



# Clarius Ultrasound Scanner – Clarius Bladder AI User Guide

R<sub>x</sub> only

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

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](http://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 have 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](http://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.  
15-03-00173

# Table of Contents

- Chapter 1: About this User Guide.....1**
  
- Chapter 2: About Clarius Bladder AI .....2**
  
- Chapter 3: Indications for Use.....2**
  - Note to User – Scanners and Pre-sets for Bladder ..... 2
  - Note to User – Auto Hiding Controls ..... 2
  - Note to User – Imaging Artifacts, Performance, and Limitations..... 2
  - Operating System ..... 3
  - Note to User - Performance Specifications of Clarius Bladder AI and Measurement Output Information..... 3
    - Performance Data and Uncertainty..... 3
  - How to Use Clarius Bladder AI ..... 4
  
- Chapter 4: Revision History.....15**

# *About this User Guide*

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

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

# About Clarius Bladder AI

# 1

## Indications for Use

Clarius Bladder AI is intended for semi-automatic non-invasive measurements of bladder volume on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., curvilinear and phased array scanners). The user shall be a healthcare professional trained and qualified in ultrasound. The user shall retain the ultimate responsibility of ascertaining the measurements based on standard practices and clinical judgment. Clarius Bladder AI is indicated for use in adult patients only.

## Note to User – Scanners and Pre-sets for Bladder

Clarius Bladder AI for Bladder Volume applications only works on the Clarius C3, PA and PAL scanners and in the Bladder preset. Ensure to select the Bladder preset to use the Clarius Bladder AI feature. If you do not see this preset in your Applications and/or the AI button, you will need to purchase Clarius Membership to access the advanced features.

## Note to User – Auto Hiding Controls

The Clarius App has an auto hiding feature for on-screen controls for Clarius Bladder AI. This is done to minimize distractions and improve usability. However, users are able to turn this off. Within the app, navigate to the side panel, then select « Settings », select « Advanced Settings » and locate the toggle for « Auto Hiding Controls » and toggle it off.

## Note to User – Imaging Artifacts, Performance, and Limitations

The performance of the Clarius Bladder 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 bladder ultrasound, users may adopt the following techniques to reduce these artifacts during use, such as: scanning from different angles and planes and ensuring the anatomy of interest is centered and in focus.

The Clarius Bladder AI model is sensitive to free fluid collection within the pelvis and has been found to have suboptimal performance under this condition. The user shall ensure that there is no

abdominal fluid or pathological features overlying or distorting the bladder when using Clarius Bladder AI.

The Clarius Bladder AI performance is unreliable for bladder volumes exceeding 400 ml. Please refer to the uncertainty estimates below.

## Operating System

Clarius Bladder AI is incorporated into the Clarius App software for use as part of the complete Clarius Ultrasound Scanner product offering in bladder ultrasound imaging applications, compatible with iOS and Android operating systems as follows:

- Two versions prior to the latest iOS or Android stable release build.

## Note to User - Performance Specifications of Clarius Bladder AI and Measurement Output Information

Clarius Bladder AI 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 Clarius Bladder AI model output when performance is suboptimal and can perform manual measurements instead as needed.

The following information describes the performance test results of Clarius Bladder AI based on data collected from a study showing agreement between the output of Clarius Bladder AI and the expert clinicians' measurements.

### Performance Data and Uncertainty

The Clarius Bladder AI application has been adequately verified by representative users who confirmed that Clarius Bladder AI measurements were non-inferior to those of human experts/qualified ultrasound users.

The difference between Clarius Bladder AI and manual measurements by human experts was found to be no greater than the difference between manual measurements within the clinically significant difference margin with a statistical significance level of 0.05.

The performance agreement of Bladder AI compared to human experts obtained from retrospective and prospective study is shown in the table below:

	<b>Mean difference between Human experts and Clarius Bladder AI</b>	<b>Upper limit of agreement</b>	<b>Lower limit of agreement</b>
<b>0 - 100 ml</b>	-2.31 ml	20.83 ml	-25.45 ml
<b>100 - 200 ml</b>	-6.82 ml	51.14 ml	-64.78 ml

---

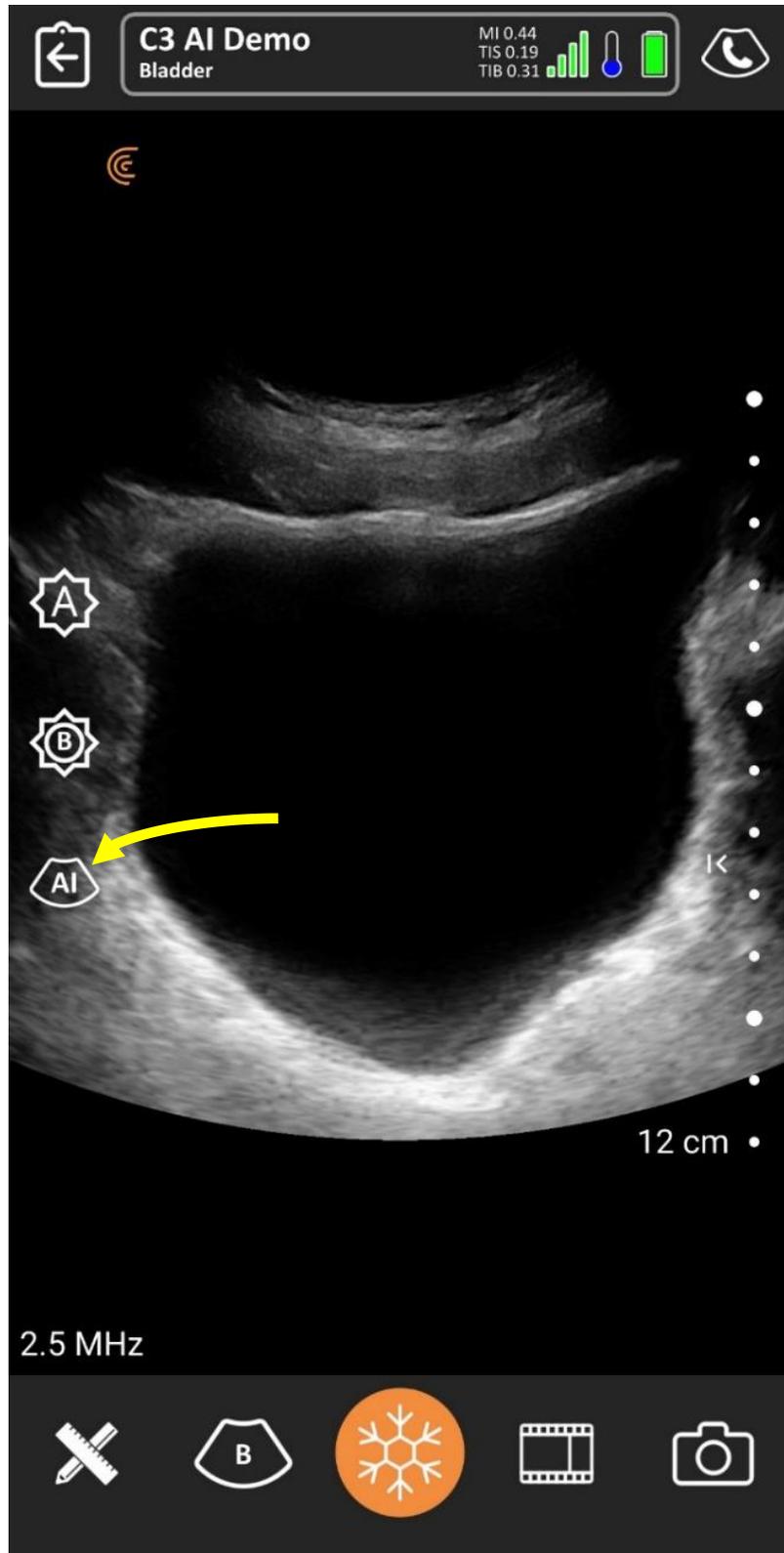
<b>200 - 400 ml</b>	-15.60 ml	60.50 ml	-91.70 ml
---------------------	-----------	----------	-----------

*\*The measurement performance assumes that Clarius Bladder AI is being compared to manual measurements by human experts.*

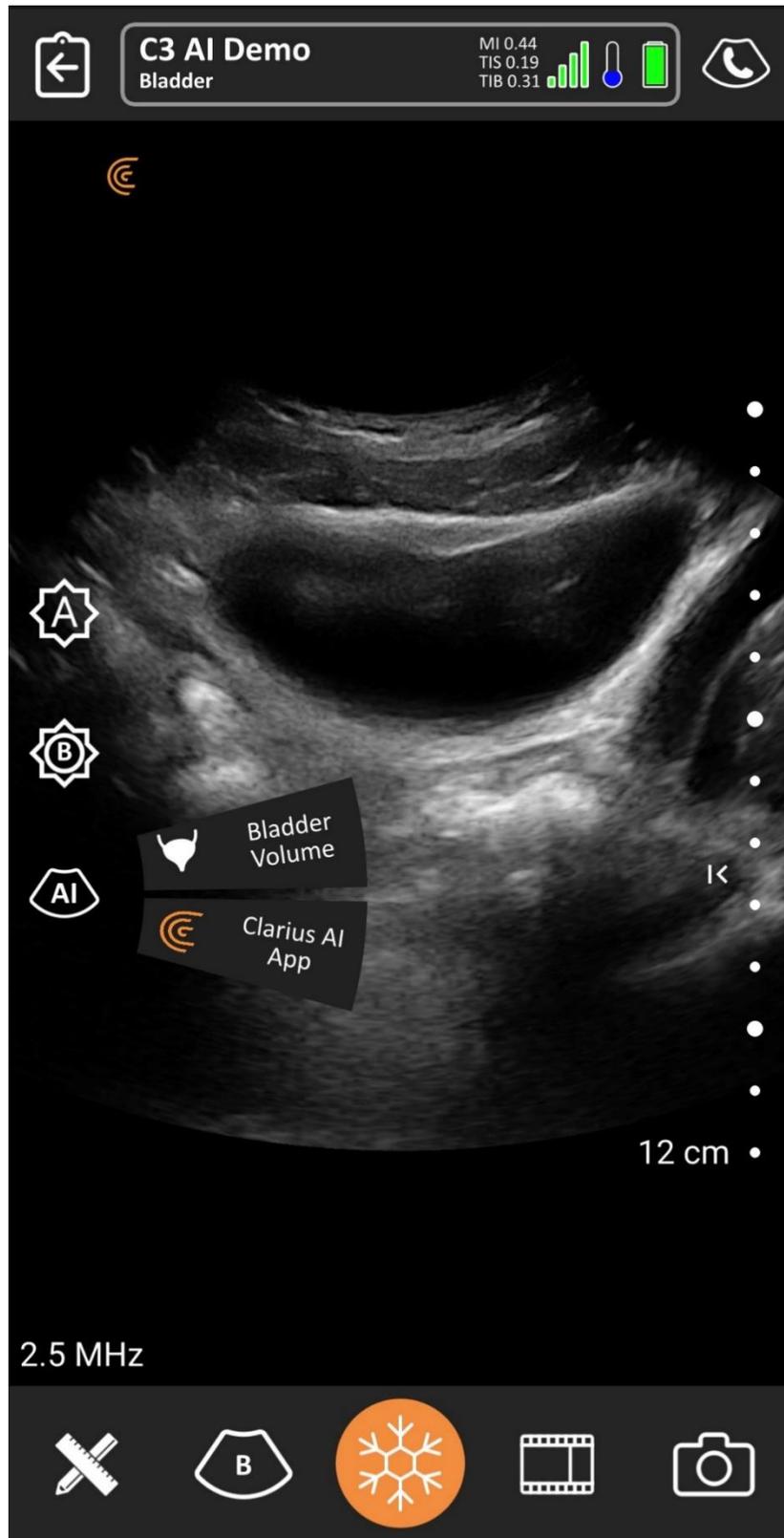
*\*The volume range for optimal performance of Clarius Bladder AI is 0 – 400 ml. Although higher bladder volumes (>400 ml) can be estimated, Clarius Bladder AI cannot guarantee the accuracy of measurements beyond this volume.*

## How to Use Clarius Bladder AI

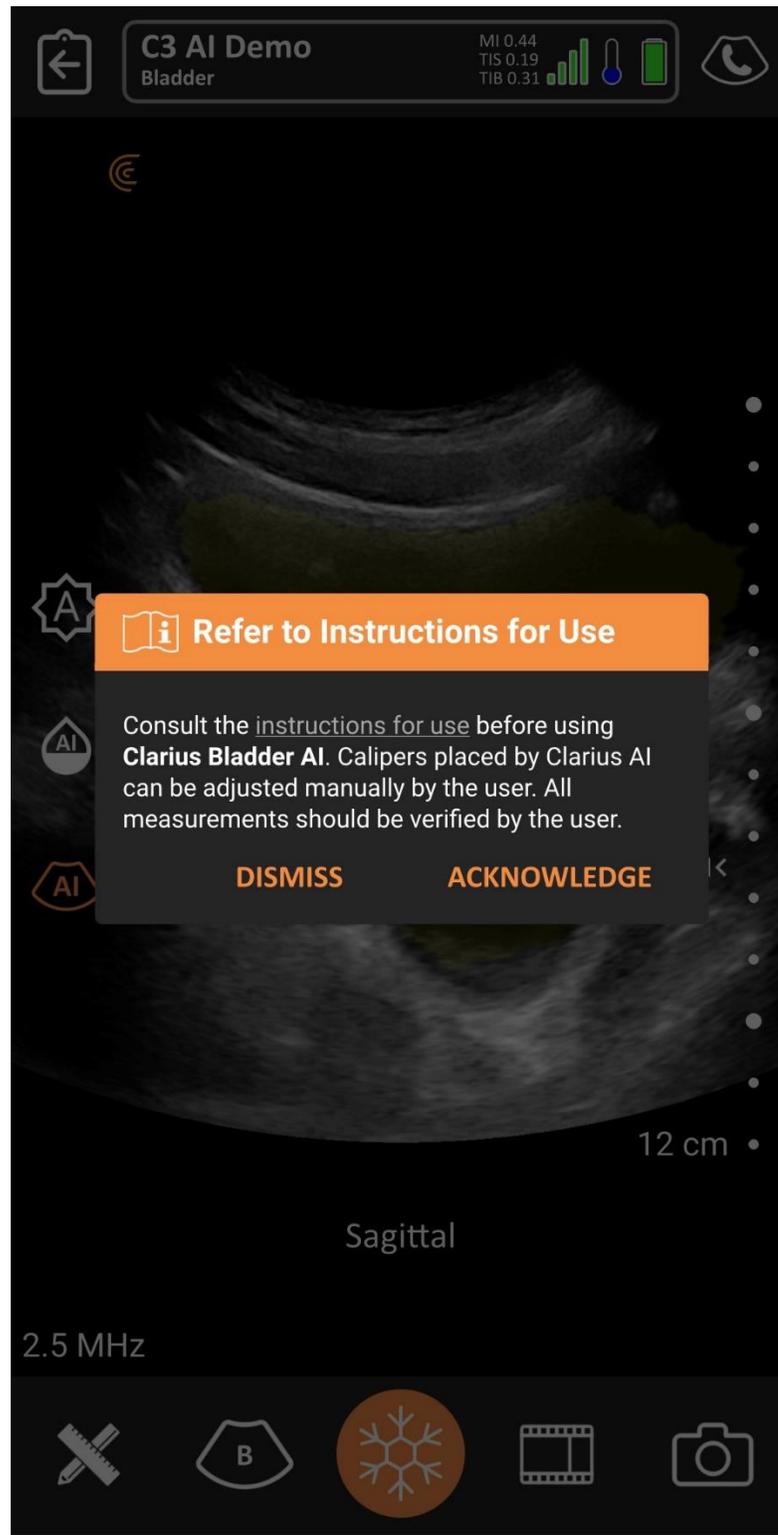
- ▼ To use Clarius Bladder AI for Bladder applications:
  1. Tap the AI Button to activate bladder detection and highlighting. The AI Button is highlighted by the yellow arrow in the image below. If the AI Button is not visible, tap on the screen to make it appear.



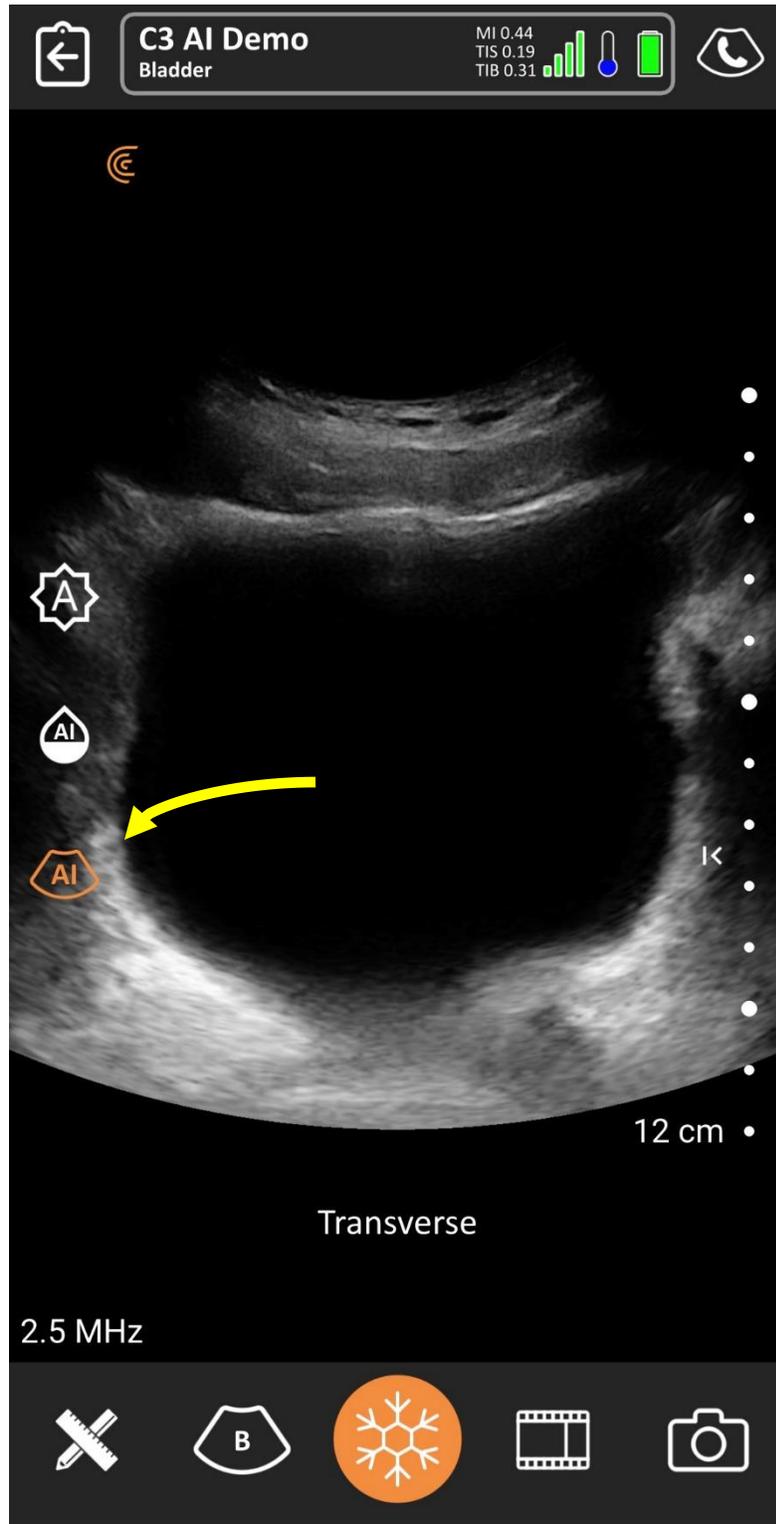
2. A circular carousel will appear with all available AI models. Please select “Bladder Volume”.



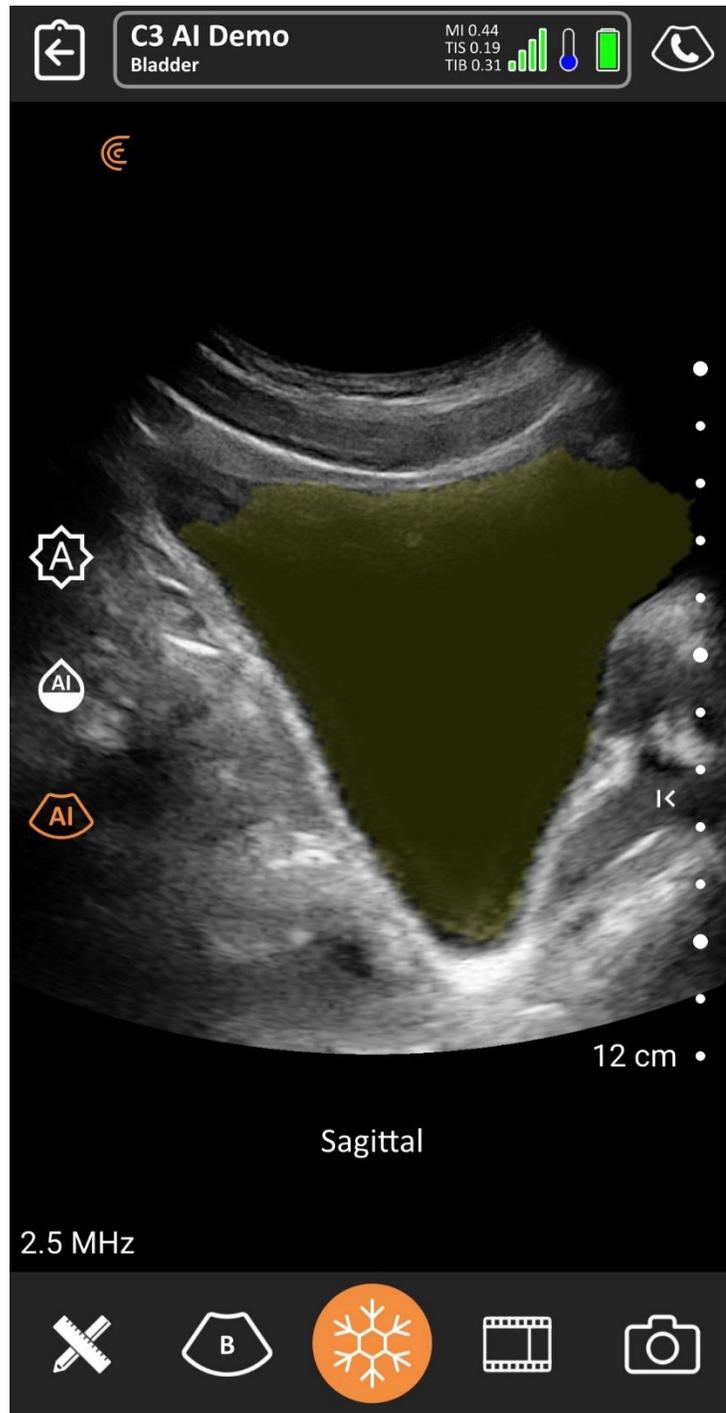
3. If activating for the first time, a pop-up will appear referring to the “Instruction for Use”. Selecting “Dismiss” will dismiss the pop-up but it will re-appear on subsequent uses of Bladder AI. Selecting “Acknowledge” will dismiss the pop-up and it will not be shown again.



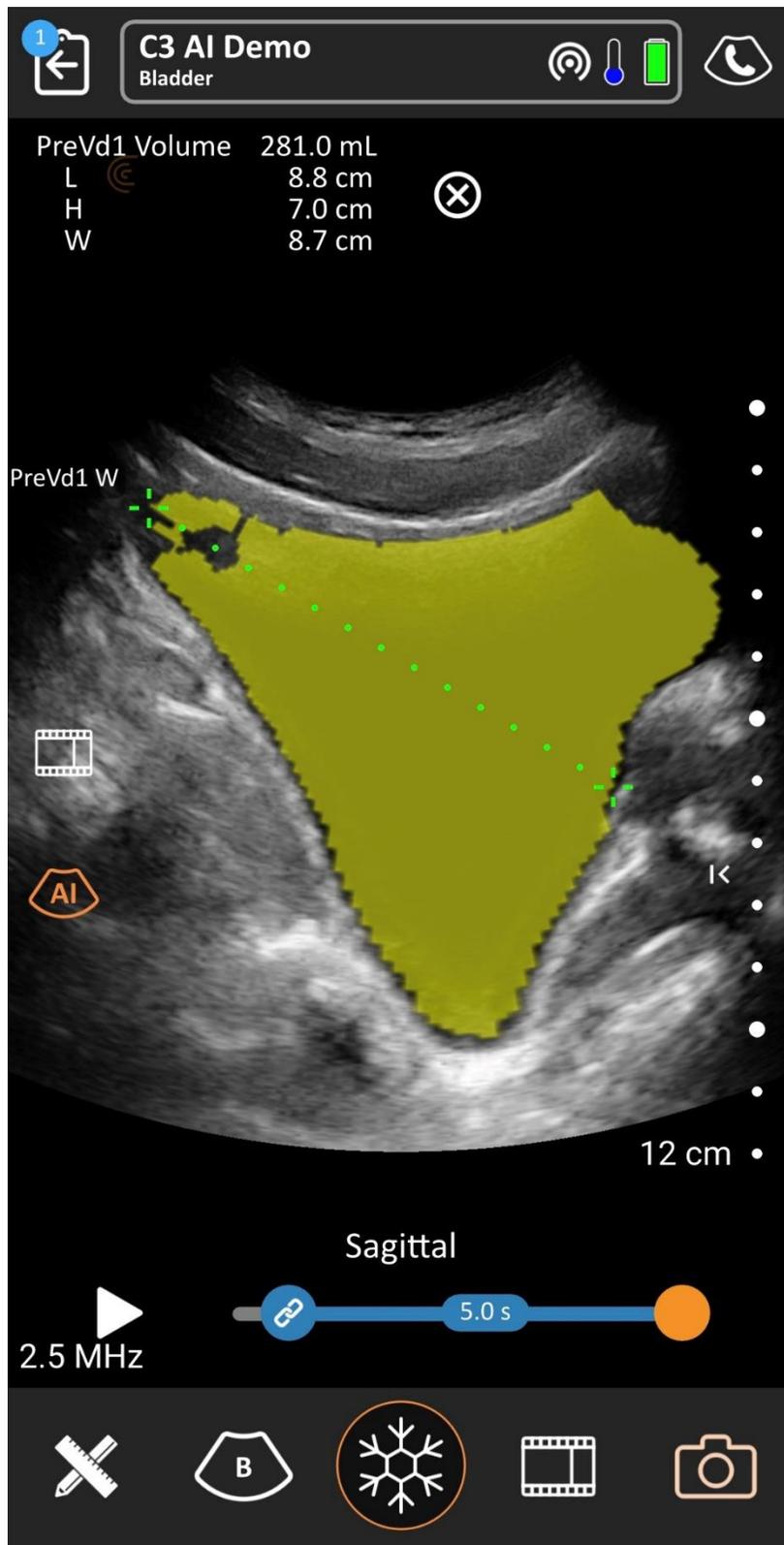
- Once the AI is activated the AI button will turn orange as shown in the image below.



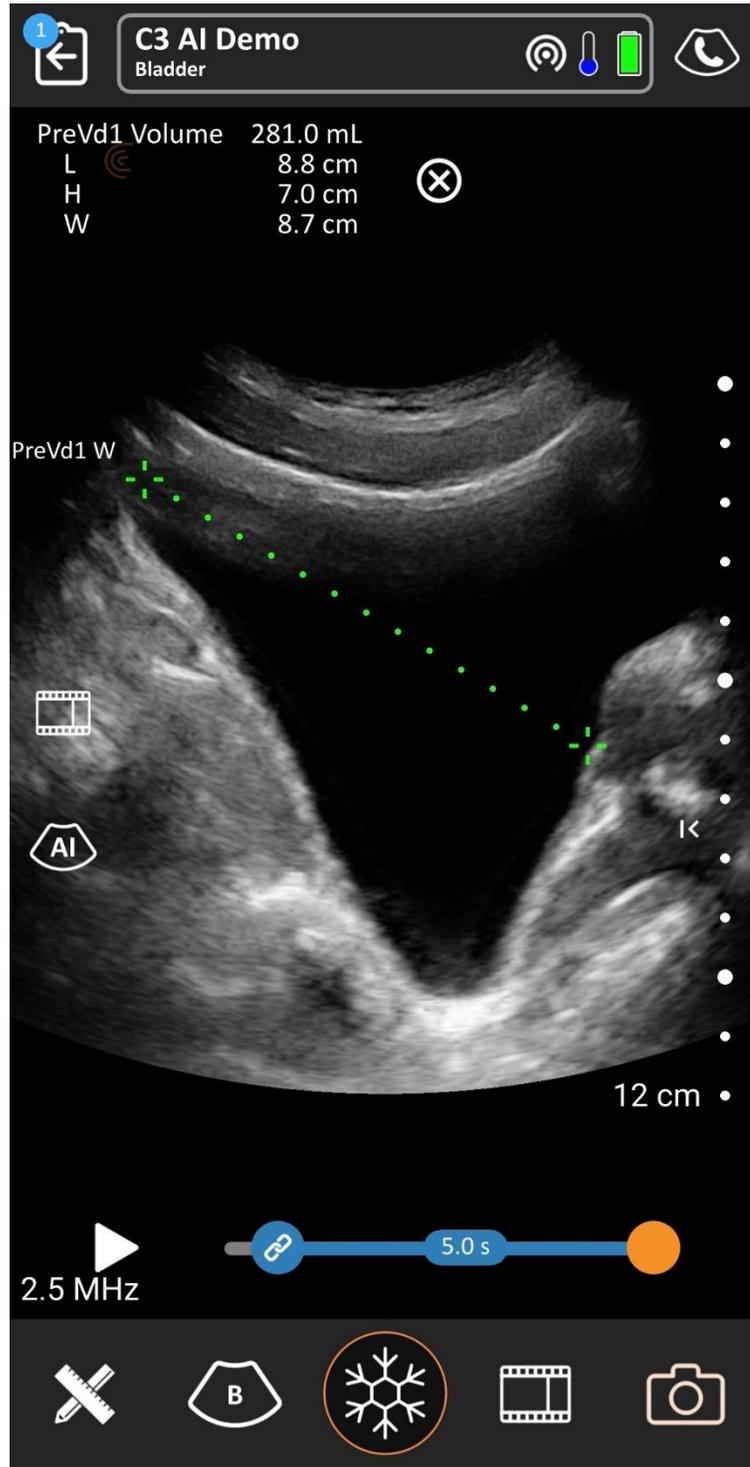
5. Once activated, and the bladder is in view, the bladder is automatically highlighted by a yellow mask on top. The highlighted bladder is shown in the picture below.



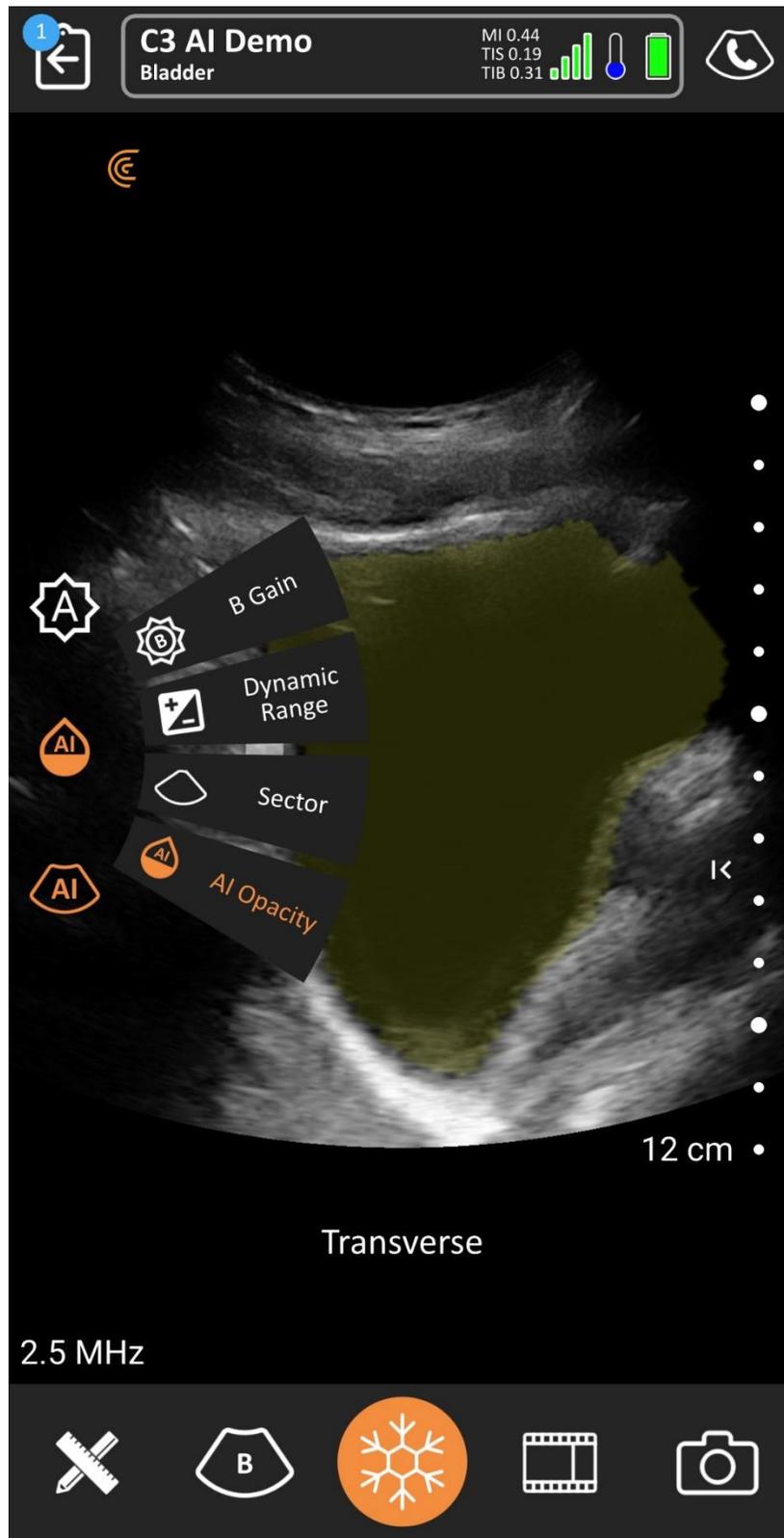
It is necessary to capture both sagittal and transverse images. To display the length, width, and height of the bladder, pause the acquisition by pressing the freeze button. The calipers will be placed automatically depending on the view, with measurements calculated automatically and shown in the top left corner of the screen. Once all 3 measurements have been captured, the bladder volume will be displayed in the top left corner of the screen.

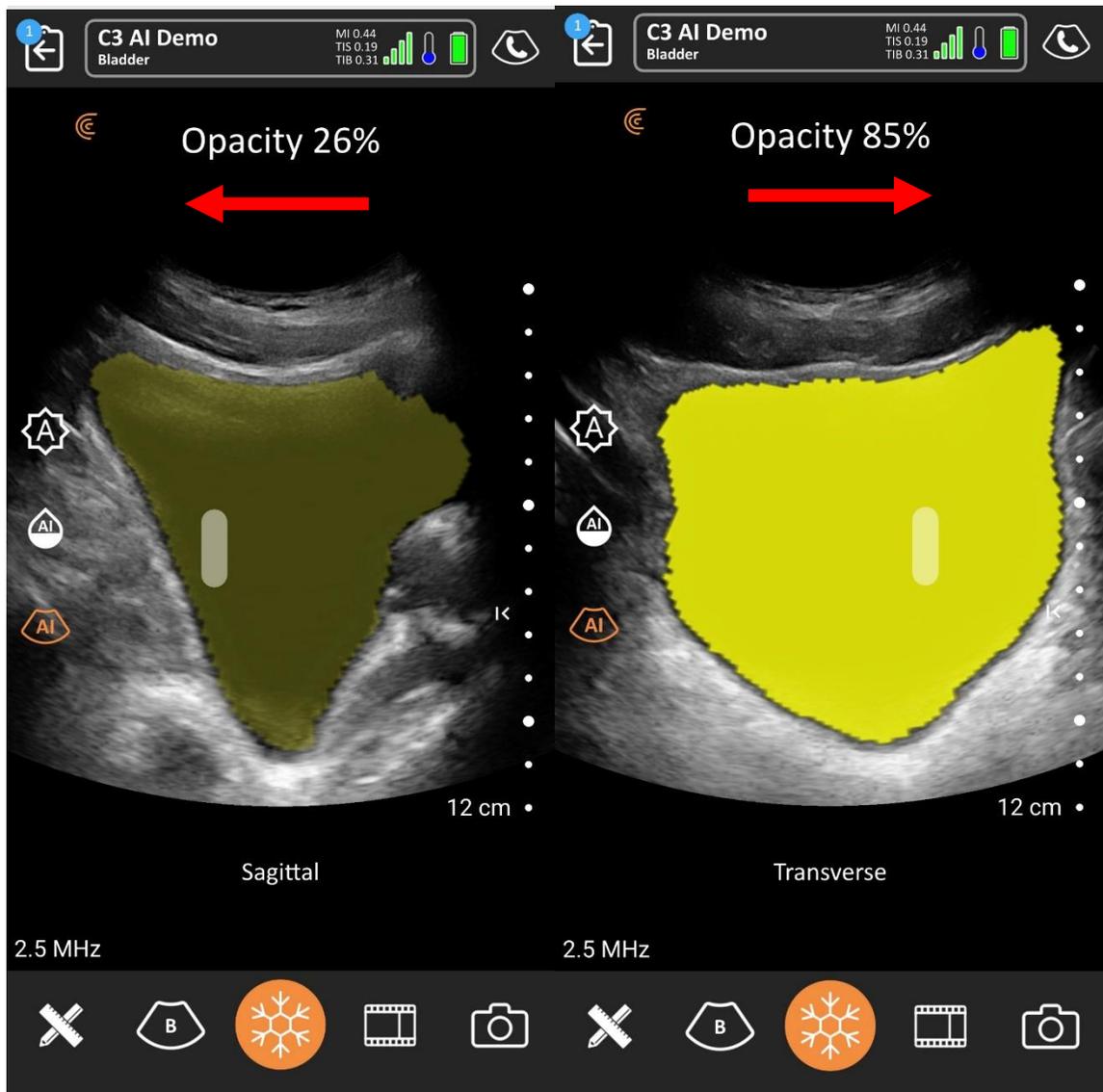


- To remove the segmentation mask and disable the AI, simply tap the AI button and select "Bladder Volume" from the AI carousel wheel. The AI button will then turn white. As a reminder, an orange coloured AI button signifies ON, whereas a white coloured AI button signifies OFF. The segmentation mask 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 bladder without the segmentation mask overlay. Please refer to the image below.

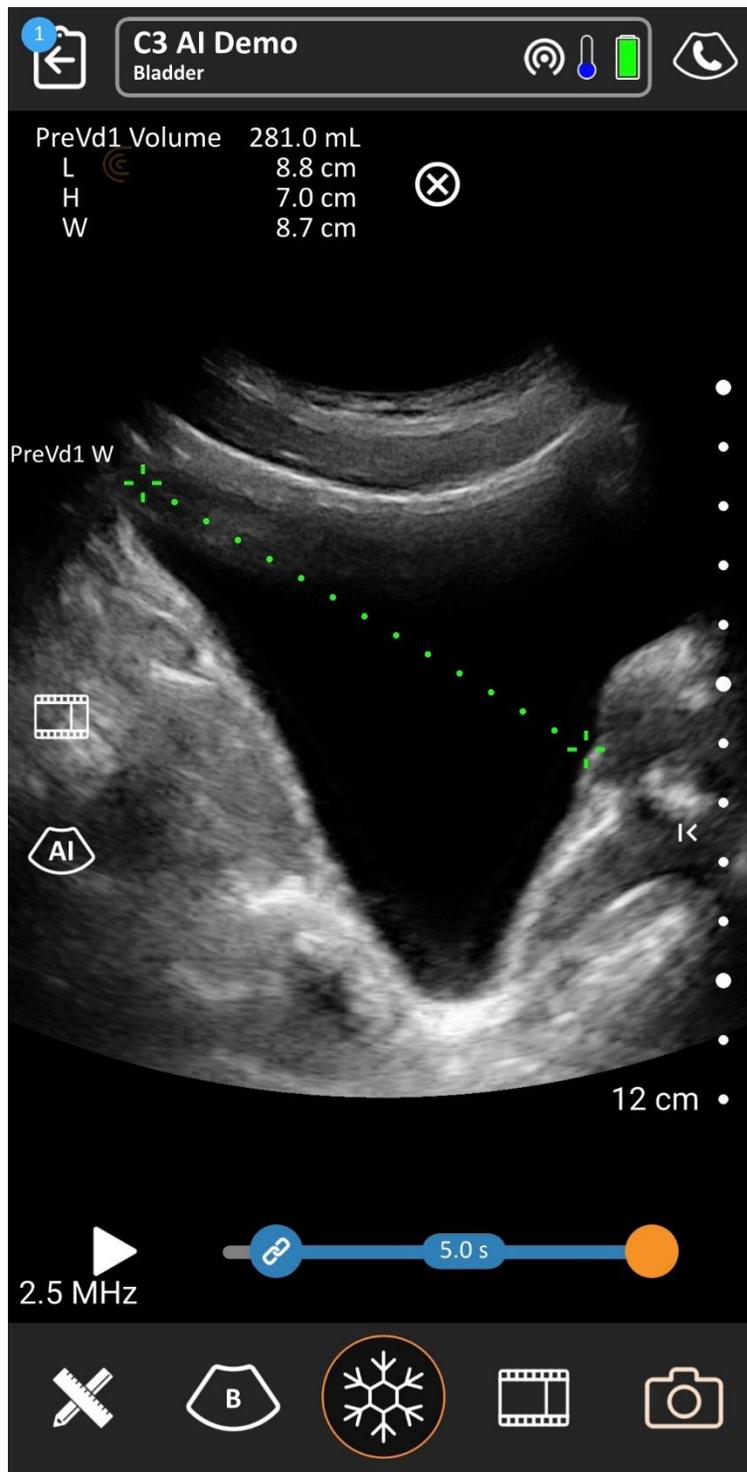


- The opacity of the mask can also be adjusted by making sure the Slider Control carousel wheel is selected to be on "AI Opacity". Scroll directions are highlighted by the red arrow in the images below. Opacity is displayed upon change.





Manually adjust measurements: To adjust the measurements manually, 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 will remain on the image as shown in the figure below. Adjust the measurement by moving the caliper crosshairs.



For instructions on manually adjusting the calipers placed by Bladder AI and video instructions, go to <https://clarius.com/user-guide/bladder-ai>.

# Revision History

User Manual Revision	Revision Date	Description
1	May 5, 2023	First official release.
2	May 18, 2023	Included step for selecting AI model from AI model list menu
3	June 26, 2023	Update UI and steps to match latest App release. Minor wording updates for consistency.
4	September 18, 2023	Added Rx Only symbol to cover page; updated Indications for Use statement with "adults only"; added warning statement regarding "abdominal fluid and pathological features"; added compatibility information for iOS and Android operating systems; added information regarding performance specifications and measurement output.



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

