Blue Bay Research, Inc.
Pensacola, Florida USA, November 2019

Ankle Arthrometer (AA)

Instructions for Use

Ankle Arthrometry

The Blue Bay Ankle Arthrometer has been designed to quantify ankle anterior-posterior and inversion-eversion motion under various conditions. The Blue Bay Ankle Arthrometer measures the movement of the foot relative to a reference on the tibia.

The BB AA includes an updated touchscreen electronic interface for researching Ankle Laxity and specifically Cruciate Ligament Deficiency and Repair.

The BBAA consists of a foot plate that is attached to the foot and a tibial pad that is attached to the distal tibia. Connecting these two is a six degree of freedom spatial kinematic likage which measures the relative motion between the two. A loading handle is attached to the anterior of the foot plate and measures the amount of anterior-posterior load and inversion-eversion moment applied to the foot plate. Only load applied through the handle is accurately measured; therefore, holding or touching the foot plate can cause errors in the load reading. The system is connected to a computer whose software calculates the displacement of the foot plate relative to the tibial pad and displays the load and motion data as well as writes data to an SD card, if so desired. The device is powered from the internal rechargeable batteries. A leg strap and a calf support are provided to fix the limb being evaluated.

An exam table must be used which has a support between the table legs that will allow the strap to be secured to provide downwards traction on the limb being tested. Unless the examiner is tall or the exam table short, a stool can be helpful in placing the load handle in a more ergonomic position for the anterior drawer test.

NOTE: The patient's ankle should never be loaded to an extent that causes discomfort. The clamping of the device on the foot may cause some discomfort due to the variety of foot shapes; however, the loading itself should not be performed up to a load that may cause discomfort.

Do not store the Ankle Arthrometer at a temperature > 120°F

Warranty : The Blue Bay Ankle Arthrometer is warranted for 2 years including calibration and lithium batteries. Free return shipping is covered for any warranty work.

Adjusting the Time

The time will display for 1 second. If needed, the time can be adjusted by touching the screen once. "Set Time" will appear on the menu along with AP and IE load calibration. If "Set Time" is selected, HH and MM will display above a + and - sign to allow adjustment of the time forwards and backwards. YYYY MM and DD will display above + and - to adjust the year, month and day forward or backwards. Make sure date and time are correct.

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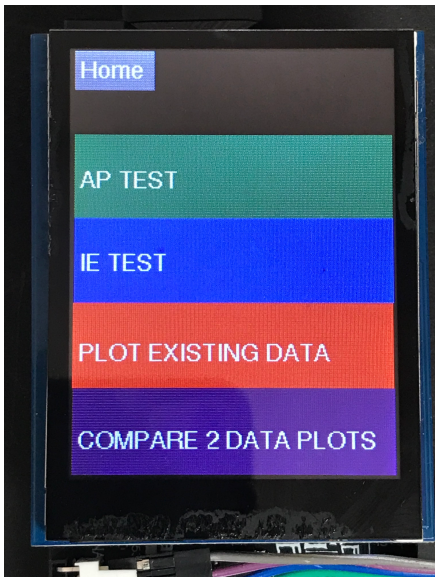
Using the BB Ankle Arthrometer



← Anterior-Posterior Test

← Inversion-Eversion Test

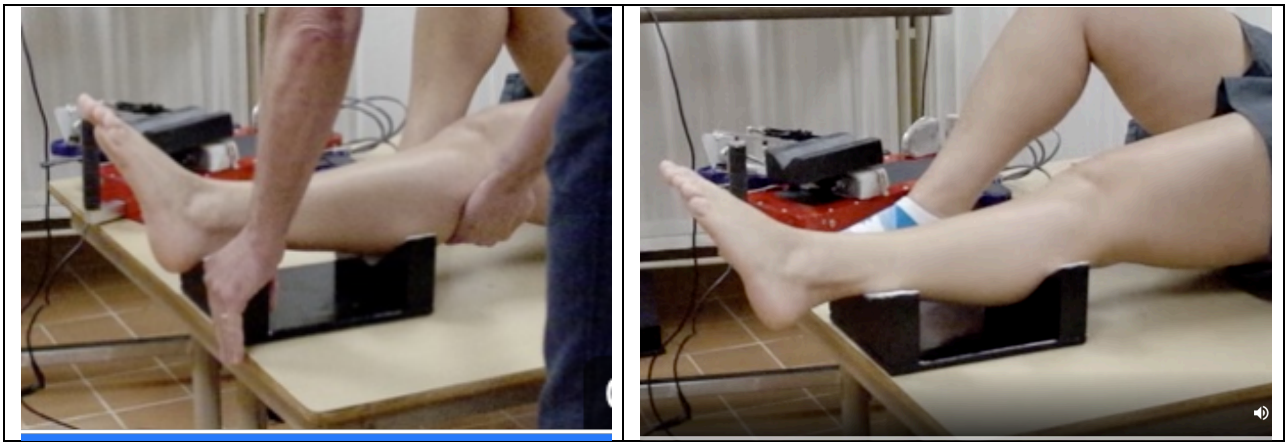
← Plot data saved to the SD Card.

← Displays two data sets for comparison purposes

Testing Procedure using the Ankle Arthrometer:

1. Lay the patient supine (face upward) on an exam table so that the patient's ankle joint is 2-3 inches off the edge of the table.

2. Place the calf support under the patient's calf. The distal end of the calf support should be near the end of the table.



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3. Strap the distal tibia to the table (crossbar) with the Velcro straps provided. The straps should pass downwards from the tibia (top of angle) and secured to the table structure under the limb. The straps should be tightened sufficiently to minimize tibial lifting during anterior foot loading. If the table allows, strapping the knee area can prevent knee flexion during posterior foot loading.

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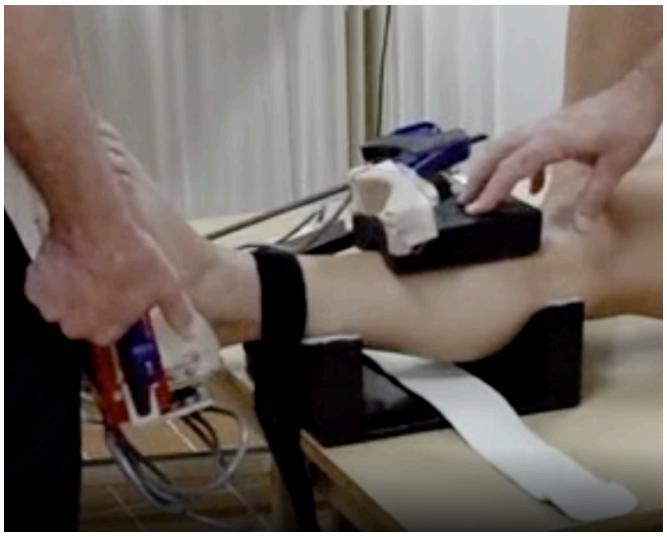
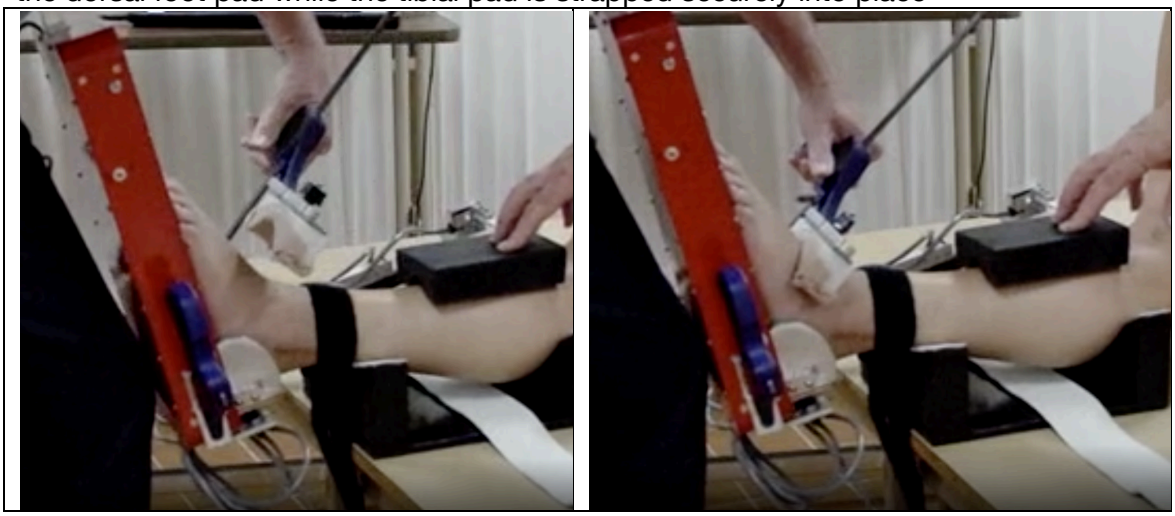
4. The foot plate is secured to the foot through medial and lateral heel pads that are tightened together and a dorsal foot pad that is tightened against the foot forcing it onto the foot plate and against the posterior heel pad.

5. The AA is mounted on the limb by first holding the assembly near the foot and setting the tibial pad on the tibia. Have one person hold the tibial pad on the tibia while the other person positions the foot plate onto the foot and secures the heel pad. ***If the examiner does not have help, the examiner should hole the ankle arthrometer box on his/her knee while adjusting/tightening the heel clamp, dorsal clamp and tibia pad.***



6. The dorsal foot pad is then lifted up and the foot plate placed into position on the foot. Clamp the dorsal foot pad down onto the foot. The foot can be tightly clamped onto the dorsal foot pad while the tibial pad is strapped securely into place



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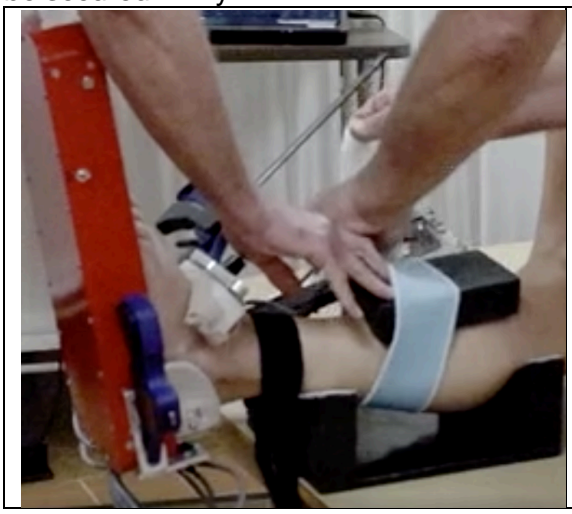
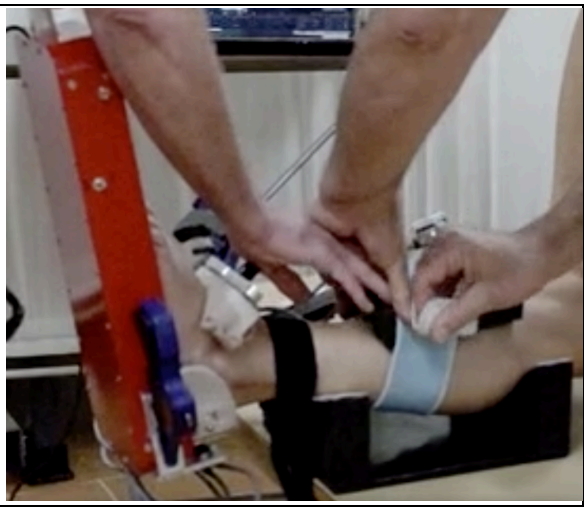
7. Strap the tibia pad onto the tibia. Once the tibial pad is secure, the dorsal foot pad can be secured firmly.

8. The examiner should place their knee against the bottom of the dorsal foot pad while pulling up on the load handle with 50-100 N force. The examiner should tighten the dorsal foot pad, then the heel pads and repeat until the device is secure.

9. The dorsal foot pad can be rotated and translated for a better fit, if necessary.

10. The examiner should check in with the patient to ensure the patient is comfortable. There is likely an effect of tightness on soft tissue compliance, slippage and active motion guarding so the fitting of the dorsal foot pad is an important factor in data reproducibility.

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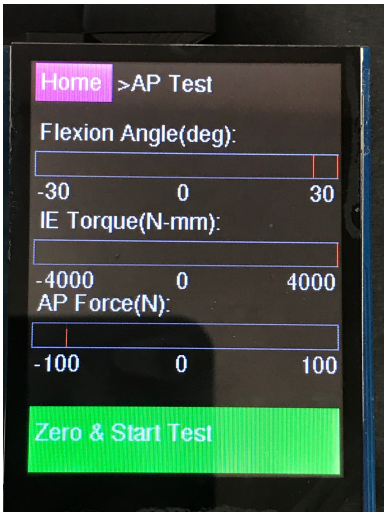
11. Once the AA is secure on the limb and the patient is comfortable, testing should begin. The foot plate will be positioned at the desired flexion (often 0.0 degrees flexion) and held there throughout testing.

Anterior-Posterior Test (A-P)



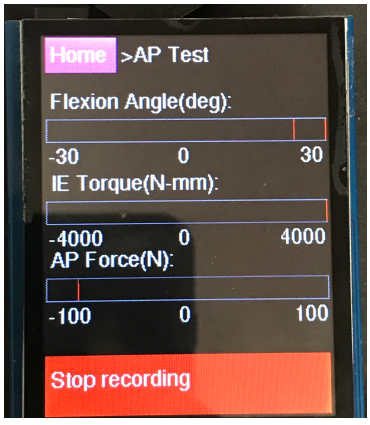
12. Touch the AP Test on the Touch Screen.

13. Watch the Flexion Angle on the Touch Screen and set the Foot Plate to the desired angle on the screen. Maintain this flexion throughout the test.

14. Lift up on the load handle until the A-P Force Reads Zero.

15. Touch **Zero & Start Test** on the Touch Screen.

16. Apply a 100-125 N load to the patient's foot posteriorly and then apply a 100-125 N load anteriorly. The load should be applied smoothly. The patient should be asked to report if the posterior heel loses contact with or slips on the posterior heel pad.



17. After the loading cycle is complete, touch "**Stop recording**" on the touch screen.

18. If the examiner is happy with the A-P test, "**Save**" will be touched on the screen. Then "Save as left" (leg) or "Save as right" (leg) will be touched. Load and displacement data and a curve will be saved to the SD Card and can be retrieved at any time.

19. If the examiner is not happy with the test, "**Don't Save**" will be touched.

20. The system calculates the translation of a point approximating the center of rotation of the ankle joint. Since this varies with the patient, this point is not accurately known for any individual patient. The result of this is that, if the foot is allowed to change flexion angle during the test, the A-P laxity will have an error due to the changing flexion angle. In addition, ankle laxity is known to vary with flexion angle such that testing at an inconsistent flexion angle will produce inconsistent laxity results. The flexion angle must be monitored closely during A-P loading. If the flexion angle is allowed to vary excessively, the test must be repeated. Similarly, rotation around the long axis of the tibia will also result in error. Therefore, the foot must be loaded in a pure anterior-posterior direction.

Inversion-Eversion Test (I-E)

21. The Inversion-Eversion test is performed similarly to the A-P test.

22. It is important for the examiner to relax the patient and remind the patient not to guard against rotation.

23. The patient should be asked to report to the examiner if there is slippage at the pads or if comfort is not sufficient to complete the test or eliminate guarding.

24. In general, the examiner should monitor the indication of A-P force, I-E moment, and flexion angle simultaneously during the entire test.

25. Moderate loading speed and practice will increase the chances of reproducible testing.

26. Touch the IE Test on the Touch Screen.

27. Watch the Flexion Angle on the Touch Screen and set the Foot Plate to the desired angle on the screen. Maintain this flexion throughout the test.

28. Rotate the load handle until the I-E Force Reads Zero.

29. Touch Zero & Start Test on the Touch Screen.

30. Apply a 100-125 N load to the patient's foot inward (inversion) and then apply a 100-125 N load outward (eversion). The load should be applied smoothly.

31. After the loading cycle is complete, touch "Stop recording" on the touch screen.

32. If the examiner is happy with the I-E test, "Save" will be touched on the screen. Then "Save as left" (leg) or "Save as right" (leg) will be touched. Load and displacement data and a curve will be saved to the SD Card and can be retrieved at any time.

33. If the examiner is not happy with the test, "Don't Save" will be touched.

Comparing Curves and Data for Left and Right Ankle

34. If the examiner wishes to compare two previous curves that have been saved on the SD card, the user will touch Plot SD Card Data on the main menu. For example, the data for the patient's right and left leg can be compared.

35. The examiner will select one or two curves, by touching the desired file, one file at a time. If only one curve is desired, select the same curve twice.

36. The two curves will then display on the screen for comparison purposes.

Device power:

The on/off **switch** is located on the side of the AA box. Turn the AA on by pressing (pushing in) the switch and turn it off by pressing the switch again.

Charging the Ankle Arthrometer

Recharge the Arthrometer's lithium batteries by plugging a standard micro USB charging cable (supplied) into the distal end of the AA device. The cable is plugged into a USB-type phone charger adapter (not included). A yellow light behind the charger means that the AA is still charging. The yellow light changes to green when the AA is fully charged. It is acceptable to leave the AA plugged in after it is finished charging. The AA will stay charged for about 12 hours if running continuously.

SD Card:

One SD card is included. The text (.txt) files that are saved include date, time, load and displacement data. The files can be opened in a text reader, MS Word, MS Excel, etc. The file name on the SD card will be named with the day of the year and the time. For example, on March 20 2019, at 10:40:29, the filename will read **07910402** (meaning the 79th day of the year at 10:40 and 29 seconds). The filename changes at 10-second intervals. NOTE: In order for the dates to display in reverse chronological order, replace the SD Card with a new one at the beginning of each new year.

NOTE: It may be helpful to record the time of the patient test to keep track of corresponding patient data.

Once the text file has been opened, it will display the year (2018), the date (1016) and the time (10:40:29) at the top. For example: **20181016104029**. The continuous reading of load (pounds) and displacement (mm) will be recorded in the text file as well.