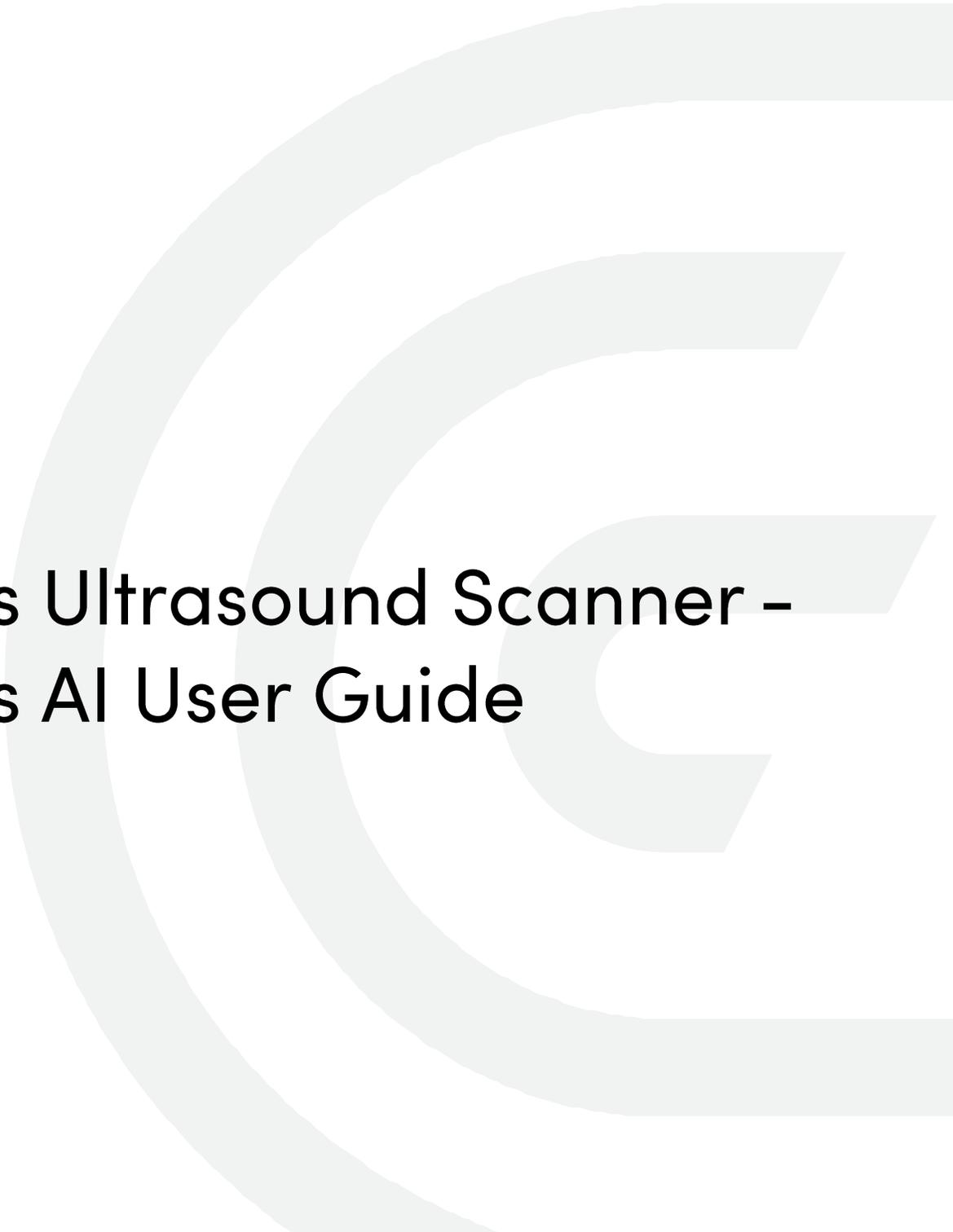




Clarius Ultrasound Scanner - Clarius AI User Guide



Disclaimer:

This disclaimer extends to all printed matter accompanying the Clarius Ultrasound Scanner.

This manual is licensed under the Terms and Conditions available at www.clarius.com/terms. You may not use this manual except in compliance with the license. The information contained in these materials is proprietary and confidential to Clarius Mobile Health Corp. ("Clarius") and is provided for the sole use of the individual or entity to whom it is addressed and therefore these materials must be kept in the strictest confidence. No portion of this manual may be copied, reproduced, republished, modified, sold, disclosed, or distributed without the prior written permission of Clarius. Unauthorized copying or distribution of this manual, in addition to infringing copyright, may reduce the ability of Clarius to provide updates and current information to users.

Clarius has taken care to ensure the accuracy of this document, however, revisions may not be possible in all situations. Information in this document may be subject to change without notice, and Clarius assumes no liability for errors or omissions. Clarius reserves the right to make changes without further notice to any products herein to improve reliability, function, or design. Clarius may make improvements or changes in the products or programs described in this document at any time.

These materials may contain third-party copyright and/or trademark materials, the use of which has not always been specifically authorized by the intellectual property owner. All copyrights and/or trademarks contained in these materials are the sole and exclusive property of their respective owners.

"Clarius", "Ultrasound Anywhere," "Point-and-Shoot Ultrasound", "Act One", "Tri-Scanner", "My New Stethoscope", "It's About the Image," the Clarius logo, and the Clarius Live logo are trademarks or registered trademarks and are the sole and exclusive property of Clarius.

Listing of applicable U.S. Patents in compliance with 35 U.S.C. s. 287: www.clarius.com/patents.

All names used in Clarius (whether online, in print, or any other media) are fictitious and are used herein for the purposes of example and demonstration on how to use the Clarius Ultrasound Scanner. Any similarity to real people is a coincidence.

© 2023 Clarius Mobile Health Corp.

All rights are reserved. Reproduction or transmission in whole or in part, in any form or by any means, electronic, mechanical or otherwise, is prohibited without the prior written consent of the copyright owner.

Published in Canada.
15-03-00171

Table of Contents

About this User Guide	1
Chapter 1: About Clarius AI	2
Indications for Use.....	2
Note to User – Scanners and Pre-sets for MSK	2
Note to User – Imaging Artifacts, Performance, and Limitations	2
Revision History	10

About this User Guide

The Clarius AI User Guide is supplemental and intended for use in conjunction with the Clarius Ultrasound Scanner User Manual in United States only.

Clarius AI is not for interventional purposes. Calipers placed by Clarius AI can be adjusted manually by the user. All measurements should be verified by the user.

About Clarius AI



Indications for Use

Clarius AI is intended to semi-automatically place calipers for non-invasive measurements of musculoskeletal structures (e.g., Achilles' tendon, plantar fascia, patellar tendon) on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., L7 and L15). The user shall be a healthcare professional trained and qualified in MSK (musculoskeletal) ultrasound. The user shall retain the ultimate responsibility of ascertaining the measurements based on standard practices and clinical judgment.

Note to User – Scanners and Pre-sets for MSK

Clarius AI for MSK (musculoskeletal) applications only works on the Clarius L7 and L15 scanners and in the following presets: Foot/Ankle, Knee, and Plantar. Ensure to select any of these presets to use the MSK AI feature. If you do not see the presets in your Applications, you will need to purchase the membership to access the advanced features. If you do not see the AI button in the selected Application, you will need to purchase the membership to obtain access to advanced AI features.

Note to User – Imaging Artifacts, Performance, and Limitations

The performance of the MSK AI model may be impacted in the presence of common ultrasound artifacts like an acoustic shadow, lateral shadow, anisotropic effect, reverberation and refraction. As these artifacts are common in MSK ultrasound, users may adopt the following techniques to reduce these artifacts during use, such as:

- Scanning from different angles and planes;
- Using a linear scanner with high center frequency;
- Ensuring the anatomy is in focus

The AI model is sensitive to fluid collection within the tendon. Fluid collection reduces the pixel brightness and echogenicity of tendons. The MSK AI model has been found to have suboptimal performance under this condition. Users should be aware that the MSK AI model is not indicated for diagnostic purposes for conditions like tendon tears and effusion. It is only indicated as a workflow tool intended to inform clinical management and is not intended to replace clinical

decision making. Users can override the MSK AI model output when performance is suboptimal and can perform manual measurements instead as needed.

As such, users should be aware of potential imaging artifacts, including fluid filled tendons and shadows, and techniques to reduce such artifacts.

▼ To use Clarius AI for MSK applications:

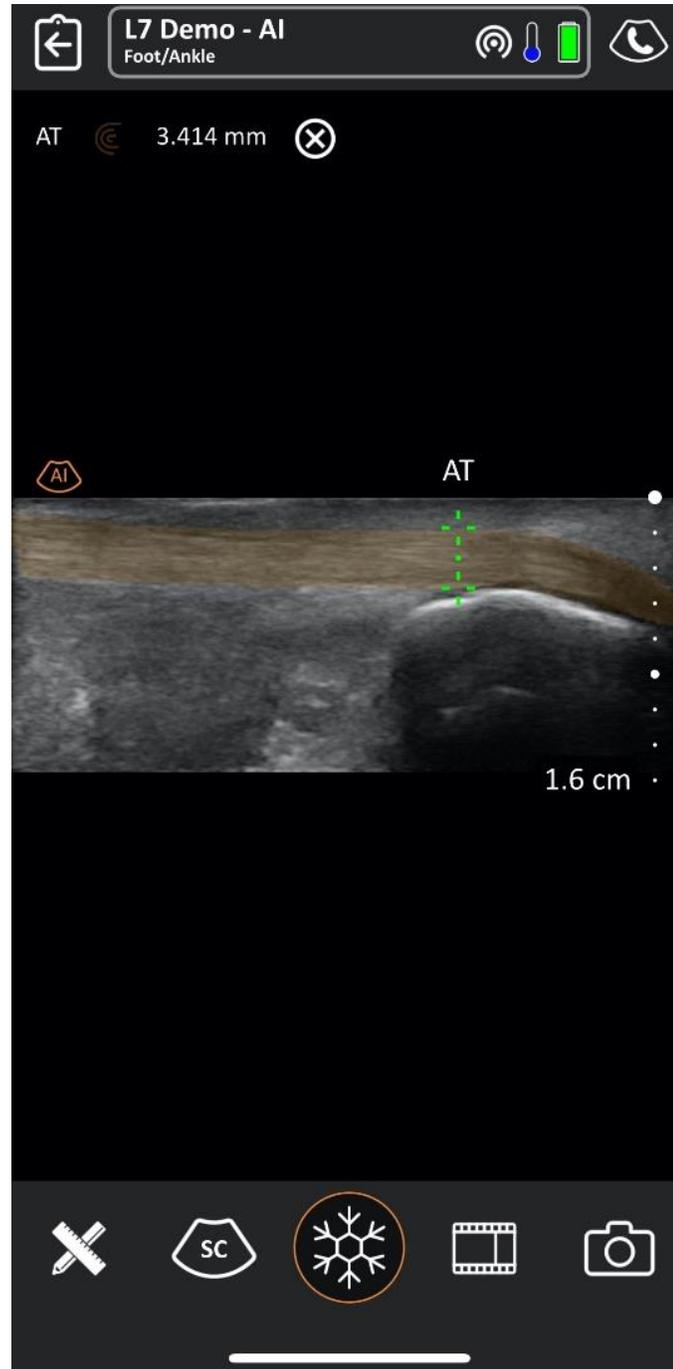
1. Tap the AI Button to activate tendon detection and highlighting. The AI Button is highlighted by the yellow arrow in the image below.



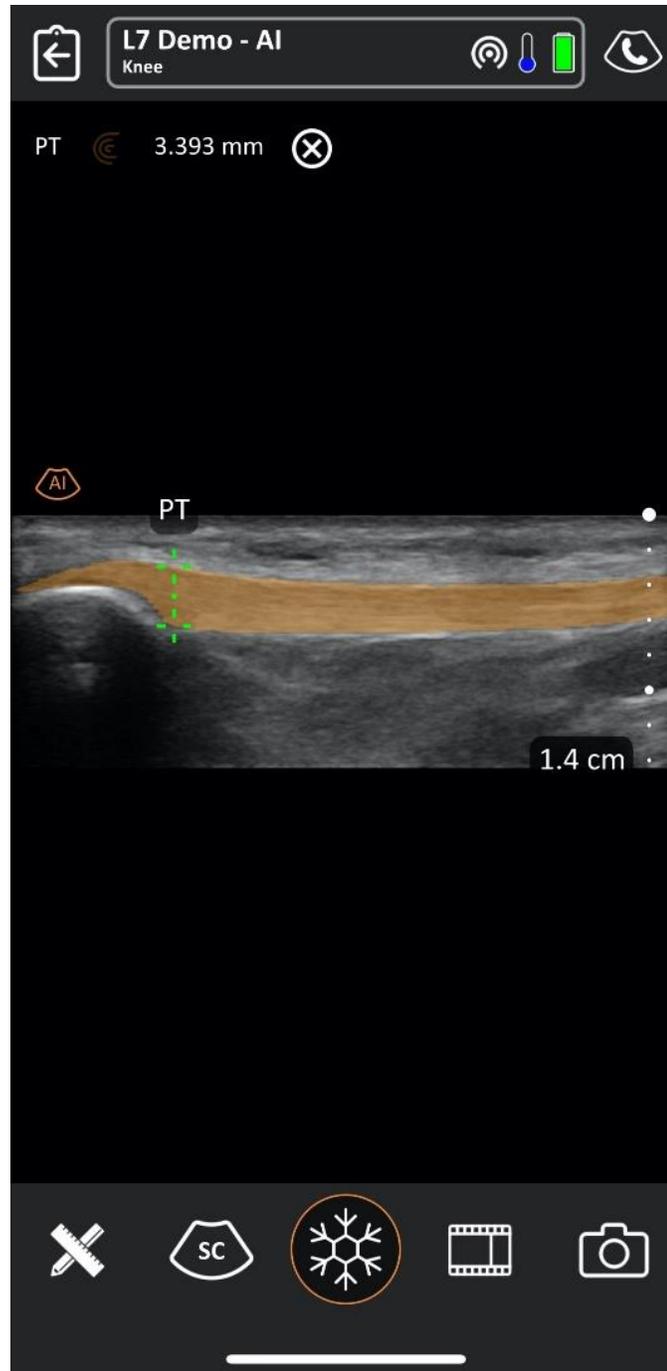
2. Once the AI is activated the AI button will turn Orange as shown in the image below.



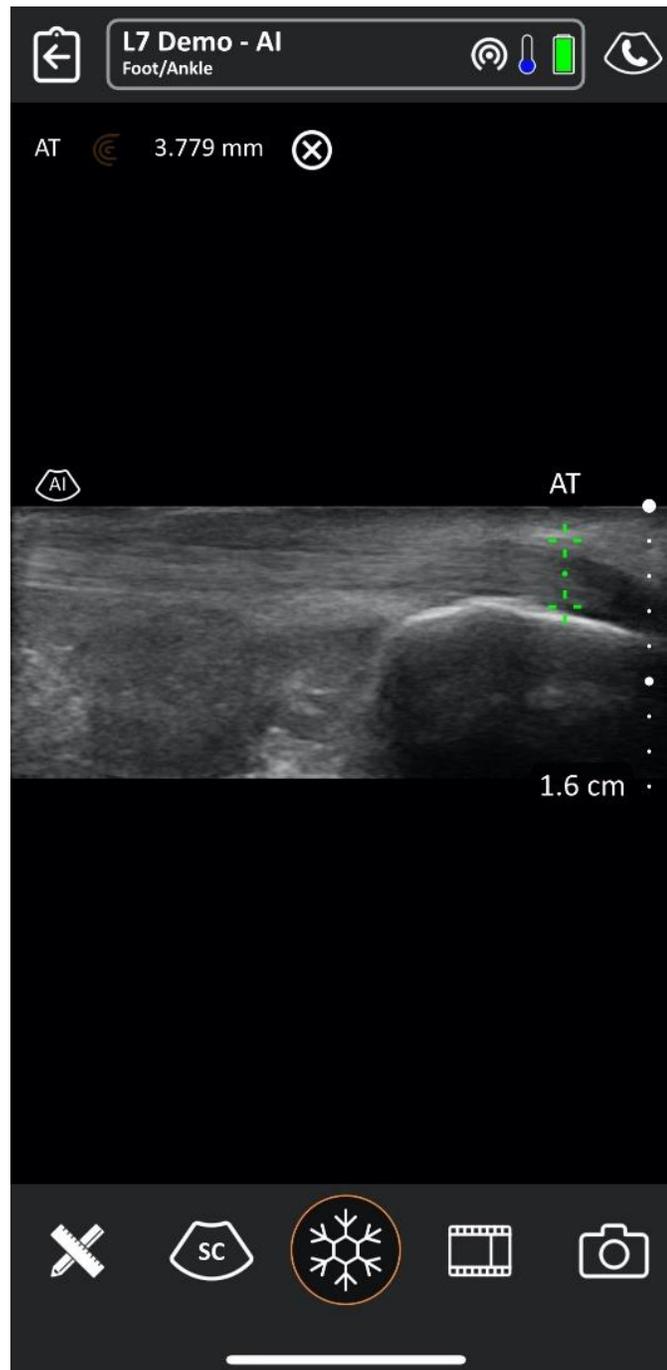
3. Once activated, and a tendon is in view, the tendon is automatically highlighted by displaying an orange mask on top. The highlighted tendon is shown in the picture below.



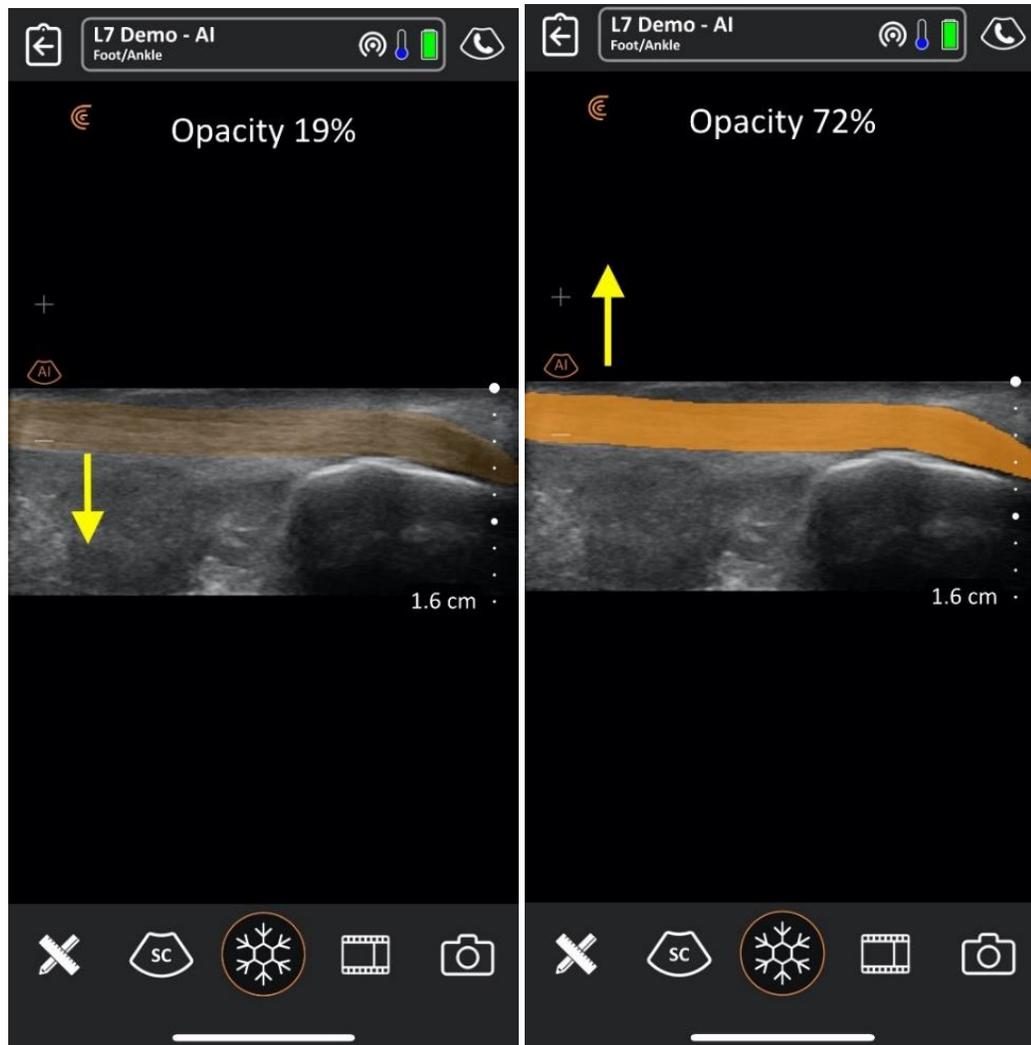
- Once a tendon is detected and highlighted by an orange mask, the tendon thickness can be calculated. To display the tendon thickness, pause the acquisition by pressing on the freeze button. The calipers will be placed automatically, and the tendon thickness will be displayed in the top left corner of the screen.

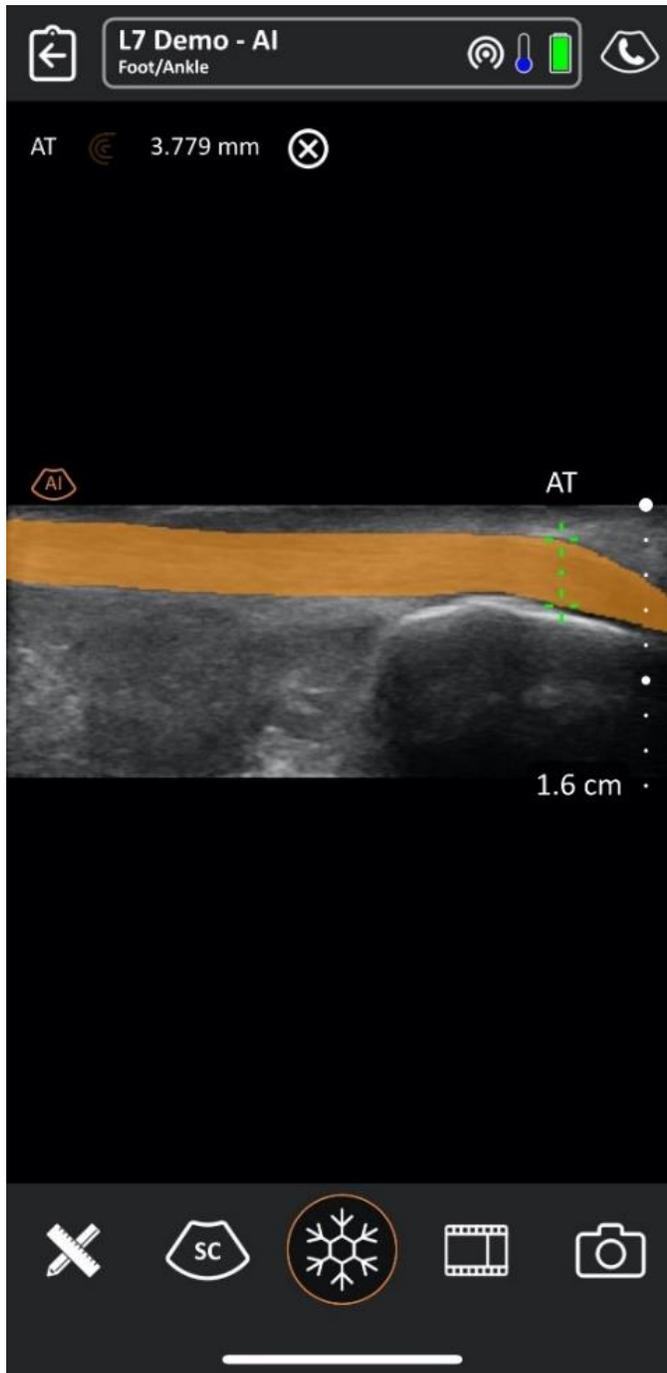


- To remove the segmentation mask and disable the AI, simply tap the AI button until it turns white. As a reminder, AI button colour orange signifies -> ON, whereas white signifies -> OFF. The tendon mask can also be disabled in Freeze mode. Once the acquisition is Frozen, simply disable the AI by tapping the button (colour should change from orange -> white). This is particularly useful for users who want to see the tendon thickness without the tendon mask overlay. Please refer to the image below.



- The opacity of the mask can also be adjusted by scrolling the AI button up and down. Scroll directions are highlighted by the yellow arrow in the images below. Opacity is displayed upon change.





Adjust measurements: To adjust the measurements, simply freeze the image by pressing the freeze button. Then remove the AI predicted overlay mask from the image by pressing the AI button. After disabling the AI feature only the measurement calipers would remain on the image as shown in the figure below. Adjust the measurement by moving the caliper crosshairs.

For instructions on manually adjust the calipers placed by MSK AI, go to <https://clarius.com/msk-ai-vid>.

Revision History

User Manual Revision	Revision Date	Description
1	February 6, 2023	First official release.
2	March 15 th , 2023	Added the statement "in United States only" under the "About this User Guide" section. Added a reference to Clarius Demo Video for instructions on manually adjust the calipers placed by MSK AI.



Headquarters:
Clarius Mobile Health Corp.
#205-2980 Virtual Way
Vancouver, BC, V5M 4X3
Canada
1-778-800-9975
www.clarius.com

