Mobil-Aider™
Joint Mobility Measurement Device

Knee Kit User Guide

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Version 1.8
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 the tibia on the femur. It enables the clinician to quantify (in millimeters) the linear translation typically tethered by the anterior cruciate ligament (ACL).

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 (2,3).

With over 200,000 ACL injuries per year in the USA, the Mobil-Aider™ will provide valuable information about the dynamic status of the joint. The ACL is assessed via 3 widely accepted clinical tests: anterior drawer, Lachman, and pivot-shift (1, 4, 6-14). A meta-analysis of 17 studies reported these three tests have a wide range of diagnostic accuracy (12). Individual modifications of the tests and examiner experience have been reported to influence test accuracy (8). Nonetheless, the Lachman test is considered the gold standard (**Figure 1**). 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 (8). Asymmetry or a soft endpoint is considered abnormal. This is challenging to quantify, even for the most experienced clinician. In fact, it has been reported the misdiagnosis of ACL injuries by emergency room physicians was 74% (5).

Figure 1. Lachman Testing

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 knee. 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 knee in the optimal range (~20 degrees of flexion), and quantify the amount of linear translation (in millimeters).

Figure 2. Mobil-Aider Knee 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 Knee Mobil-Aider Kit includes one (1) of each of the following components. The H-C attachment is optional.

Base Unit: H-A Screen H-1 Non-Screen side			**H-B (Strap) Red**
H-2 (strap) Knee Proximal Black			**H-C Yellow (optional)**
H-3 Thumb-hold Black (optional)			

Table 1. Mobil-Aider™ Attachments for Clinical Use

Attachment Identification	Attachment Use	Technique
H-2	Knee mobilization component	Classic Lachman
H-3	Standard mobilization component	Prone Lachman
H-B	Knee anterior glide (supine)	Classic Lachman
H-C	Knee anterior glide (prone)	Prone Lachman

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 instructions for device use

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 Knee Techniques

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

Tibiofemoral Anterior Glide (Lachman Test – Figure 6)

Purpose: To measure tibial anterior translation
Components: Red (H-B) attached on screen/moving side and Black (H-2) attached on non-screen side.
Position: Patient is positioned in supine. The contour of the device will put the patient in ~20° of knee flexion. Ensure the hamstring muscles are relaxed by palpating the tension in the tendons.
Stabilization: Clinician palpates the tibiofemoral joint line and aligns the axis of the Mobil-Aider with the joint line. The device is stabilized proximally on the anterior femur with the corresponding strap and tightened as much as comfortably possible.
Mobilization: The moveable component of the device is placed in contact with the anterior tibia. It is secured with the corresponding strap and tightened as much as comfortably possible. An anterior force is applied to the tibia.

Figure 6. Classic Lachman

Tibiofemoral Anterior Glide (Prone Lachman - Figure 7) - optional attachment

Purpose: To measure tibial anterior translation
Components: Yellow (H-C) attached on screen side to stabilize and Black (H-2) attached on non-screen/moving side
Position: Patient is positioned in prone. The contour of the device will put the patient in ~20° of knee flexion.
Stabilization: Clinician aligns the axis of the Mobil-Aider with the knee joint line. The device is stabilized proximally on the posterior femur.
Mobilization: The moveable component of the device is placed in contact with the posterior tibia. An anterior force is applied to the posterior tibia.

Figure 7. Prone Lachman

References:

1. Benjaminse A, Gokeler A, van der Schans CP. Clinical diagnosis of an anterior cruciate ligament rupture: A meta-analysis. Journal Orthopedics Sports Physical Therapy. 2006;36(5):267-288.
2. 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.

3. 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.
4. Galway RD, Beaupre A, MacIntosh DL. Pivot shift: a clinical sign of symptomatic anterior cruciate insufficiency. Journal of Bone & Joint Surgery. 1976;54B(4):763-764.
5. Guillodo Y, Rannou N, Dubrana F, Lefevre C, Saraux A. Diagnosis of anterior cruciate ligament rupture in an emergency department. Journal of Trauma. 2008;65(5):1078-1082.
6. Gulick DT, iOrtho+ mobile app, iOS, Android, and web versions, 2018.
7. Gulick DT. Ortho Notes: A Rehabilitation Specialist's Pocket Guide. Philadelphia, PA: Davis Publishing; 2018.
8. Jarbo KA, Hartigan DE, Scott KL, Patel KA, Chhabra A. Accuracy of the Lever sign test in the diagnosis of anterior cruciate ligament injuries. Orthopaedic Journal of Sports Medicine. 2017;5(10):1-7.
9. Maitland GD. Peripheral manipulation. 3rd ed. London; Boston: Butterworth-Heinemann; 1991: pp, 322.
10. Marshall JL, Wang JB, Furman W, Girgis FG, Warren R. The anterior drawer sign: what is it? Journal of Sports Medicine. 1975;3(4):152-158.
11. Mitsou A, Vallianatos P. Clinical diagnosis of ruptures of the anterior cruciate ligament: a comparison between the Lachman test & the anterior drawer test. Injury. 1988;19(6):427-428.
12. Scholten RJ, Opstelten W, van der Plas CG, Bijl D, Deville WL, Bouter LM. Accuracy of physical diagnostic tests for assessing ruptures of the anterior cruciate ligament: a meta-analysis. Journal of Family Practice. 2003;52(9):689-694.
13. Tonino AJ, Huy J, Schaafsma J. The diagnostic accuracy of knee testing in the acutely injured knee. ACTA Orthopedia. 1986;52(4):479-487.
14. Torg JS, Conrad W, Kalen V. Clinical diagnosis of anterior cruciate ligament instability in the athlete. American Journal of Sports Medicine. 1976;4(2):84-93.

Charging Port (Figure 8)

The Mobil-Aider™ knee 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 fuel gauge will indicate the status of the battery
- Duration of the charge will be influenced by usage

Figure 8. Docking Station with Charging Port

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

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