Mobil-Aider™
Joint Mobility Measurement Device

Ankle Kit User Guide

MA-CL-4003-A
Version 1.1
US Patent # 11,123,007
FDA Cleared as Class 1 Exempt

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The Mobil-Aider™ – innovative orthopedic technology

Indications for Use

The Mobil-Aider™ is an orthopedic device used to **measure the linear translation** of two joint surfaces. It enables the clinician to quantify (in millimeters) the linear translation.

Introduction

At this time, the only method of obtaining joint mobility feedback is subjective. The clinician relies on the "feeling" of the joint motion, the "sense" of tissue tension, and the "quality" of the resistance to motion.[1,2]

There are approximately 2 million ankle sprains in the USA annually. Ankle injuries are often downplayed as being minor annoyances, but the reality is over 70% result in re-injury. There is a 3.5 times greater risk of sustaining another ankle sprain once an initial injury occurs. Ankle stability is clinically assessed with an anterior drawer test. This test is known as the Lachman of the Ankle (**Figure 1**).[3-9] Whether the test results are interpreted as dichotomous (positive = torn; negative = intact) or graded (Grade I, II, II), there is a subjective element to the data. Asymmetry or a soft endpoint is considered abnormal. This is challenging to quantify, even for the most experienced clinician. [10-11]

Figure 1. Anterior Drawer

The Mobil-Aider™ can help to mitigate this problem. The Mobil-Aider™ is a simple, portable (weighs less than 13 ounces), and economical device to interface between the hands of the clinician and the joint of the patient to measure the linear displacement of the ankle. The Mobil-Aider™ device will help the practitioner stay in the proper plane of motion parallel to the joint surface (avoiding angular or sheer motions), position the joint in the optimal range, and quantify the amount of linear translation (in millimeters).

Figure 2. Mobil-Aider Ankle Kit

The concurrent validity and reliability of the Mobil-Aider™ has been successfully tested in the laboratory. Bench testing revealed very high reliability (Cronbach alpha = 0.992 - 0.997) as well as concurrent validity (ICC & Pearson correlations = 0.986 - 0.998).

Figure 3. Identification of Mobil-Aider™ Attachments

The Ankle Mobil-Aider Kit includes one (1) of each of the following components.

Base Unit: H-A Screen H-1 Non-Screen side			**H-C Yellow**
H-E Green		**H-3 Black**	

Table 1. Mobil-Aider™ Attachments for Clinical Use

Attachment Identification	Attachment Use	Technique
H-3	Standard mobilization component	All ankle mobilizations/tests
H-C	Ankle anterior glide (prone)	Anterior drawer/mobilization
H-E	Ankle medial/lateral glide	Ankle mobilization

Table 2 and 3 provide the Absolute Contraindications and Relative Precautions, respectively, for joint mobilizations.

Table 2. Absolute Contraindications

• Cancer in treatment area	• Joint swelling
• Spinal cord injury	• Joint arthritis
• Acute inflammation	• Nerve injury
• Fracture in treatment area	• Surgery in the treatment area
• Stroke or heart problems	• Blood clotting disorder
• Joint laxity	• Circulation problems

Table 3. Relative Precautions

• Suspected cancer in treatment area	• Skin rash/wound in treatment area
• Joint replacements	• Connective tissue disorder
• Pregnancy	• Bone disease
• Blood clotting therapy	• Long-term use of corticosteroids

Mobil-Aider™ Instructions

Overview

The Mobil-Aider™ is designed to be used for a variety of manual techniques. Through the interlocking dove-tail design, the attachments can be interchanged to accommodate numerous joint contours. Each of the colorful attachments is identified with a letter embossed on it. The table below provides a recommended attachment for the corresponding joint mobilization technique.

However, since every individual has a unique shape, the clinician may find another attachment to be a better "contour" for some individuals. Regardless of the attachment selected, H-B and H-C will only match the dovetail on the "screen side" (**Figure 4**) and H-2 and H-3 will only match the dovetail on the "non-screen side"(**Figure 5**).

Figure 4. Screen side

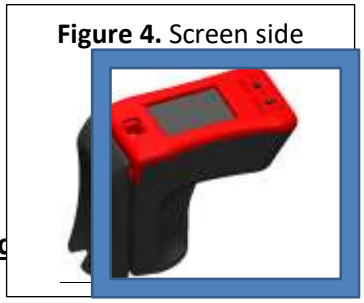
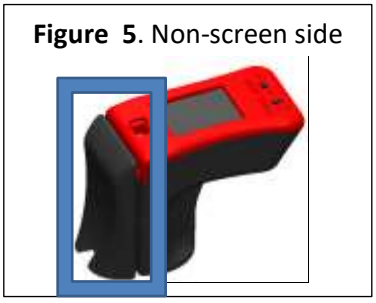


Figure 5. Non-screen side



General instruc

Key points:

1. Individuals using the Mobil-Aider™ should be properly trained in manual techniques prior to use.
2. It is recommended to assess the uninvolved joint first to obtain a baseline value and allow the patient to be comfortable with the technique(s).

Technique:

1. Select the appropriate components for the technique.
2. Slide each component into the appropriate slot until the spring plunger snaps into place. Failure to engage a component completely into the slot can pinch the patient's skin with use.
3. Position the patient and explain the technique.
4. Power the Mobil-Aider™ device on by moving the switch to the **ON** position.
5. The fuel gauge (image of a battery) will indicate the status of the battery (in %)
6. Select the **"A" or "B" mode** by moving the mode switch to "A" or "B"
    a. **A Mode** = holds the maximal reading on the screen for 3 seconds prior to resetting to zero; recommended for joint testing and initial joint measurements of mobility.
    b. **B Mode** = real-time readings allow the clinician to see a reading on the display for the position of the joint at any point in time; recommended for joint mobilizations.
7. Align the axis (space between the screen-side and non-screen-side) of the Mobil-Aider™ with the joint line.
8. Stabilize the proximal component of the Mobil-Aider™ against the patient with one hand of the clinician.
9. Secure the distal component of the Mobil-Aider™ against the patient with the clinician's other hand.
10. Good contact between the device/patient will enhance the comfort of the technique and reduce likelihood of error.
11. Assure the patient is relaxed.
12. Translate the distal segment anterior on the stabilized proximal segment.
13. View the screen for the value of the translation (displayed in millimeters of motion).
14. The clinician may also be able to appreciate the qualitative aspect of the technique, i.e. the endfeel.
15. If the technique is to be repeated, simply relax the grip on the device to allow the device to return to the zero position (screen should read "0"). If in the A mode this will occur is 3 seconds. If in the B mode it will occur instantaneously.

Key to graphics:

X = point of stabilization

 = direction of applied force

Specific Instructions for Ankle Techniques

It is recommended to perform all techniques on the uninvolved ankle first to obtain a baseline value and allow the patient to understand the technique.

T

alocrural Anterior Glide (Figure 6)

Figure 6. Anterior Drawer

Purpose: To measure talocalcaneal anterior translation and/or improve plantarflexion

Components: Yellow (H-C) attached on screen and Black (H-2) attached on non-screen side.

Position: Patient is positioned in prone. The contour of the device will put the patient slight plantarflexion.

Stabilization: Clinician palpates the talocrural joint line and aligns the axis of the Mobil-Aider with the joint line. The device is stabilized proximally on the distal tibia.

Mobilization: The moveable component of the device is placed in contact with the talus/calcaneus. An anterior force is applied.

Talocrural Posterior Glide (Figure 7)

Figure 7. Posterior Glide

Purpose: To measure talocalcaneal anterior translation and/or improve dorsiflexion

Components: Green (H-E) attached on screen and Black (H-2) attached on non-screen side.

Position: Patient is positioned in supine. The contour of the device will put the patient slight plantarflexion.

Stabilization: Clinician palpates the talocrural joint line and aligns the axis of the Mobil-Aider with the joint line. The device is stabilized proximally on the distal tibia.

Mobilization: The moveable component of the device is placed in contact with the talus/calcaneus. A posterior force is applied.

Subtalar Medial Glide (Figure 8)

Figure 8. Subtalar Medial Glide

Purpose: To measure medial translation and/or improve eversion

Components: Green (H-E) attached on screen side to stabilize and Black (H-2) attached on non-screen/moving side

Position: Patient is positioned in sidelying.

Stabilization: Clinician aligns the axis of the Mobil-Aider with the joint line. The device is stabilized proximally on the tibial tibia/fibula.

Mobilization: The moveable component of the device is placed in contact with calcaneus and a medial force is applied.

References:

1. Chang J, Chang Chien C, Chang G, Chung K, Has A. Adaptability of learning on joint mobilization skill with augmented feedback by using a joint translation simulator. Physiotherapy. 2007;93(s1):S75.
2. Gorgos KS, Wasylyk NT, Van Lunen BL, Hoch MC. Inter-clinician and intra-clinician reliability of force application during joint mobilization: a systematic review. Manual therapy. 2014;19(2):90-6. doi:10.1016/j.math.2013.12.003. PubMed PMID: 24405786.
3. Gulick DT, iOrtho+ mobile app, iOS, Android, and web versions, 2021.

4. Gulick DT. Ortho Notes: A Rehabilitation Specialist's Pocket Guide. Philadelphia, PA: Davis Publishing; 2018.
5. Frost HM, Hanson CA: Technique for testing the drawer sign in the ankle, Clinical Orthopedics 1977;123:49-51
6. Kjaersgaard-Andersen P, Frich LH, Madsen F et al: Instability of the hindfoot after lesion of the lateral ankle ligaments: investigations of the anterior drawer and adduction maneuvers in autopsy specimens, Clinical Orthopedics 1991;266:170-179
7. Kovaleski JE, Norrell PM, Heitman RJ, Hollis JM, Pearsall AW. Knee and ankle position, anterior drawer laxity, and stiffness of ankle complex. Journal of Athletic Training. 2008 May-June;43(3):242-248
8. Dutton M, Orthopaedic Examination, Evaluation, & Intervention: A Pocket Handbook. NY: McGraw-Hill, 2005
9. Martin RL, Davenport TE, Paulseth S, Wukich DK, Godges JJ. Ankle Stability and Movement Coordination Impairments: Ankle Ligament Sprains. JOSPT. 2013;43(9):1-40.
10. Tohyama H, Yasuda K, Ohkoshi Y et al: Anterior drawer test for acute anterior talofibular ligament injuries of the ankle: how much load should be applied during the test? American Journal Sports Medicine 2003;31:226-232
11. Phisitkul P, Chaichankul C, Sripongsai R, Prasitdamrong I, Tengtrakulcharoen P, Suarchawaratana S. Accuracy of anterolateral drawer test in lateral ankle instability: A cadaveric study. Foot & Ankle International. 2009;30(7):690-695

Figure 9. Docking Station with Charging Port

Charging Port (Figure 9)

The Mobil-Aider™ ankle kit comes with a charging port. The Mobil-Aider™ device is rechargeable. When first obtaining the device, please charge completely via the charging port

- To charge the Mobil-Aider™, all attachments must be removed.
- Slide the device screen-side first onto the charging/docking station
- Plug the android end of the recharging cord into the back of the charging port
- Attach the USB end into the AC adapter
- Plug the AC adapter into the wall outlet
- The red light pipe under the device will indicate it is charging
- The fuel gauge will indicate the status of the battery
- Duration of the charge will be influenced by usage

Possible Error Sources

1. Failure to align the axis of the device with the joint axis will influence the quantity of motion
2. Failure to achieve muscle relaxation could decrease translation
3. Failure to keep the device tight against the patient's skin may result in an erroneous reading (interface error)

General Maintenance

Cleaning: The Mobil-Aider may be cleaned with anti-microbial wipes. After wiping off the device, allow the surface to air-dry. Liquids of any kind should never be applied to the device. It should never be submerged in any liquid at any time.

Calibration Check (optional component)

Figure 9. Calibration Block

- The device is calibrated prior to shipping.
- An optional calibration block is available for purchase (**figure 9).** This calibration block will allow the owner to periodically assess the consistency of the Mobil-Aider™. To use the calibration block:
  - First remove all attachments from the base device
  - Slide screen-side of the device onto the dovetail of the challenge block in the direction of the arrow.
  - Place the calibration pin in the 2, 5, 10, or 14 slot.
  - With the power "on" and the device in the "A" mode, translate the non-screen side of the device down to the challenge block pin & hold for 2 seconds for a reading to be displayed.
  - The screen value should be within 5% of the selected pin, i.e. 2 mm pin = 2.0 ± 0.2 or from 1.8 – 2.2 mm
  - Testing can be repeated in the "B" mode. Translate the non-screen side of the device down to the challenge block pin & hold for 2 seconds for a reading to be displayed.
  - If the value is not within this range, the device should be returned for calibration.
  - Package the device with sufficient padding and enclose the completed "Repair Form."
- If a calibration block is not purchased, there is always the option to complete a "Repair Form" to be return the device for calibration. Please call first for pricing.

Trouble-shooting

If any electrical component fails, the mechanical aspects of the device will still work but the screen will simply not display a read -out. This does not pose any risk to the user or the patient.

Table 4

Problem	Potential Concern	Action
User tries to put the attachment into the device incorrectly	Dovetail components will not permit the attachments to be inserted into the wrong side, i.e. large dovetail will not fit & small dovetail will fall out	Dovetail connection will only allow the components to attach as designed
User does not slide the attachment completely into the dovetail connection	Patient could have a skin pinch	User needs to push the attachment into the dovetail slot until the spring plunger engages
Spring plunger fails	Attachment will fail to lock into place; user should not use the device	Inspect integrity of spring plunger; user can return for repair or replacement
Uneven finish/burrs on the device	May scratch the skin	Return device for repair or replacement
No reading on the screen	Unit is not powered “on” or device is not charged	Turn device “on” and/or recharge device
Battery not charging	Battery, charging port, or charging wire failure	Try a different charging wire; Return device for repair or replacement
Crack in the screen	Read-out is not present or unable to be read	Return device for repair or replacement
Incorrect reading with challenge block	Inaccurate measure	Return device for recalibration
Device is dropped and/or there is a rattling noise inside device	Inaccurate measure	Assess with challenge device

Limited Warranty

Mobil-Aider™ is designed to perform in accordance with specifications provided by Therapeutic Articulations, LLC. The purchaser should consult the specifications prior to use.

The Mobil-Aider™ is warranted by Therapeutic Articulations, LLC to the original purchaser for a period of one (1) year from the date of purchase. The Mobil-Aider™ is warranted to be free from defects in materials and workmanship. The purchaser should contact Therapeutic Articulations, LLC by mail or email as follows to obtain a return authorization number:

Therapeutic Articulations, LLC
64 Bethel Church Road, Spring City, PA 19475 USA
dawn@mobil-aider.com
610.570.7153

Upon receipt of the Mobil-Aider™, Therapeutic Articulations, LLC will examine the device. If Therapeutic Articulations, LLC finds the device to be defective as a result of materials and/or workmanship, repairs or replacement of the device will be at the expense of Therapeutic Articulations, LLC.

Please note, misuse, abuse, or unauthorized repairs/alternations of the device will void this warranty. Therapeutic Articulations, LLC will not be liable for commitments or agreements made by any of its employees, agents, or dealers not in compliance with the above stated warranty.

Therapeutic Articulations, LLC reserves the right to design or modify the device without incurring any liability whatsoever to any prior purchaser.

QUALITY MANAGEMENT SYSTEMS FORM

Return Authorization

Request for Return of Therapeutic Articulations Product

Requestor (Section 1)

NAME	
ADDRESS	
CITY	STATE
COUNTRY	ZIPCODE
PHONE	
SHIPPED VIA	SHIPPER TRACKING NO.
EXPECTED DATE OF PICKUP	EXPECTED DATE OF DELIVERY

Reason for request

- ☐ Malfunction Feedback Report # _____
- ☐ Ordered Wrong Part
- ☐ Other_____
- ☐ Provide Shipping Container For Returned Product

COMMENTS

Therapeutic Articulations Part Number	Returned Product Description	Serial / Lot Number	Replacement Needed
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No

RETURN REQUESTED BY	DATE	RA# ISSUED BY	DATE

Route to Receiving when Complete

Contract Manufacturer/Receiving (Section 2)

NAME & ADDRESS RECEIVED FROM (*IF DIFFERENT THAN ABOVE)*

RECEIVED BY	DATE

☐ Packing Slip Verified

Route to Therapeutic Articulations QA/RA when Complete