

Dear Health Promotion Clinical Director,

We are so happy that you are offering bone density testing for your athletes. The GE EXP II Achilles is one of three SOI approved ultrasound densitometers. Included are two resources for the Achilles, to help ensure that you are able to deliver the service according to our protocols. They focus on obtaining accurate results, safely and efficiently.

## **Resources for use of the Achilles Densitometer**

- 1. The Health Promotion <u>Achilles EXP II User Guide</u> should be reviewed thoroughly by the supervising HPCD before volunteer training starts.
- 2. After review of the User Guide, watch the **Achilles Instructional Videos**. The videos contain minor errors and will eventually be rescripted and filmed for our program. These YouTube films will help get you started and each should be carefully, as they will show you how to correctly set up the machine before testing can begin.



- Osteoporosis Screening
- Bone Density Screening using Achilles How To Set Up Machine
- Bone Density Screening using Achilles How To Perform A Screening
- Bone Density Screening using Achilles How To Describe Exam and Discuss Results
- 3. The <u>Achilles EXP II Operator Manual</u> Keep the Achilles User Guide and Operators Manual in the screening area to do trouble shooting if necessary.
- 4. The document **Bone Mineral Density Screening in Health Promotion** addresses the issues that contribute to bone health disparities for individuals with IDD screening.

## Helpful Tips

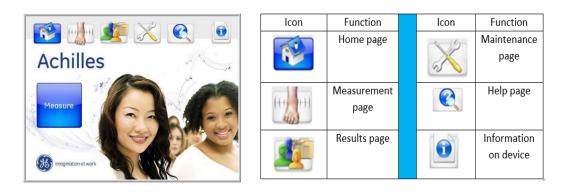
- 1. When the machine case is opened, take some photos with your phone, of how it is packed to simplify returning the machine safely.
- 2. Plan to have two or more people involved during the machine set up and trial runs. You'll want to practice on one another to ensure you're comfortable with operation.

- 3. When filling the distilled water reservoir, make sure the water line is right to the top. It may seem like it should be full long before it actually is. Without the minimum water in the tank, the device won't pass calibration.
- 4. Be sure to have your volunteers test both heels.
- 5. Be generous when spraying the isopropyl alcohol on the transducer balloons, the quality assurance phantom device and the athletes' heel area. Athletes may want to dry their heel with a Kleenex or paper towel, but it's not necessary.
  - a. When moving through the digital screens displayed on the machine, the volunteer will encounter a screen asking for athlete demographic information, but this can be passed by as this information isn't needed for a T-score. After the athlete's gender and the right or left heel image is selected, complete the test on the first heel. Then the volunteer should select the "retest" option and select the image to re-define the heel as right heel and proceed with the second test.
  - b. In the rare event that a valid reading on the one of the two heels cannot be obtained, indicate the reason on the HAS form so the second heel test can be counted. If only one heel is tested and no valid reason is noted, the results cannot be used.
- 6. Only screen athletes ages 20 and older.
- 7. When recording the T-scores, a "+" or "-" symbol MUST be written before the T-score, or the test result cannot be use.
- 8. If the athlete has a T-score of -1.0 or lower, they need to be referred to their health care provider. Refer to the <u>Athlete Health Report 2022</u> for more information. Athlete should be reminded to share this completed form with their health care provider. Be sure to have plenty of these forms as well as the <u>updated HAS</u> form for each athlete who completes the Health Promotion venue. These and other new resources are posted on the <u>HP Web</u> <u>Resources page</u>.
- 9. Make sure all the distilled water is drained from the machine before shipping, as sloshing water can destroy the machines operating system.
- 10. Wipe the machine down with a Sani-wipe before repacking.
- 11. Education tools to use during or after BMD testing: Food models including a cup of milk, a carton of plain yogurt (no sugar added), a bottle of Fairlife Skim milk, a bottle of Calcium Citrate with 500 mg/serving (2 tablets), two bottles of vitamin D supplements, one with 2000 IUs and one with 5000 IUs. Refer to the HP Clinical Director's manual for tips on education to offer during and after testing.

Please let us know if you would like to visit by phone to answer any other questions. If you have problems while trying out the machine prior to the event or during it, don't hesitate to call or text me. Please take some photos of the machine being used. If an athlete's face is shown, you'll need to get permission including their name, phone number, mailing address and e-mail. If you have time after the event, please share any suggestions on running the BMD station. We will create a FAQ document and would appreciate your input.

Senior Clinical Manager Health Promotion and MedFest Special Olympics 2600 Virgnia Ave NW, Washington, DC 20037 E-mail HealthPromotion@specialolympics.org

Achilles Bone Density User Manual
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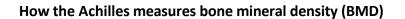
The Achilles LCD touch screen guides all Achille's processes. It's intuitive and easy to follow. Screen prompts use the shown icons to inform operator of process options. Please refer to Achilles Operator's Manual for more detailed information on screen images and flow.

## **Achilles Bone Density User Manual**

## **Equipment and supplies**

Items in Pelican shipping case	Items to be provided by local
	program
Achilles measurement device	<ul> <li>70 % isopropyl alcohol</li> </ul>
<ul> <li>Operator manual</li> </ul>	Distilled water
Power cord	Paper towels
Quality assurance phantom	Chairs without wheels
<ul> <li>Specialized screwdriver</li> </ul>	Signage
<ul> <li>Spray bottle for alcohol</li> </ul>	<ul> <li>Small table or stacking drawers</li> </ul>
<ul> <li>Water filling bottle</li> </ul>	Box of tissue
• Fill cap to pour water from	Garbage can
Printer tape	Surge protector
Extra membranes	Microfiber cloth
<ul> <li>Foot shim for smaller feet</li> </ul>	<ul> <li>Heavy duty extension cord</li> </ul>
	Funnel



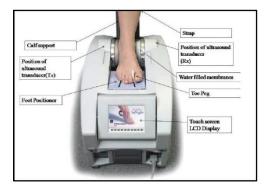


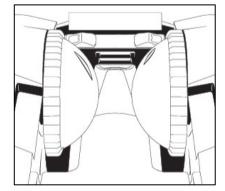
The Achilles EXPII device is an ultrasonic bone sonometry system. The device converts soundwaves into electrical signals, measures the speed of sound (SOS) and attenuation of the soundwaves (broadband ultrasound attenuation – BUA). It combines the two, to determine the Stiffness Index. See Figure 8.

## What the Achilles measures

The Achilles determines broadband ultrasound attenuation (BUA) by measuring the attenuation of ultrasound waves in decibels (dB) at a particular frequency in megahertz (MHz). The typical range of BUA in the normal population ranges from 20-125 dB/MHz. The device also measures speed of sound (SOS) which is used in the quality assurance of the device operation.

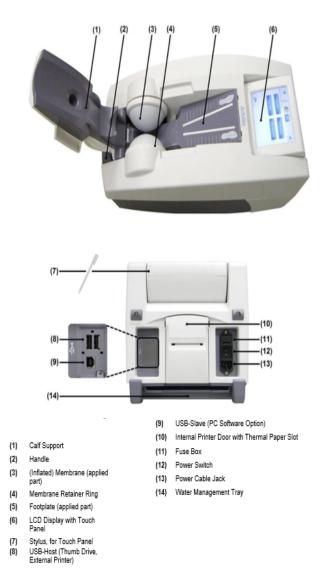
The more structurally 'dense' bones are, the more the sound wave will be blocked through the bone. Normal bone results in a higher attenuation, or higher BUA measurement, than osteoporotic bone. Bone which has a high degree of conductivity, such as normal bone, allows for sound waves to move quickly through the bone. Conversely, as bone becomes more osteoporotic or porous, the speed of sound wave will slow down and a lower BUA will be measured.





Membranes inflate with warm water. These will gently press against the heel bone and transmit sound waves.

#### **Achilles EXP11 Components**



The **Achilles EXP II Operators Manual** provides detailed instructions on how to operate the device, including screen shots of the **LCD with Touch Panel**.

The menu driven LCD screen guides users through each aspect of device use including installation, device features and accessories, setting up the device for use, performing the exam, troubleshooting and preparing the device for shipping the device. Read this manual thoroughly before operating the Achilles or interpreting results. Keep the Operator Manual with the equipment at all times and periodically review procedures and safety precautions.

## Accessories shipped with the Achilles Device



Accessories needed for device operation. Each shown accessory will be included with the Achilles device shipped from SOI. All items must be repacked into the Pelican case when returning the device. This will ensure that the next program to use the device will have what is needed to provide the screening service to athletes. Replacement parts can be ordered if necessary.

If one or more of these accessories are misplaced, missing and therefore not included in the return shipment of the device, please inform the Health Promotion by <u>email</u> and include a signed and dated note explaining the situation in the Pelican case. **How to Clean and Disinfect the System: Low-level** disinfection must be performed after each athlete, to help prevent possible cross contamination of infection between people. Only use 70% isopropyl alcohol for cleaning to avoid damage to the device.

- **Clean Calf Support** Remove Calf Support from the device and use the alcohol spray bottle and soft tissue or microfiber to clean the entire Calf Support surface.
- **Clean Footplate** Remove Footplate from the device. Use the isopropyl alcohol spray bottle and soft tissue or microfiber cloth to clean the entire Footplate surface. Let it air- dry. Repeat this step.
- **Clean Membranes** Before you perform measurements each day, inspect the membranes. Use the alcohol spray bottle and soft tissue or microfiber cloth to gently clean the membranes. Sand and grit can puncture the membrane. Be careful not to puncture or tear the membranes when cleaning. Replace the Footplate in the heel well.
- **Clean Housing** Use a micro-fiber cloth dampened with alcohol to gently clean the LCD screen to avoid damaging the screen. Use a soft cloth to clean the surfaces of the housing after you complete other cleaning procedures or whenever necessary.
- **Drain Water Management Tray** Each day, before performing measurements, detach the Water Management Tray and drain any accumulated water. Operators need to check and empty the Water Management Tray periodically during operation to prevent leakage into the measurement area.
- **Environmental conditions** Do not store the device in freezing conditions, as moisture in the device will freeze and damage the device. Operate the device within range of 60-95 Fahrenheit (15-35 Celsius). Operate in a clean, well ventilated environment, free from dust, smoke, and other airborne contaminants. Do not operate outdoors to reduce risk debris and direct sunlight which can damage membranes.



**Moving the device by handle.** Lift the device gently by Handle. Remove any water in the Water Tray and Footwell before moving it. The water in the reservoir does not need to be removed. Note: water from the reservoir and water tray needs to be removed before shipping.

## Add Water Procedure steps 1-6

The water reservoir must be completely full of distilled water before turning the machine on. Do not power up the device without water in the pump. Only use distilled water in the Achilles to avoid mineral damage to the pump.



1. Open the calf plate (the hinged lid over the footwell.) Lift and remove the calf-support.





 Remove the black fill peg with the specialized screwdriver Remove at least one membrane. Rotate the membrane ring counterclockwise, remove it and then remove the membrane.



2. Pull from end of Footplate and remove it.



- 5) Remove at least one membrane. Rotate the membrane ring counterclockwise, remove it, and then remove the membrane.
- 6) Add distilled water until the water level reaches the threads of the fill port. Replace black fill peg, membrane and Retainer Ring. Thread correctly to avoid stripping the threads.



3. Ensure the end of the device is elevated before adding water. Prop up the handle end with Calf Support. If elevated, the reservoir will fill completely.

If the reservoir is low on water, the pump may fail to retract completely due to vacuum pressure inside of the pump and QA will fail.



- 7. Replace Fill Plug, Membrane and Retainer Ring. Click continue, and the membranes will inflate.
- 8. Check membranes for leaks, air bubbles or irregularities.

#### Inspect Membranes

Are membranes clean and free of dirt or debris? If not, spray with alcohol to rinse off debris. If needed, gently wipe with a microfiber cloth or soft tissue. Avoid use of paper towels on membranes to prevent scratches.

Are membrane surfaces flat without puckering? If membranes are incorrectly situated on have puckers, the device will not pass QA.

#### Do membranes show a leak when filled with water?

Click Fill Membrane on screen and inspect the filled membranes for leaks. **DO NOT** replaces the membranes when they are inflated. Click Drain Membranes. If either membrane leaks, replace both and recheck.



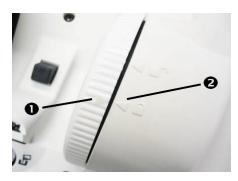
A membrane with a leak

**Replace Membranes** Change the membranes if they begin to leak or if the device prompts you to change them. Replace both membranes at the same time.

- If the membranes are filled with water, click **Drain Membrane** before replacing.
- Remove the Calf Support and the Footplate
- Rotate Membrane Retaining Ring counterclockwise and remove.
- Remove both membranes.
- Dry and clean the area behind the membranes so the new membranes will stick as you attach them.



6. Attach the new membranes. Make sure that the edges of each membrane are fully attached as shown. The ridge around the edge of the membrane (2) fits into the groove where the membrane will be attached (2).



7. **Reattach retaining rings over the membranes.** Ensure the rings are completely rotated clockwise, and the triangle on rings (1) are right against the triangle on the cover (2) as shown. Refill the membranes to check for leaks.

#### **Release Air from the Membranes**

As the water in the pump is heated and cooled, it can de-gas (gas that is in solution within the water is liberated) and accumulate in the membranes. This is most likely to happen in the days immediately after a complete fill or complete replacement of the water. Even after a successful Add Water procedure, some air may accumulate in the top of the membranes. If the filled membranes have a large bubble of air at the top, follow these steps to release the excess air.

- 1) Ensure the membranes are deflated.
- 2) Remove the calf-support, footplate, and membrane retaining rings.
- 3) Carefully remove membrane ridge from groove to vent excess air out of the top of the membranes.
- 4) Reattach membranes and membranes retaining rings.

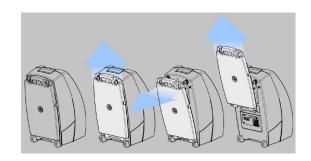
#### **Drain Water Tray Procedure**

Follow process if water begins to seep onto floor; before storing device when not in use. Drain System before shipping this product.



#### **Drain the Device**

- Power down and unplug power cable from the device.
- Prepare a container for the water.
- Remove the fill plug.
- Tilt the device on its front (handle) end.
- Shake device gently to ensure all water is drained.



#### Drain the Water Management Tray

- Power down and unplug the device
- Ensure that fill plug and membranes are attached.
- Stand the unit on its end and slide tray up. Lift it away and off the unit as shown.
- Drain the Water Management Tray into a container by tipping to a corner.



**Reattach the Water Management Tray** to the unit by seating the lower end into the slots on the rear glides, mounting the foot holes onto the unit's front feet, and then sliding the tray down into place. Reposition the device for measurement.

**Perform Quality Assurance (QA) Procedure** The water reservoir must be completely full of distilled water before turning the machine on. The Achilles device requires completing QA before first time use, or after device has been turned off. Remove QA Cylinder stored beneath the foot plate. Prepare the Spray Bottle filled with 70% Isopropyl Alcohol.

The QA or the phantom, is stored beneath the foot plate. This protects it from damage and helps ensure that it is available during the screening process.







Spray both membranes and both sides of the QA cylinder generously with alcohol.



Place the QA Cylinder between deflated membranes.

**Steps to calibrate device**: The Achilles must be calibrated once every 7 days using the QA phantom, and/or when the device is turned off. The device will cue the operator when it is switched on as to the need for QA.

- **Step 1: Device notifies when QA measurement required.** Begin a session by following the on-screen instructions and using the QA phantom and rubbing alcohol. Briefly, the operator will spray both sides of the phantom and both membranes on the device with rubbing alcohol and then select next on the screen.
- **Step 2: Press "continue" on the screen.** The membranes will fill with water and there will be a countdown on the screen. Do not disturb the Achilles device during the QA process.
- **Step 3: Evaluate QA result.** The device will indicate whether or not the QA measurement was successful on the screen and will automatically print the result. In the case of a "fail" result,
  - confirm the water reservoir is filled to the top and rerun the phantom
  - confirm that there are no leaks in the membranes and that sufficient alcohol was used on the phantom
  - check troubleshooting guide for further suggestions

## Steps to complete a BMD exam on an individual

**Step 1: The individual must be comfortably seated in a stable chair.** Ensure the individual can comfortably sit back in the chair with the foot correctly aligned in the Achilles footwell. The leg should rest comfortably on the calf support and the heel placed firmly against the back wall of the footwell. The first two toes straddle the ridge on the footwell of the device.

**Step 2:** Ask individual to remove shoes and socks from both feet. Avoid testing heels with abrasions, bleeding sores, infection or diseases like eczema and psoriasis on the foot or heel. Test both heels, starting with the left.

**Step 3: Determine if foot insert is needed.** An anatomical foot insert is supplied to ensure the proper alignment of the foot with the transducers. To determine if the foot insert (foot shim) is needed, ask the individual about shoe size; if they are less than a size 6, then the shim is required. No shim is needed for a foot greater than a size 6. Ask the individual to remove his or her foot from the footwell and place it on top of the device; place the foot shim into the device, if needed.

**Step 4: Enter individual-specific data into the Achilles device and begin measurement.** Enter gender, age and which foot is being tested into the device. Prompts will appear on the touchscreen for each entry needed. When switching to second heel, press "retest" and specify the new heel (right or left) then proceed with the second test.

**Step 5: Apply Isopropyl Alcohol.** 70% Isopropyl rubbing alcohol must applied to ensure good contact is made on each side of the heel. Two to three sprays, creating a thin layer of alcohol should be placed on each side of the heel as well as on each membrane of the device. Proceed quickly to the measurement before the alcohol dries.

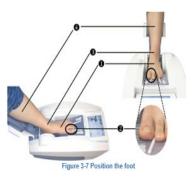
**Step 6: Position heel in footwell.** Place the foot into the footwell. Verify the heel is gently but firmly placed against the back of the footwell. Ideally, the heel should be centered between both membranes to ensure an accurate reading. Click continue on the data entry screen.



Position the athlete (side view)



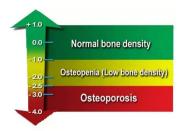
Position the athlete (top



Position the foot

**Interpret Results** Do not share results with as the athlete T-scores are explained at along with bone health counseling and referrals are addressed at Checkout. Interpretation of T-scores follows the World Health Organization definition,

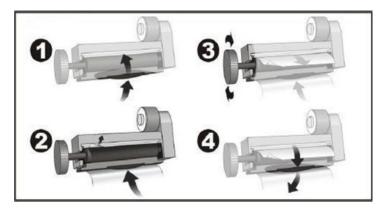
"Osteoporosis is present when BMD is 2.5 standard deviations (SD) or more below the average value for young healthy adult (a T-score of <-2.5 SD). A second, higher threshold describes "low bone mass" or osteopenia as a T-score that lies between -1 and -2.5 SD."



## How to Replace Printer Tape

It is not necessary to print results as T-scores for left and right heels are recorded on the athlete HAS form or entered into a tablet. There may be times when printing results is appropriate. Instructions to replace the thermal printer tape are printed inside the printer cover.





## **Steps to Replace Printer Tape**

- Grasp the top of the printer cover and pull it open
- Lift the Paper Release Lever (1 in Figure 4-12) and remove the empty paper roll.
- Put the new roll into device (②) with the lead edge of the paper at the top and facing toward you. The slick side of the paper should be up. The printer will not print if the paper is in backwards.
- Feed the paper into the print mechanism by turning the Paper Advance knob (③).
- Feed the paper through the slot in the printer cover.
- Lower the Paper Release Lever (④).

**Periodic Maintenance** The following preventive maintenance procedures are recommended to maintain proper operation and help prevent possible device service.

Maintenance	Frequency	Notes	
Clean and Disinfect System	For individuals: After each athlete For device: as per schedule	See procedure in this section of the manual	
Inspect Membrane for a leak, puckering or dirt	Daily	ee procedure in this section of the manual	
Clean under foot plate	At least daily or after about 50 athletes are screened	Alcohol, water and dirt collect under the foot plate and should be wiped out to prevent overflow into water reservoir	
Quality Assurance	Every 7 days and if machine is turned off	System will flag the requirement	
Drain and replace the distilled water	After screening for a full day, or after 100 tests	Alcohol or other debris can contaminate water and prevent QA from passing.	
Replace Pump Water	When advised by Alpha Source technician. (see page	The pump seldom if ever needs replacement if distilled water is used. However, if you get an error message to replace water pump, contact SOI. Instructions to replace the water pump are included in the replacement kit.	

## **Common Sources of Error when using the Achilles**

#### Equipment

Infrequent use of QA phantom

Equipment not properly maintained (not kept clean, water changed, membrane replaced inspected and replaced as needed)

Failure to use foot shim for athletes with a small foot size

#### Operator

Not properly trained and mentored

#### Individual

Athlete was moving or animated during the test Has thicker heel bones; not uncommon in big-boned people, particularly in men and weightlifters. Has edema of the feet

### Procedural

Improper alignment of the heel Lack of sufficient alcohol on either the sides of each heel or on the membranes Failure to test both heels Membranes are dirty, have a leak, a puckered area and need replacing. Water reservoir is not fully filled with water because device wasn't correctly elevated when filling. Ensure water is replaced as recommended to minimize potential mineral or alcohol contamination

**Troubleshooting** Problems may occur while operating the device that indicates improper action from user, the system status, or errors in the device. Here are some of the general problems and suggestions.

- The device needs to be within operating temperature and warm enough to pass QA Please ensure use within the operating temperature and allow a few minutes for the unit to warm up.
- The device must have proper water level to pass QA Fill the device by following the Add Water Procedure. This ensures the pump is fully retracted.
- **Poor coupling can cause QA failures.** ONLY use 70% isopropyl alcohol or ethanol. Spray both left and right sides of the QA cylinder twice. Spray both membranes twice. Do not allow the alcohol to dry before the QA process begins.
- Leaking or imbalanced (different size) membranes can cause QA failures. Leaking membranes lead to low water level which is the primary reason the QA test fails. Imbalanced membranes can cause poor coupling. Replace either leaking or imbalanced membranes.
- A damaged QA Cylinder can cause QA failures. Ensure that the thin film inside the QA cylinder is not torn or detached from the cylinder. Also check the QA Cylinder for cracks or sharp edges which can damage the membrane.
- A dirty transducer surface can cause QA failures. Remove the membrane rings and membranes. Spray the surface with isopropyl alcohol and wipe the transducer surface with microfiber cloth.

Troubleshooting Guide Based on Error Messages				
Error Msg	Possible Cause	What to Do		
More water needed	The water in reservoir is insufficient or the water is not clean.	Perform an Add Water procedure; empty and then refill the device.		
System requires Perform QA	QA is overdue. You must perform a QA at least once every seven days and the last QA must have passed.	Perform a QA procedure.		
Deflation fail	Screen says, "Air is in the pump".	Perform an Add Water procedure to empty and then refill the device.		
Signal too small	The measurement signal was too small to process. This could be caused by incorrect person preparation, positioning, air in the membranes, or the density of the person's heel. The device may need refilling.	Check athlete position. Release air from the membranes. Apply more alcohol to the heel and repeat measurement. Add water to device. If the error appears again, measure the other heel.		
Membrane is leaking	A membrane may have been punctured.	Replace the membranes. Make sure you use a lint- free towel or cloth and the alcohol spray to clean the membranes, not a rough material such as paper towel.		
Printed tape is blank	The paper roll may have been installed backwards.	Ensure that a paper roll is installed and that it is not in backwards. Make sure the slick side of the paper is up.		
Membranes do not inflate	The Membranes may be stuck to the transducer surfaces.	Reinstall the existing membranes. This may free the membranes from the transducer surfaces. You might also need to clean the transducers surfaces.		
Discrepancies between the T- scores of the right and left heel are higher than expected.	<ul> <li>Accurate measurements require that</li> <li>System is full of good quality Water.</li> <li>Ample alcohol is applied to both heels.</li> <li>Ample alcohol is applied to membranes.</li> <li>Good athlete positioning.</li> <li>Minimal athlete movement.</li> </ul>	Gait abnormalities are common. If a person favors one side of their body, the skeleton may be denser in that side of the body. This may be due to gait abnormalities, prior injuries, etc. Referral and treatment recommendations are based on the lowest of the two scores.		

# If Troubleshooting efforts do not fix a problem, contact the <u>Health Promotion discipline manager</u> for support. You may be referred to the GE technician for further assistance.

**Probo Medical** contracts with GE to provide technical support to Achilles users. Be prepared before calling, by taking a picture of the machine label with S/N and other pertinent numbers to facilitate help from the technicians. Have Achilles device serial number available before calling for technical assistance.

Probo Medical GE Achilles Contact	866-513-8322
Mary Pittaway, Regional Clinical Advisor	406-544-3969

Title and Format	Content	Where there are minor errors in script,	Image
	description	corrections are noted below.	
Achilles Operator Manual Included with device in shipping case. Linked here as well for easy printing	Complete instructions on use of Achilles EXPII	Manual recommends only one heel be tested.	
Bone Density Screening using Achilles - How To Set Up Machine 11 minutes YouTube	How to prepare the machine for use: add and drain water, inspect and replace membranes and replace printer paper	Does not show how to prop device with calf rest to ensure filling water reservoir completely.	
Bone Density Screening using Achilles - How To Perform A Screening 2 minutes YouTube	How to seat athlete, prepare heel and membranes with alcohol,	Athletes need to have both heels tested. Gait abnormalities, prior injuries, can cause lower T-scores in one side of the body and not there other. Treatment is based on lowest score. We recommend screener sits across rather than beside the athlete. Use tissue rather than paper towel to wipe heel.	
Bone Density Screening using Achilles - How To Describe Exam and Discuss Results 20 minutes YouTube	How the device measures BMD, what a T-score means, what lifestyle measures can help protect bone and how to share results with the doctor.	T-score is not related to gender. It predicts fracture risk regardless of gender. The lower the score (below zero) the higher the fracture risk. People with IDD generally have low vitamin D levels. We recommend athletes ask their doctor about having their D levels checked and then take the dose of supplemental D needed to maintain a blood level of 40-60 ng/ml.	
Osteoporosis Screening 4 minutes YouTube	Shows an example of a woman having a BMD exam on the Achilles.	Both heels and both membranes must be wet with alcohol before testing. The example shown is for Z- scores which compare the result with a person of like gender and age. We test for T- which predict fracture risk. A 55 year old would also need estrogen or testosterone replacement or medication, plus adequate calcium intake, healthy vitamin D levels of 40-60 ng/mL and exercise to improve their BMD. Most adults need 5000 IU per day.	