusable hand-held Stylus, which is connected through an electronics adapter to a laptop computer. Measurements are displayed and stored on the laptop computer.

OsteoProbe® is intended to be used in a medical exam room, on the order of a physician, by healthcare professionals (nurses, physicians, or physician's assistants) trained in sterile technique, handling and disposal of biohazardous sharps, as well as application of local anesthetic. OsteoProbe® users must complete an official training session prior to using the system. Training includes proper handling of the Stylus and Tips, measurement technique, reprocessing, and patient preparation. All components, including Tips, are provided non-sterile. The Tips may be sterilized by steam autoclave. The reusable components of the system may be reprocessed using a cleaning and intermediate-level disinfection procedure. The system has a 2-year expected service life.

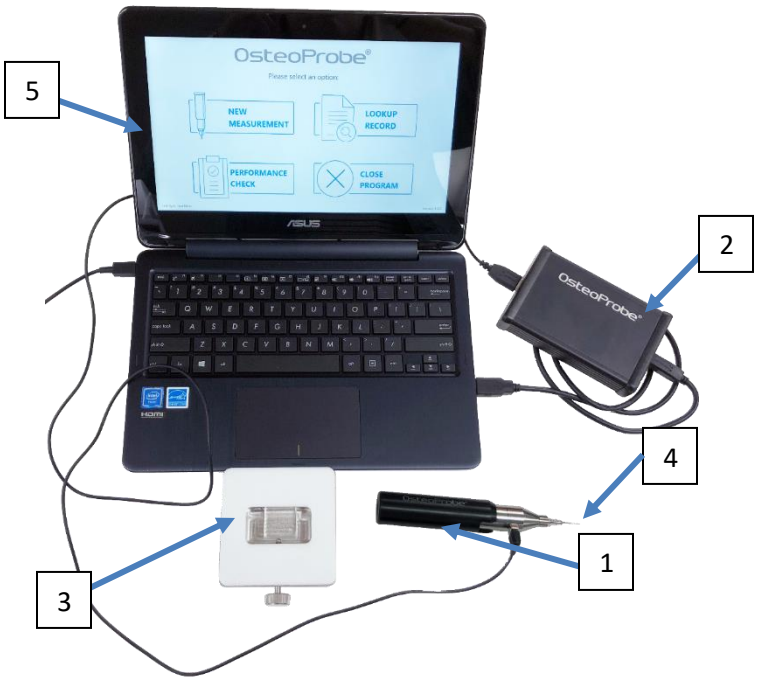
2.2 Indications

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

2.3 Contraindications

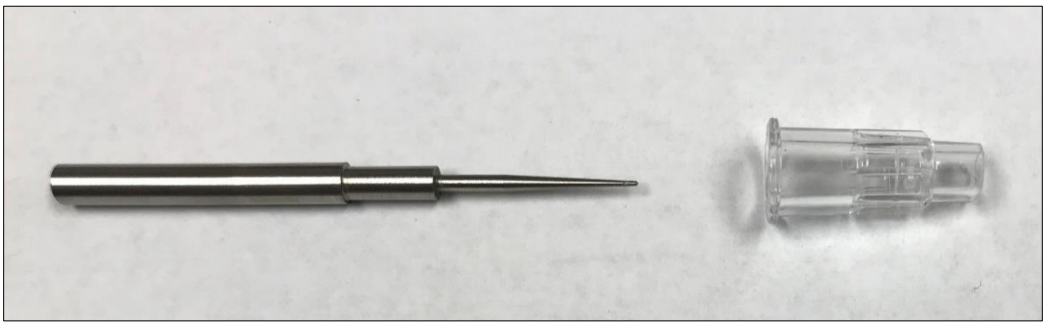
Patients with an allergy to local anesthetic, an active infection, or a systemic infection should not be measured. There are no other known contraindications.

2.4 Description of the Device



The OsteoProbe system consists of a Stylus (1), an Electronics adapter (2), a Holder (3), a single-use disposable Tip Assembly (4), and an Operator Interface (5).

2.4.1 The Tip Assembly



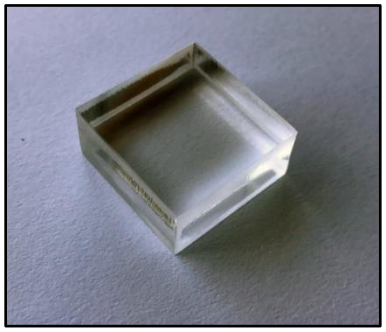
The Tip is a single-use stainless steel disposable that is attached to the Stylus to perform a measurement. It is the only part of the device intended to contact the patient. The Tip is retained by a polycarbonate guard. Both the Tip and the Guard make up the Tip Assembly.

⚠ **Warning:** Tip Assemblies are shipped *unsterile* and should be sterilized according to the procedure in Section 4.3.2: Tip Assembly Sterilization.

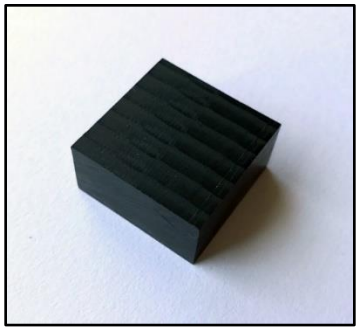
2.4.2 The Stylus

The Stylus consists of an outer Handle and an internal Body. The Stylus contains an actuation mechanism and sensor that measures the indentation depth of a Tip.

2.4.3 The Holder & Reference Materials



Reference Block



Performance Check Block

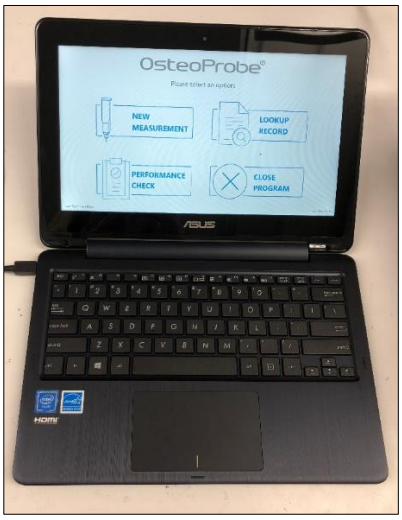
The Holder secures Reference Materials for measurement. Indentations are made on Reference Blocks after each measurement. Indentations can be made on Performance Check Blocks to ensure system is functioning as expected.

⚠ **Warning:** Reference Blocks are single use only and cannot be sterilized or reprocessed.

2.4.4 The Electronics

The Electronics adapter converts the signal from the Stylus which is read by the software on the Laptop.

2.4.5 The Operator Interface



A laptop collects, displays, and stores measurement data.

3.0 Safety Warnings & Cautions

℞ ONLY

Definitions:

⚠ **Warning**	Indicates risks to the safety of the patient or user. Failure to follow warnings may result in injury to the patient or user.
⚠ **Caution**	Indicates risk of improper use and/or damage to the equipment. Failure to follow cautions may result in loss of function of product damage.
Note	Indicates special information to clarify instructions or present additional useful information.

3.1 Warnings

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

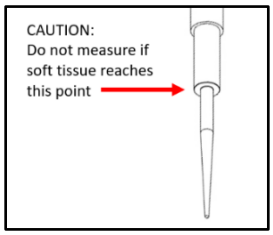
1. OsteoProbe® has not been studied for use in diagnosis of bone fracture risk or to prescribe a therapy.
2. OsteoProbe® has not been studied for use in adolescents or children.
3. Failure to follow the instructions, warnings, and precautions in this manual may lead to injury or damage to the equipment.
4. Measuring an area other than the left or right tibia could lead to serious harm to the patient.
5. This equipment is only to be used by qualified personnel, who have completed training of the use of the equipment.
6. To avoid the risk of electrical shock, only use the equipment with the provided Power Supply and AC Cable.
7. To avoid risk of electrical shock, equipment must be used on battery power or only be connected to a supply mains with protective earth.
8. To avoid the risk of electrical shock, do not contact the Stylus to a source of voltage other than the Stylus Cable and Electronics.
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. Introducing unsterile equipment into an operating room could lead to cross-contamination.
11. Tip Assemblies are shipped *unsterile* and should be sterilized according to the procedure in Section 4.3.2: Tip Assembly Sterilization. Using an unsterile Tip Assembly to make a measurement could lead to serious harm to the patient.
12. Do not use a Tip Assembly if it is non-sterile or if its sterility has been compromised.
13. Tip Assemblies are single use only and cannot be resterilized or reprocessed.
14. Do not use Tip Assemblies if the package is damaged.
15. Tip Assemblies are sharp and may be hazardous to the user. Use caution when handling, using, and disposing of Tip Assemblies.
16. The sterilization instructions provided have been validated 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.
17. Tip Assemblies should not be sterilized in the Tubes and the Tip Guards must be removed before placing the Tip Assemblies in sterilization pouches to avoid rendering the sterilization protocol less effective.
18. Only use Tip ID Stickers from the Tip Box the Tip Assemblies came from.
19. Reference Blocks are single use only and cannot be sterilized or reprocessed.
20. Improper cleaning and disinfection of the Stylus, Stylus Cable, or Holder could lead to serious harm to the patient or operator.
21. 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.
22. If the device becomes grossly contaminated, contact Active Life Scientific, Inc. for return/disposal instructions.

3.2 Cautions

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

1. The following conditions may complicate measurement, increase variability, or prevent measurement entirely:
    - Local edema[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[a]
    - Excessive soft tissue at the site of measure such that the Tip cannot reach the tibia (often associated with severe obesity)

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



2. To reduce the risk of damage to the equipment, only use the approved cleaning, disinfection, and sterilization methods described in Section 6.0: Operating Instructions.
3. Do not immerse the equipment in liquid.
4. Do not attempt to sterilize any part of the equipment, except the Tip Assemblies (see Section 4.3.2: Tip Assembly Sterilization).
5. Avoid rough handling or dropping of the equipment or any component of the equipment to prevent damage by mechanical shock.
6. Tips can be blunted by getting dropped or by touching the metal of the Holder. If this occurs at any time, including prior to sterilization, the Tip should be discarded to avoid increased variability in measurements.
7. All components of the equipment should be stored and transported in the provided Carrying Case.
8. 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.
9. 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.
10. 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.
11. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the OsteoProbe®, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
12. A risk of increased emissions or decreased immunity may result if any additional cables are attached.
13. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
14. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
15. To avoid increased variability in measurements, ensure that each indentation site is at least 1 mm away from other indentations sites and at least 4 mm away from any edge of the Reference Block.
16. Some patients may not wish to undergo the procedure due to fear of needles.
17. Risks have been reduced as far as possible. Residual risks include discomfort or infection.
18. OsteoProbe measurements correlate with ASTM Vickers and Rockwell hardness testing of plastics.

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

3.3 Electromagnetic Compatibility

The OsteoProbe® is intended to be used in a professional healthcare environment. Proper use of the OsteoProbe® will result in successful patient measurements of acceptable accuracy and precision. The Essential Performance of the OsteoProbe® is related to the accuracy of the measurement sensor. If the OsteoProbe® is used improperly, including using it in the presence of excessive electromagnetic disturbances, the device may experience degraded performance. This could include decreased measurement accuracy and/or precision, or unexpected errors requiring the device to be reset.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

The OsteoProbe® requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these accompanying documents.

⚠ CAUTION: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the OsteoProbe®, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ CAUTION: A risk of increased emissions or decreased immunity may result if any additional cables are attached.

⚠ CAUTION: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ CAUTION: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Guidance and manufacturer's declaration – electromagnetic emissions		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The OsteoProbe® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are no likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The OsteoProbe® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Warning: this system is intended for use by healthcare professionals only.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The OsteoProbe® is intended for use in the electromagnetic environment specified below. The customer or the user of the OsteoProbe® 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	±8kV contact ± 15kV air	+8kV contact + 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 610004-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1kV line(s) to line ±2kV line(s) to earth	+1kV line(s) to line +2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % *UT*; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *UT*; 1 cycle and 70 % *UT*; 25/30 cycles h) Single phase: at 0° 0 % *UT*; 250/300 cycle	0 % *UT*; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *UT*; 1 cycle and 70 % *UT*; 25/30 cycles h) Single phase: at 0° 0 % *UT*; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OsteoProbe® requires continued operation during power mains interruptions, it is recommended that the OsteoProbe® be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be a levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

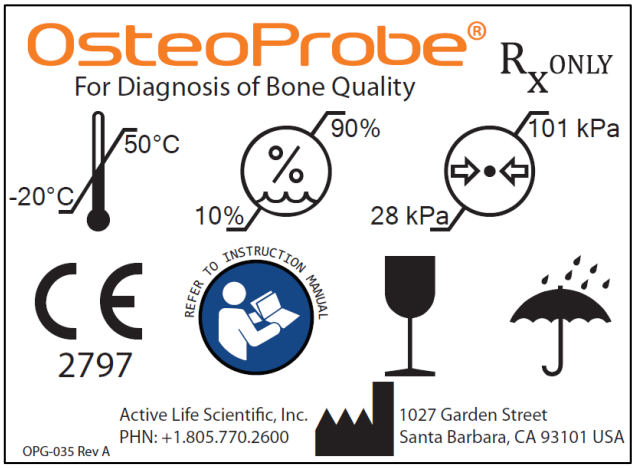
Guidance and manufacturer's declaration – electromagnetic immunity			
The OsteoProbe® is intended for use in the electromagnetic environment specified below. The customer or the user of the OsteoProbe® should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the OsteoProbe®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Guidance and manufacturer's declaration – electromagnetic immunity			
The OsteoProbe® is intended for use in the electromagnetic environment specified below. The customer or the user of the OsteoProbe® should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	Recommended separation distance d = [3.5/3] √P 80 MHz to 800 MHz d = [7/3] √P 800 MHz to 2.7 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: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
• Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OsteoProbe® is used exceeds the applicable RF compliance level above, the OsteoProbe® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the OsteoProbe®.			

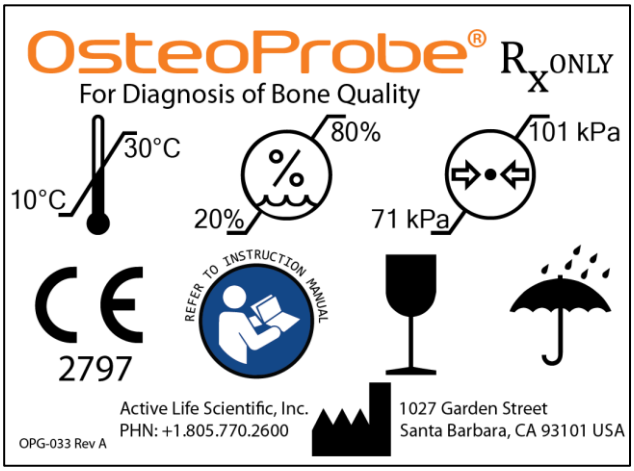
Guidance and manufacturer's declaration – electromagnetic immunity			
The OsteoProbe® is intended for use in the electromagnetic environment specified below. The customer or the user of the OsteoProbe® should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
IMMUNITY to proximity fields from RF wireless communications equipment	MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the OsteoProbe®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance E = [6/d] √P d = [6/E] √P where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/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: 
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment the OsteoProbe®				
The OsteoProbe® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OsteoProbe® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OsteoProbe® as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	80 to 800 MHz *d* = [3.5/3] √*P*	800 MHz to 2.7 GHz *d* = [7/3] √*P*	710, 745, 780, 5240, 5500, 5785 d = [6/9] √P	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 d = [6/28] √P
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

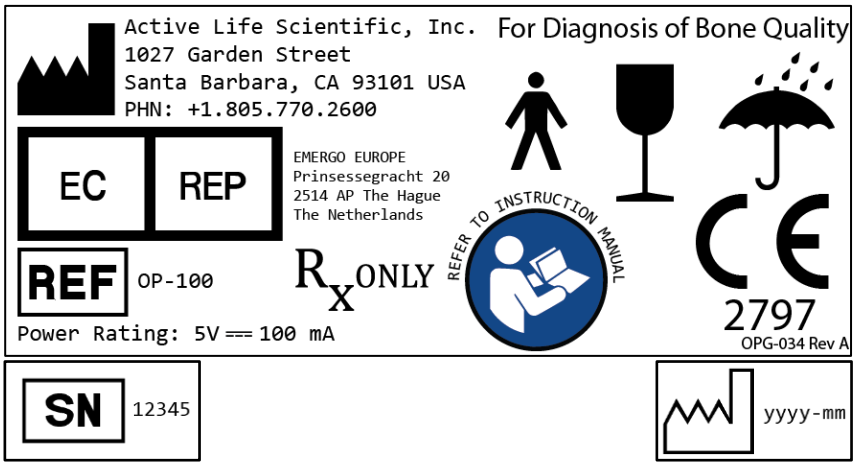
3.4 Safety Labels



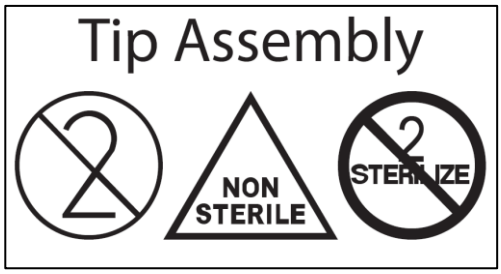
[On exterior of Shipping Box]



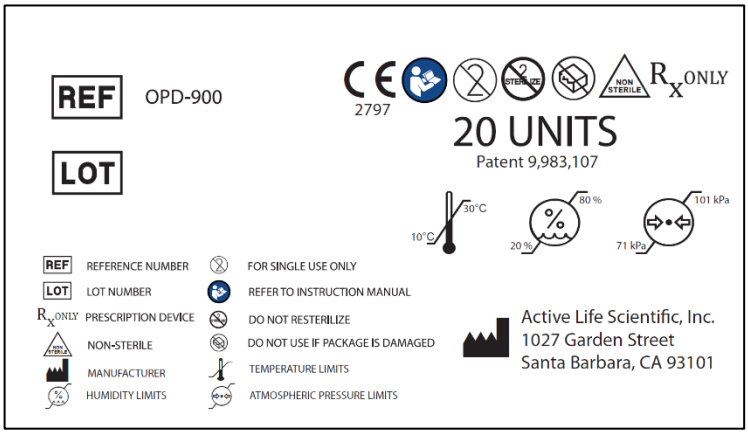
[On exterior of Carrying Case]



[On exterior of E-Box]



[On each individual Tip Assembly Tube]



[On each pack of Tip Assemblies]

ACTIVE LIFE SCIENTIFIC
the bone quality company

OsteoProbe Tip Assembly Sterilization Instructions

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

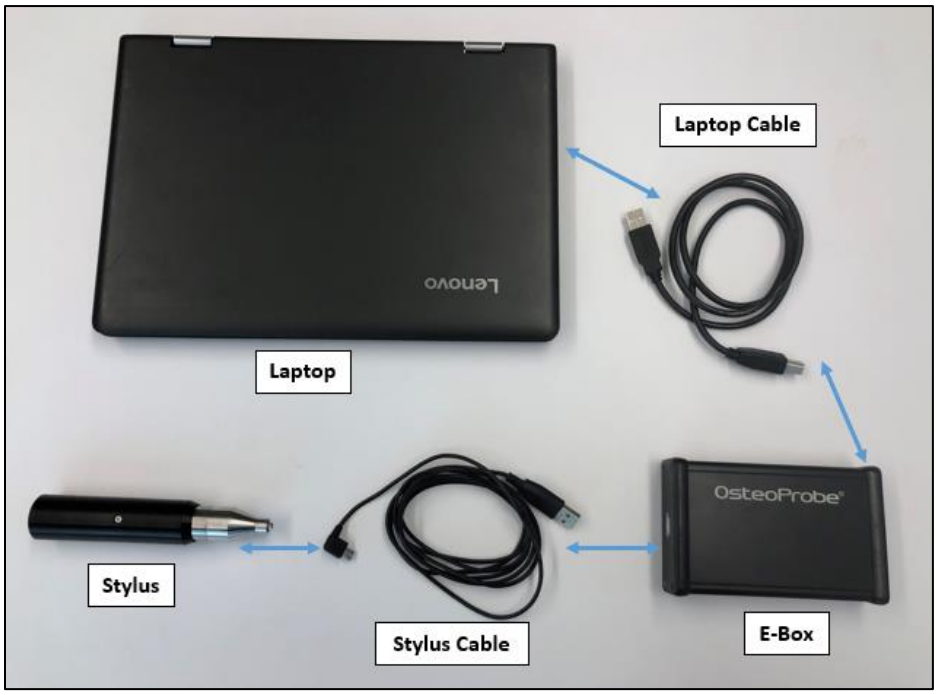
WARNING: The instructions provided on the reverse have been validated by Active Life Scientific, Inc. as being CAPABLE of preparing the device for use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials, and personnel in the processing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

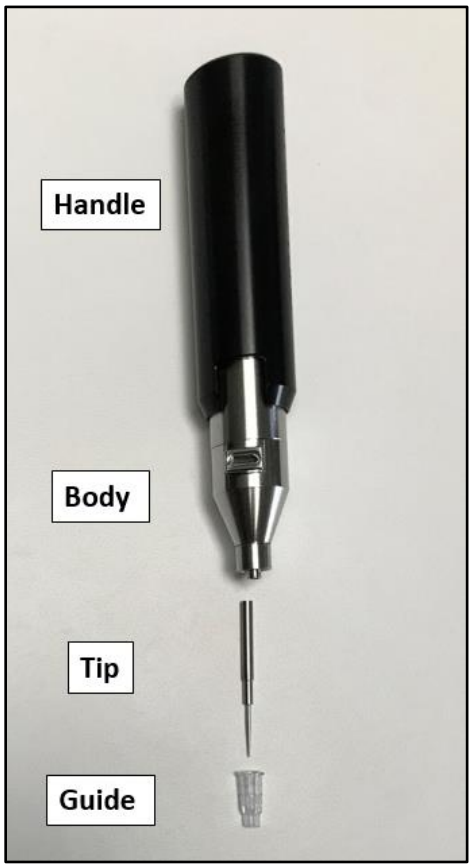
WARNINGS	The Tip Assembly is sharp and may be hazardous to the user. Use caution when handling, using, and disposing of Tip Assemblies.
Limitations on reprocessing	Tip Assemblies are single use only and cannot be resterilized or reprocessed.
INSTRUCTIONS	
Point of use:	N/A – Tip Assemblies are to be 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. Uncap the Tube and remove the Tip Assembly. 2. Remove the Foam Cover and disassemble the Guide and the Tip. 3. Carefully insert the Tip and Guide into a 3" x 8" FDA-cleared 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 the 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:	1027 Garden Street | Santa Barbara CA 93101 | USA +1.805.770.2600

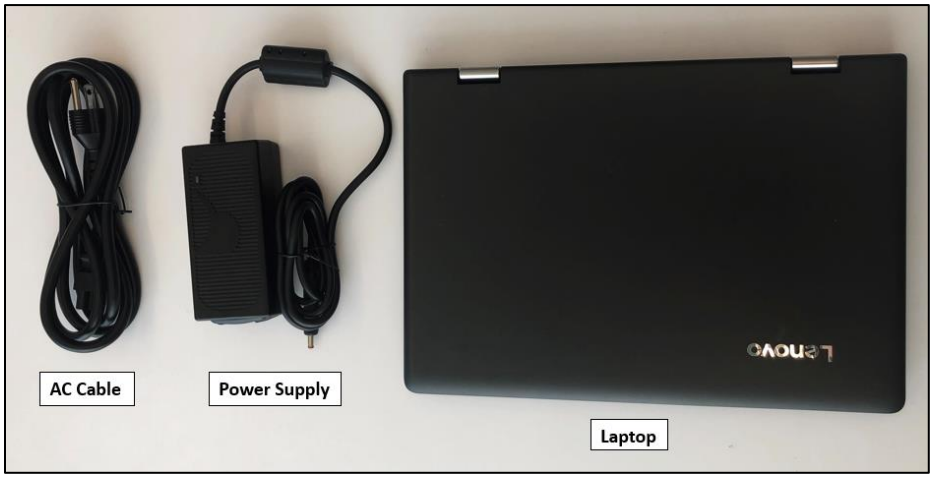
[Included inside each pack of Tip Assemblies]

4.0 System Setup

⚠ All components of the equipment should be stored and transported in the provided Carrying Case.







4.1 Connecting the System

Use the AC Cable to connect the Power Supply to an appropriate power outlet.
Plug the connector of the Power Supply into the Laptop.
Plug the USB-B connector of the Laptop Cable into the Electronics and plug the USB-A connector into the Laptop.
Plug the USB-A connector of the Stylus Cable into the Electronics and plug the Micro-B connector into the Stylus.

4.2 Securing a Reference Block

Place block in Holder and tighten down Holder Screw, ensuring that the block sits completely flat in the Holder.

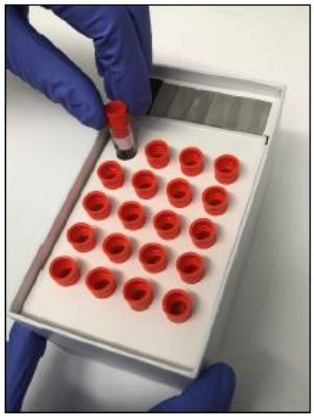
Note: The Holder Screw does not need to be tightened down excessively to properly secure the Reference Block in place.

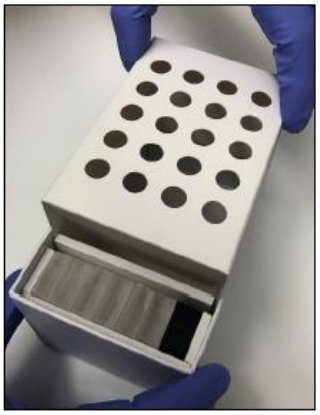
4.3 Handling Tip Assemblies

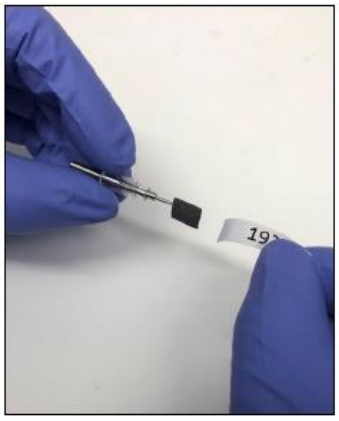
⚠ CAUTION: Tips can be blunted by getting dropped or by touching the metal of the Holder. ⚠

4.3.1 Preparing Tips for Sterilization

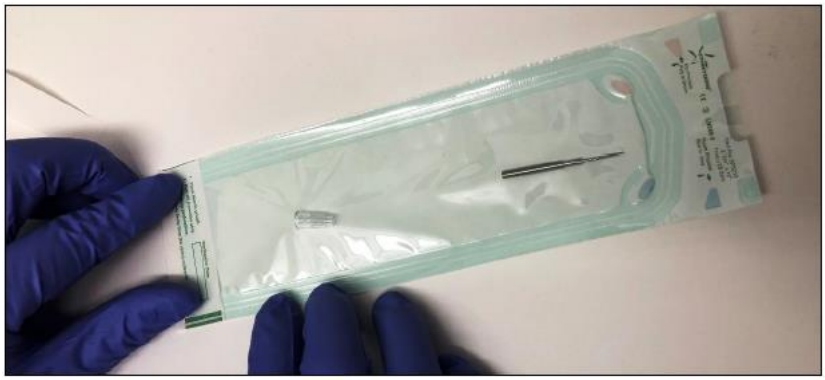
Remove Tip Assembly from shipping packaging for sterilization. See Section 4.3.2 for sterilization instructions.







Remove the Cap from the Tube and remove the Tip Assembly. Discard the Cap and Tube. Remove the Probe Guard from the Tip Assembly and discard. Separate the Tip and the Guide and carefully insert both into a sterilization pouch suitable for steam sterilization.



4.3.2 Tip Assembly Sterilization

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

⚠ **WARNING:** The instructions provided below 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.

⚠ **WARNING:** Tip Assemblies are sharp and may be hazardous to the user. Use caution when handling, using, and disposing of Tip Assemblies.

⚠ **WARNING:** Tip Assemblies are single use only and cannot be resterilized or reprocessed.

⚠ **WARNING:** Do not use Tip Assemblies if the package is damaged.

⚠ **WARNING:** Tip Assemblies should not be sterilized in the Tubes and the Probe Guards must be removed before placing the Tip Assemblies in sterilization pouches to avoid rendering the sterilization protocol less effective.

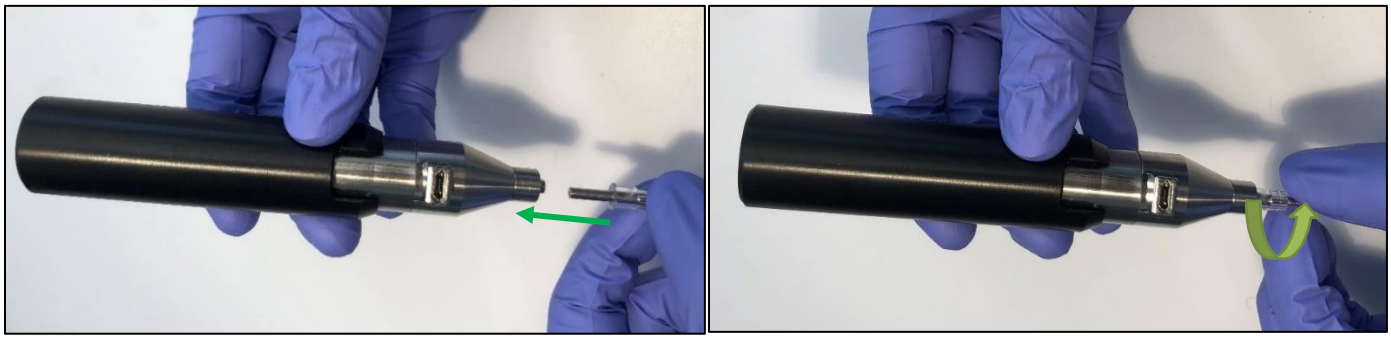
⚠ **WARNING:** Tip Assemblies are to only be used with the Tip IDs from the Tip Box they came from. Take care to ensure that the Tip IDs stay with the Tip Assemblies from the Tip Box they came from.

When sterilizing more than one pouch at a time, make sure the plastic side of the pouch always faces the paper side of the adjacent pouch. Up to 20 pouches can be placed into the same sterilization basket [Keep Tips and Tip Boxes connected] and up to 2 sterilization baskets can be used for a single sterilization cycle. Run a Gravity Steam Sterilization Cycle - 60 minutes at 121° C with 30 minutes drying time. **Do not exceed 130° C.**

When the sterilization and drying cycles are complete, store in a dry place.

4.3.3 Loading Tip Assembly onto the Stylus

1. Hold the Tip Assembly by the Guide and carefully pass the Tip Assembly through the opening into the Stylus leur fitting.
2. Tighten down the Guide until it is secured to the bottom of the Stylus.



Note: The Guide should not wiggle or feel loose when properly loaded onto the bottom of the Body.

4.4 Software Overview

1. Log In Screen

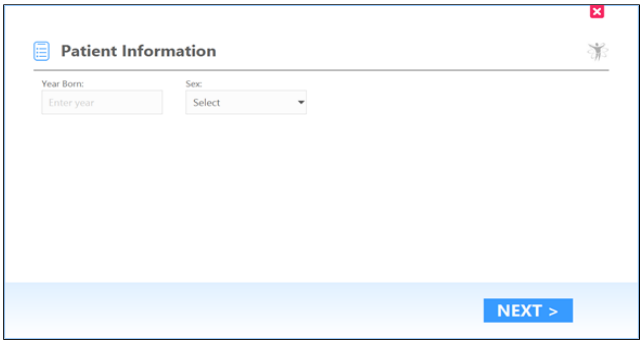
Enter the Software Username and Password and select "LOG IN" to log in to the OsteoProbe® Software.

2. Main Menu Screen

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

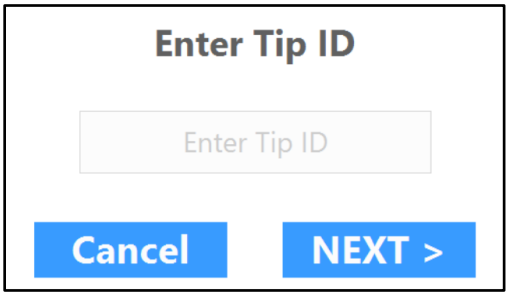
3. Patient Information Screen

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

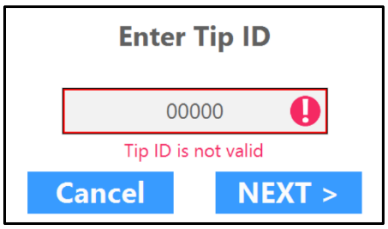


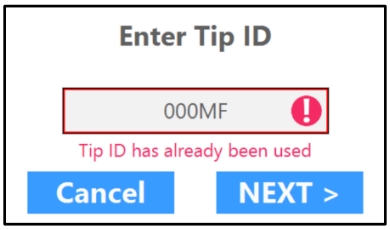
4. Tip ID Prompt

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.



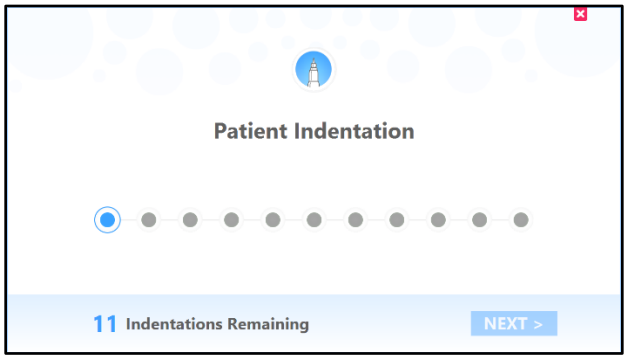
Red text will indicate if the Tip ID is not valid or has already been used.



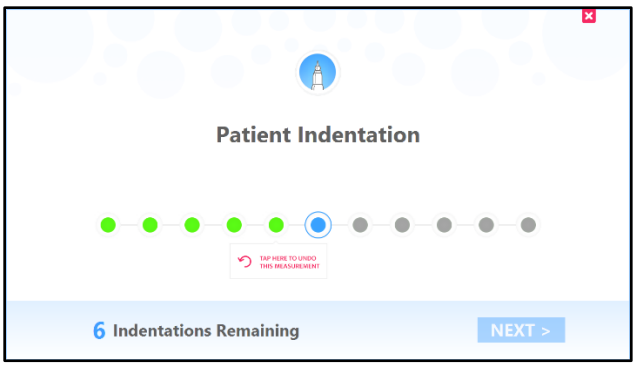


5. Patient Indentation Screen

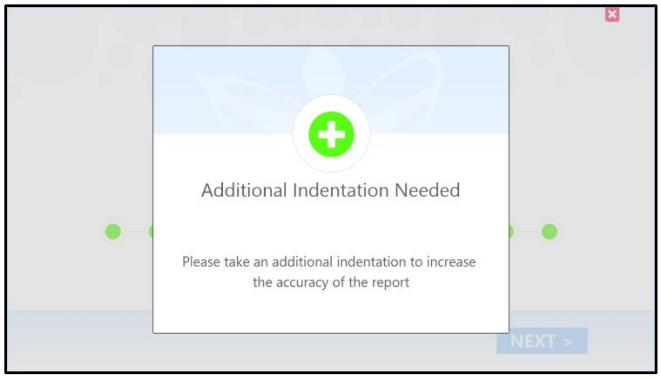
The indentation count will be displayed on the screen as indentations are performed.



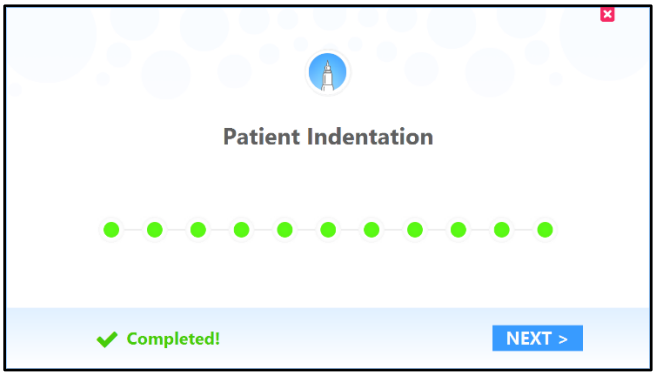
If a measurement appears without actuating the device, select “TAP HERE TO UNDO THIS MEASUREMENT” to remove the false indentation.



If prompted, perform additional indentations as indicated by the Software.

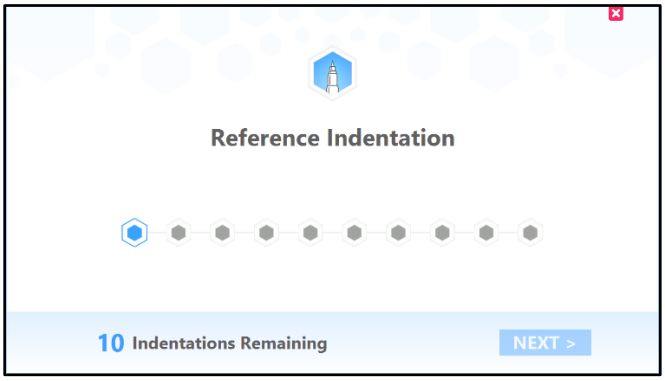


After the patient indentations are completed, select “NEXT” to proceed to the Reference Indentation Screen.

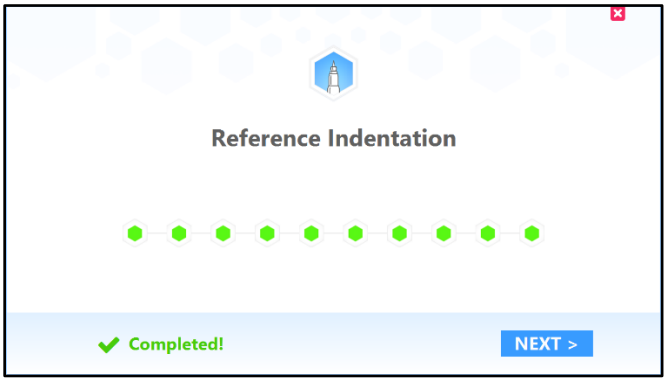


6. Reference Indentation Screen

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.

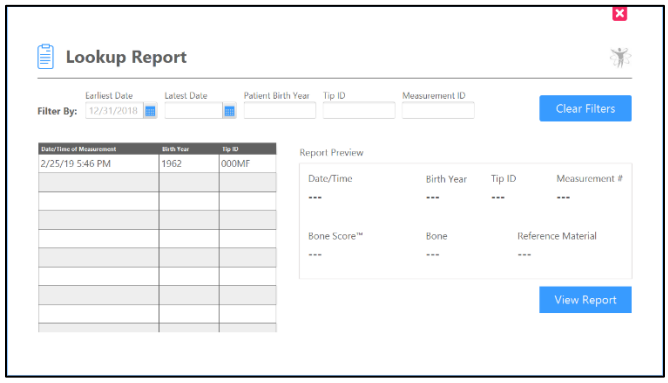


7. Measurement Report Screen

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.

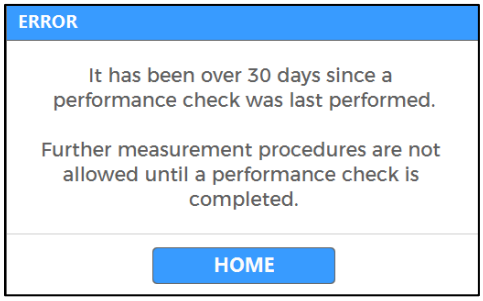
8. Lookup Report

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

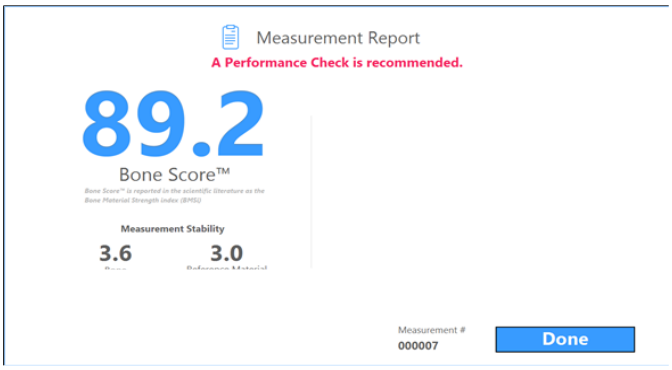


9. Software Indicators

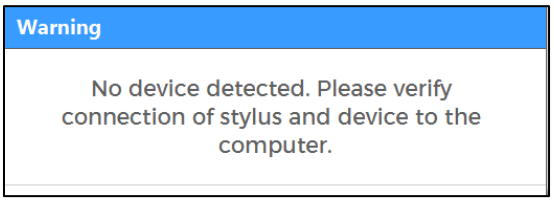
The software will indicate when a Performance Check is required and will not allow new measurements to be made until a Performance Check is completed.



The software also monitors the device performance and may suggest a Performance Check if it detects a potential issue.



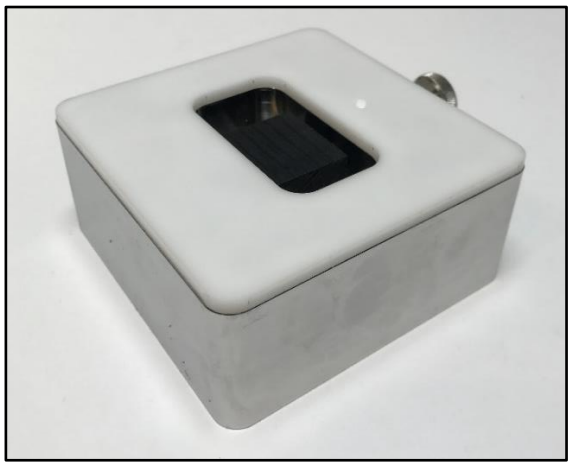
If the Electronics is disconnected from the Laptop at any time, the software will indicate that there is no device detected. An auditory tone will also sound indicating the disconnection.



5.0 Performance Check

A successful Performance Check is required at least once every 30 days to ensure the device is functioning as expected.

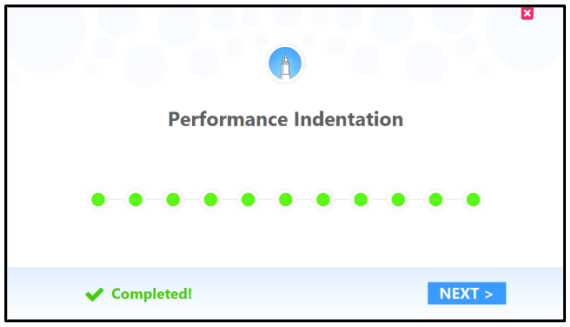
1. Secure a Performance Check Block in the Holder.



2. Load a Tip Assembly onto the Stylus.

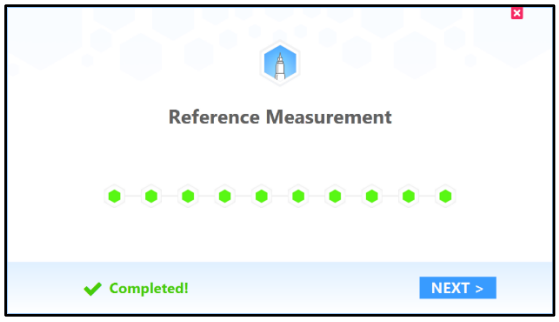
3. Select “PERFORMANCE CHECK” on the Main Menu of the OsteoProbe® Software to enter the Performance Check Mode.

4. Perform indentations on the Performance Check Block.

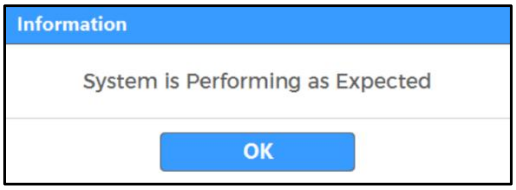


5. Remove the Performance Check Block and secure a Reference Block in the Holder.

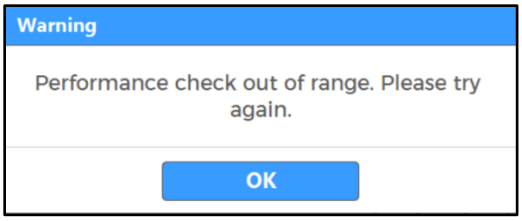
6. Perform 10 indentations on the Reference Block.



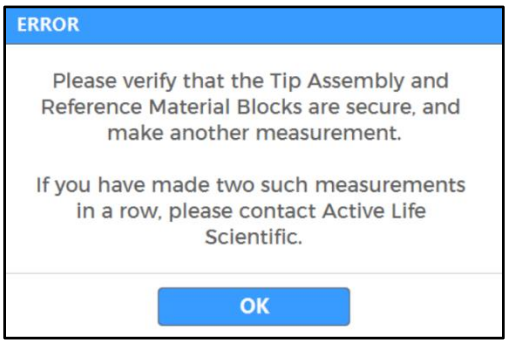
7. The software will automatically determine whether the device is functioning properly.



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



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



10. Dispose of the Performance Check Block after a single use.

6.0 Operating Instructions

6.1 Planning and Patient Positioning

Refer to the patient's chart and discuss all relevant contraindications for use with the patient.

Refer to Section 4.0**Error! Reference source not found.** for more

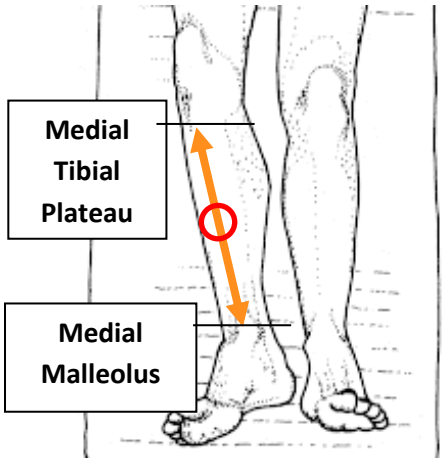
Position the patient in decubitus supine position.

Either tibia can be used for the measurement unless some local contraindication is present, in which case the other leg can be used.

Put on clean gloves.

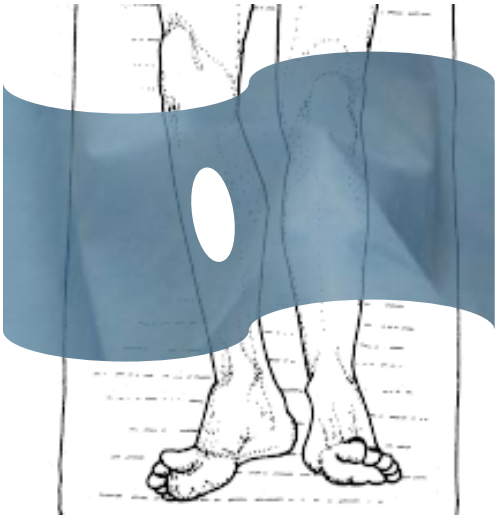
Position the leg in external rotation to orient the flat surface of the medial tibia diaphysis horizontal (i.e., parallel to the exam table).

6.2 Patient Preparation



Locate the mid distance between the medial border of the tibial plateau and the medial malleolus.

Prep the investigative area in standard sterile fashion. Perform a careful disinfection of a wide area of the anterior mid tibia region using a betadine or chlorhexidine disinfectant.



Place a sterile drape over the patient's leg with an opening at the area identified for measurement.

Perform local anesthesia infiltration both subcutaneously and in the periosteal surface.

DISCLAIMER: The use of any medication, including any local anesthetic (e.g., lidocaine, mepivacaine, etc.), given is the responsibility of the treating healthcare professional and not an official recommendation of Active Life Scientific, Inc. Active Life Scientific, Inc. is not the manufacturer of any local anesthetic, and the user should be familiar with the manufacturer's instructions or directions for use for all indications, side-effects, contraindications, precautions and warnings of any local anesthetic. Active Life disclaims all liability for the use, application or interpretation of the use of this information in the medical treatment of any patient.

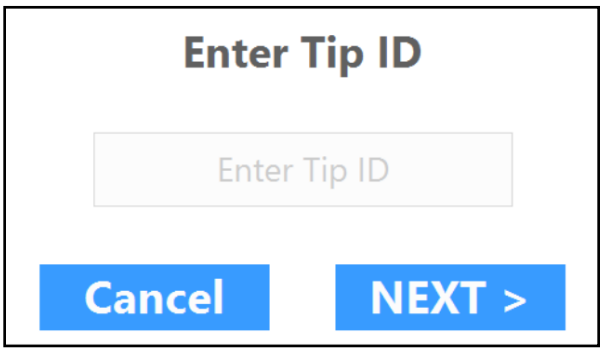
6.3 Measurement Preparation

Prepare a clean workspace near the patient with enough room for all materials. Place the Holder on a flat, stable surface in or near this workspace.

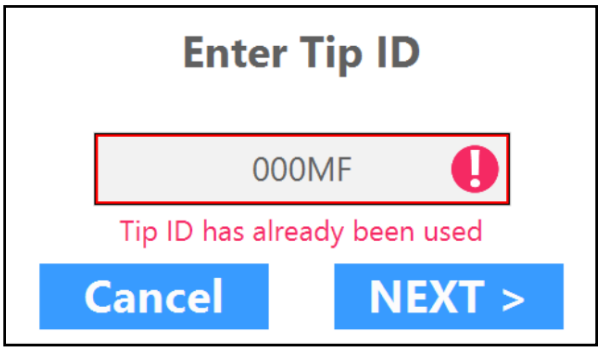
Select “NEW MEASUREMENT” on the Main Menu Screen to begin a new measurement.

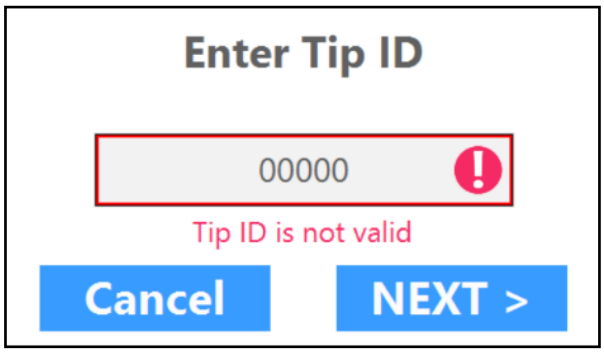
Fill out the patient information fields, then select “NEXT” to proceed to the Tip ID prompt.

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.





6.4 Making a Measurement

Refer to Section 4.3 Handling Tip Assemblies for more information

The procedure is a full sterile procedure.

Open a sterilized Tip Assembly pouch within the clean workspace. The opened sterile pouch is used as a sterile field.

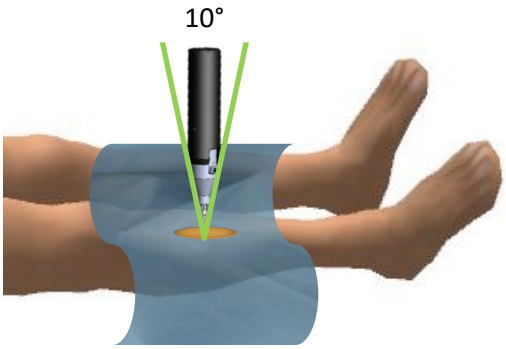
Place Stylus into sterile field. Put on sterile gloves and remove the Tip Assembly from the pouch.

Mate the Guide with the Tip and insert the sterile Tip Assembly into the Stylus.

⚠ **WARNING:** Using a Tip Assembly that has contacted anything unsterile could lead to serious harm to the patient. ⚠

Pierce the skin and periosteum at the measurement site and navigate the Tip down until it reaches the cortical bone surface.

Once in place, adjust the angle of the device to become perpendicular to the tibia surface (< 10° from normal) and compress the Handle of the device toward the patient's leg to make an indentation.



For every indentation, the Handle of the device is compressed slowly and smoothly (~1 ½ to 3 seconds).

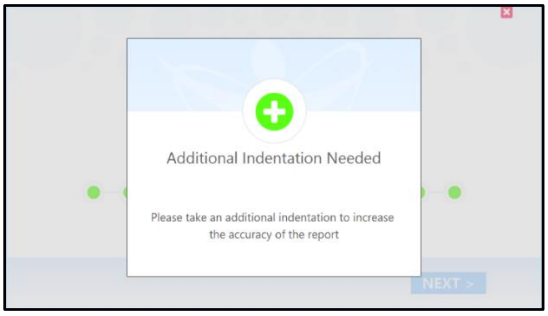
An auditory tone will sound as each indentation is registered.

If a measurement appears when an indentation has not been made, select “TAP HERE TO UNDO THIS MEASUREMENT” to remove it. Ask an assistant or don a new set of sterile gloves after interaction with the Operator Interface.

Without pulling the Tip out of the skin, move the Tip to a new location, about 2 mm away from the previous indentation, and repeat the indentations until the software indicates that patient indentations are complete. A minimum of 8 and a maximum of 18 indentations are possible.

If additional indentations are required, the software will prompt the operator.

All indentations are typically performed within a 1 cm^2 area.



After the patient indentations are completed, a different auditory tone will sound. Select “NEXT” to proceed to the Reference Indentation Screen.

The same focus and precision used for patient indentations should be used for the reference indentations.

Maintain perpendicularity and consistent actuation speed.

Follow the software prompts and perform 10 indentations on the Reference Block.

After the reference indentations are completed, a different auditory tone will sound.

Select “NEXT” to proceed to the 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.

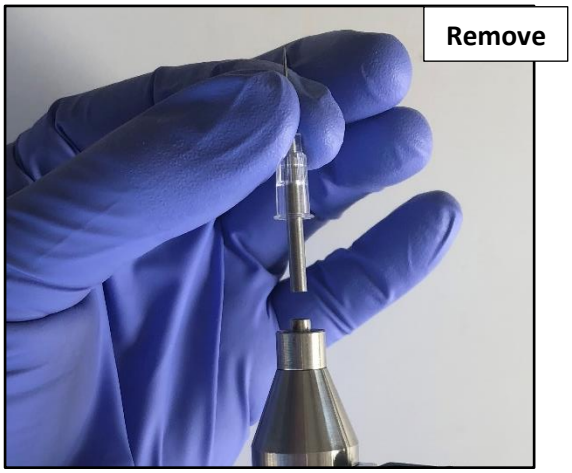
Apply a sterile bandage to the measurement site on the patient’s leg.

6.5 Disposal of Sharps and Biohazards

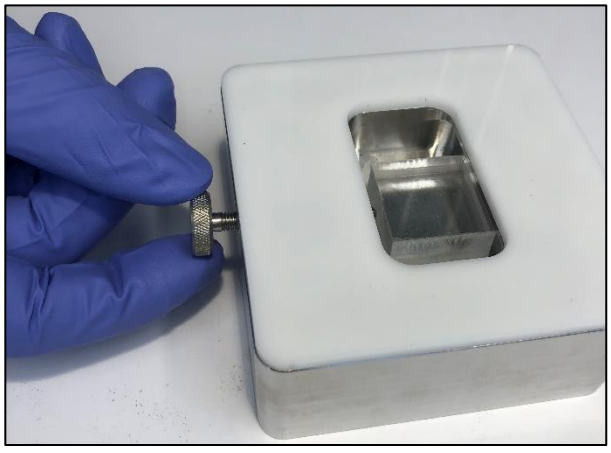
Special care should be taken when removing the Tip Assembly for disposal as it is now **a biohazardous sharp.**

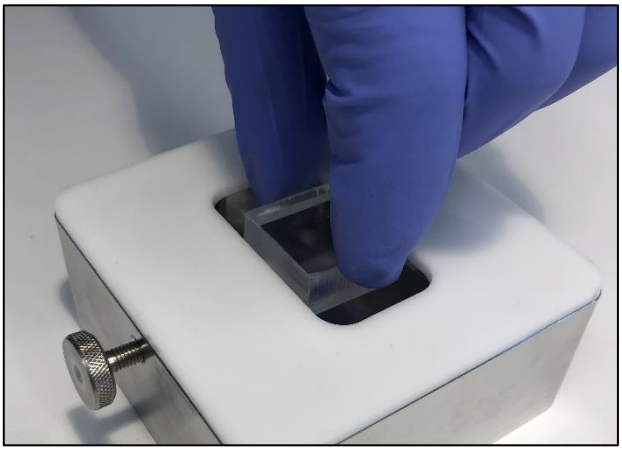
Hold the Stylus with the Tip facing away. Begin rotating the Guide to disengage it from the Stylus.

Once the Guide is disengaged, pinch the shaft of the Tip and pull both the Guide and Tip away from the Stylus simultaneously. Immediately dispose of the entire Tip Assembly in an appropriate Sharps container.



Unscrew the Holder Screw and remove the Reference Block. Dispose of the used Reference Block in an appropriate Biohazard container.





Dispose of gloves and all other contaminated equipment in an appropriate Biohazard container.

6.6 Cleaning and Disinfection Procedure (Stylus, Holder, and Stylus Cable)

Manufacturer: Active Life Scientific, Inc. Method: Cleaning (Manual) & Intermediate-Level Disinfection
Device(s): Stylus, Holder, & Stylus Cable

WARNINGS	• The Stylus, Holder, and Stylus Cable must be cleaned and disinfected after every use on a patient. • Wear appropriate protective equipment (e.g. gloves) during reprocessing and handling. • Use only the cleaning and disinfecting procedure outlined in this document. Using unspecified cleaning and/or disinfecting procedures may damage the components or may result in incomplete disinfection.
Cautions	• Use only the cleaning and disinfecting procedure outlined in this document. Use of cleaning and/or disinfecting procedures, including cleaning agents and germicidals, not specified in this document may damage the components. • Do not submerge or soak the components in any liquids. • Do not use automated washers or disinfectors to clean or disinfect the Stylus, Holder, or Stylus Cable. • Do not sterilize the Stylus, Holder, or Stylus Cable.

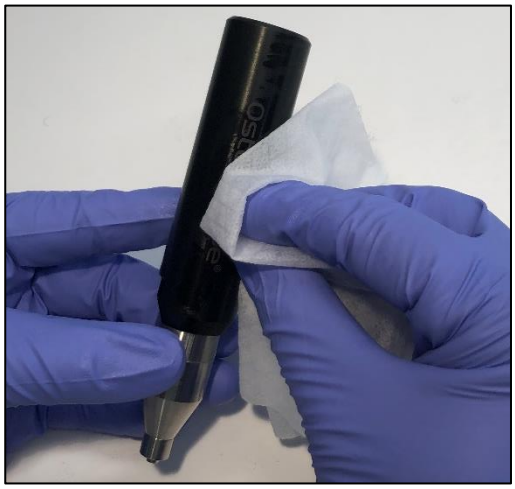
WARNING: The instructions provided below have been validated by Active Life Scientific, Inc. as being CAPABLE of preparing the device for use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials, and personnel in the processing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

Put on clean gloves <u>before</u> beginning the cleaning and disinfection procedure.

6.6.1 Cleaning the Stylus

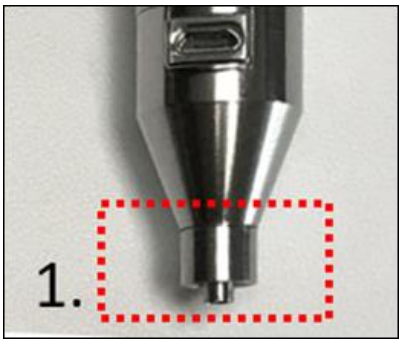
Dispense a new towelette (Super Sani-Cloth® Germicidal Disposable Wipes). Wipe down the exterior of the Stylus with the towelette while continuously actuating the device.

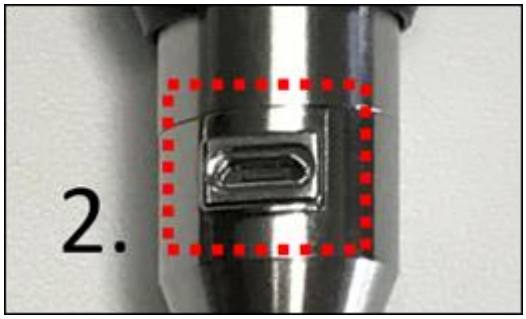
Visually inspect the Stylus for cleanliness. If visible soil remains, repeat previous steps.

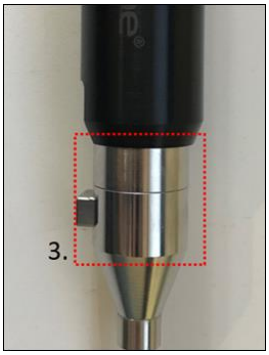


6.6.2 Disinfecting the Stylus

Dispense a new germicidal disposable wipe and wipe down exterior of the Stylus for at least 2 minutes while continuously actuating the device. After wiping down for at least 2 minutes, use a new towelette to diligently wipe down the seams and crevices in the following areas for at least 1 minute:

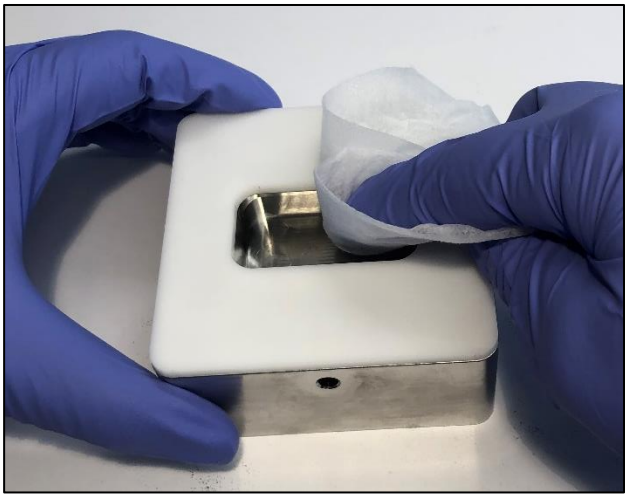


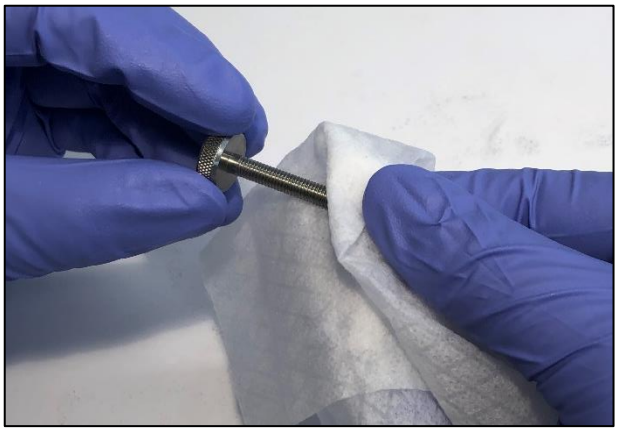




After diligently wiping down the seams and crevices for at least 1 minute, dispense a new towelette and wet all exterior surfaces of the device while paying particular attention to the areas above. Use as many towelettes as needed to ensure the surfaces remain wet for at least 2 minutes while continuously actuating the device.

Allow treated surfaces to air dry completely.





6.6.3 Cleaning the Holder & Holder Screw

Remove the Holder Screw from the Holder.

Wipe down the exterior surfaces and pocket of the Holder with a towelette.

Dispense a new towelette and wipe down the Holder Screw.

Visually inspect the Holder and Holder Screw for cleanliness.

If visible soil remains, repeat until clean.

6.6.4 Disinfecting the Holder & Holder Screw

Wipe down the exterior surfaces and pocket of the Holder using as many new towelettes as needed to **ensure the treated surfaces remain wet for at least two minutes.**

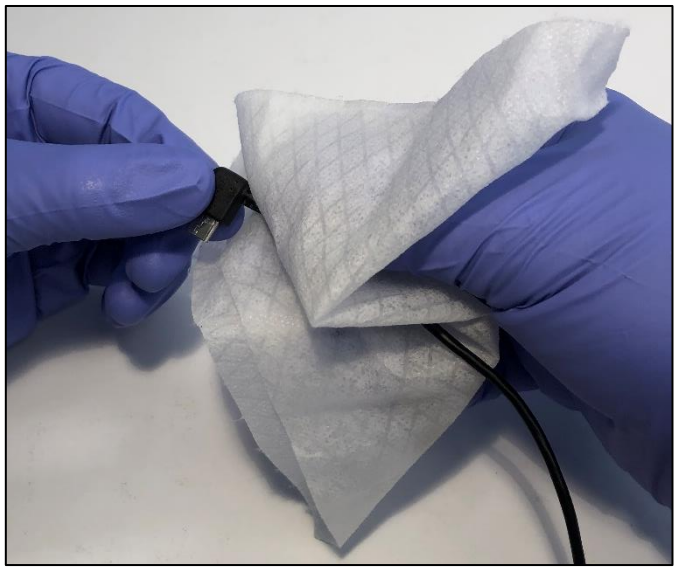
Wipe down the Holder Screw using as many new towelettes as needed to **ensure the treated surfaces remain wet for at least two minutes.** Allow the treated surfaces to air dry completely. Reassemble the Holder Screw into the Holder.

6.6.5 Cleaning the Stylus Cable

Wipe down the Stylus Cable.

Visually inspect the Stylus Cable for cleanliness.

If visible soil remains, repeat until clean.



6.6.6 Disinfecting the Stylus Cable

Wipe down the Stylus Cable using as many new towelettes as needed to **ensure the treated surfaces remain wet for at least 2 minutes.** Allow the treated surfaces to air dry completely.

Dispose of gloves and all used towelettes in an appropriate Biohazard container.

Inspect the Stylus, Holder, and Stylus Cable for any damage. Do not use if a component is damaged. Return damaged components to Active Life Scientific, Inc. for repair. Place all components back in their pockets in the Carrying Case for storage and store the Carrying Case in a dry place.

6.7 Cleaning Procedure (Laptop and Electronics)

The Laptop and Electronics can be cleaned as needed.

6.7.1 Cleaning the Laptop

Ensure that the Laptop is disconnected from the Power Supply and completely shut down. Use a dry towelette 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 towelette that has been slightly wetted with IPA.

6.7.2 Cleaning the Electronics

Wet a towelette 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.

7.0 Disposal

7.1 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 Disposal of Tip Assemblies

Used Tip Assemblies should be considered contaminated 'sharps' and disposed of accordingly. See Section 6.5: Disposal of Sharps and Biohazards.

7.3 Disposal of Reference Blocks

Used Reference Blocks should be considered contaminated and disposed of accordingly. See Section 6.5: Disposal of Sharps and Biohazards.

8.0 Technical Specifications

8.1 System Information

The OsteoProbe® system operates on a hardened Windows based laptop that prevents installation or removal of software, modification to operating system parameters, blocks USB ports, and encrypts all measurement data. The laptop computer requires no additional software to meet cybersecurity requirements.

Parameter	**Parameter Value**	
System Classification	EU Class:	Class IIa
Safety Certifications	EU Certification:	IEC 60601-1: 2012
	EMC Certifications:	IEC 60601-1-2:2014 (4TH EDITION) CRISPR 11:2015+A1:2016 IEC 61000-4-2:2008 IEC 61000-4-3:2010 IEC 61000-4-4:2012 IEC 61000-4-5:2005 IEC 61000-4-6:2013 IEC 61000-4-8:2009 IEC 61000-4-11:2004 IEC 61000-3-2:2014 IEC 61000-3-3:2013
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 2.1: Intended 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
Resolution	BMSi:	0.1 BMS units
Accuracy	Displacement Sensor: Measurement:	±1 µm ± 2%
Precision	Repeatability St. Dev.:	0.811 BMS units
	Reproducibility St. Dev.:	1.066 BMS units
Internet Connectivity	Wireless: Ethernet:	802.11b/g/n RJ-45 (100/1000 Mbps)
Transport Conditions	Ambient Temperature: Relative Humidity: Atmospheric Pressure:	-20°C to 50°C 10% to 90%, non-condensing 28k Pa to 110 kPa
Operating & Storage Conditions	Ambient Temperature: Relative Humidity: Atmospheric Pressure:	10°C to 30°C 20% to 80%, non-condensing 71 kPa to 101 kPa

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:

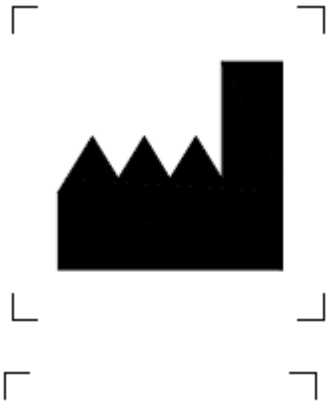
customer.care@activelifescientific.com

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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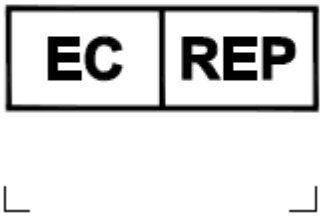

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