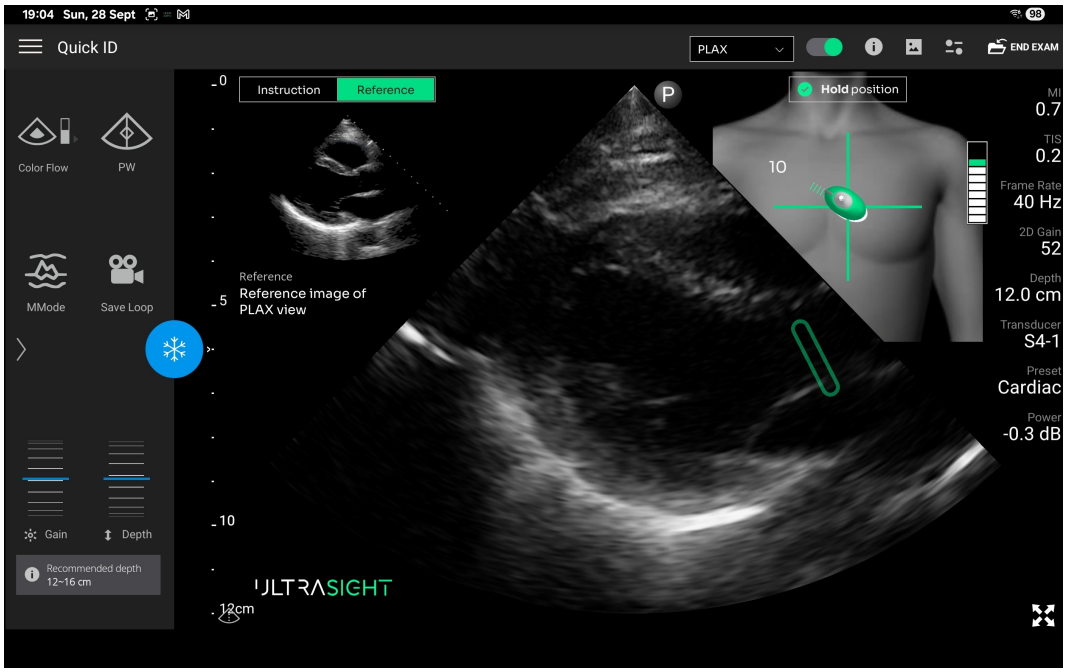
ULTRASIGHT

UltraSight for Impella



Quick User Guide (QUG)

Document No.: UM-0003

Revision Revision 1, November 2025

Copyright © 2025 UltraSight Ltd. All rights reserved.

This document is intended for use by customers and is licensed to them as part of their UltraSight product purchase or to meet regulatory commitments as required by the FDA under 21 CFR 892.2050 (and any amendments to it) and other local regulatory requirements. Use of this document by unauthorized persons is strictly prohibited.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form and by any means, electronic, mechanical, photo-reproductive, recording, or otherwise, without the express prior written permission of UltraSight Ltd.

UltraSight Ltd. reserves the right to change or improve its products and accompanying technical literature without prior notice of changes or improvements.

The marks contained herein represent some of the trademarks or registered trademarks of UltraSight Ltd. or its subsidiaries and affiliates in the United States and/or other countries. Unless otherwise noted, all materials are protected as the copyrights, trade dress, trademarks, and/or other intellectual properties owned by UltraSight Ltd. and/or its subsidiaries and affiliates or by other parties that have licensed their material to UltraSight Ltd. All rights not expressly granted are reserved.

No part of this manual may be reproduced or copied in any form and by any means - graphic, electronic, mechanical, magnetic, optical, chemical, including photocopying, typing, translated into any language or computer language, or information retrieval systems - without the written permission of UltraSight Ltd.

All intellectual property rights, including those created by patent grant or registration of a utility model or a design, are expressly reserved. Any unauthorized use is illegal.

© 2025 UltraSight Ltd. All rights reserved. UltraSight™ and the UltraSight logo are trademarks of UltraSight Ltd. and are registered in the U.S. and other countries.

MD Rx only

UltraSight Ltd.
Pinhas Sapir 8 St., Scientific Park,
PO Box 594, Ness Ziona 7403631, Israel

Phone: +1 (857) 371-3320
Email: info@ultrasight.com
Web: www.ultrasight.com

Disclaimer

The ULTRASIGHT FOR IMPELLA software should only be used in the manner specifically set forth in this user manual. Use of the ULTRASIGHT FOR IMPELLA software in a manner not expressly described in this user manual (which may be updated from time to time by UltraSight) may lead to improper product performance and potential for hazard and will void all warranties of any kind that are extended by UltraSight in connection therewith. The performance of the ULTRASIGHT FOR IMPELLA software can only be assured under the following conditions: (i) The application has been used for its indicated use (see Indications for Use in this User Manual), (ii) this application has only been used in accordance with the operating instructions contained in this User Manual, (iii) all fittings, extensions, readjustments, changes required for the use of the ULTRASIGHT FOR IMPELLA software have solely and exclusively been carried out by an UltraSight authorized representative, (iv) the user has been registered at UltraSight.

For medical questions, please consult a qualified healthcare professional. In the event of a medical emergency, contact your local emergency services provider immediately.

Neither UltraSight nor any of its principals, directors, employees, affiliates, representatives, or assigns shall be responsible in any way for any physical harm and/or property damage arising from the operation or use of either the ULTRASIGHT FOR IMPELLA software or this user manual. Without limiting the foregoing, UltraSight makes no warranty of any kind regarding this user manual. In addition, UltraSight shall not be liable for errors contained in this user manual or for incidental or consequential damages in connection with the furnishing or use of any material contained within this user manual.

Accordingly, the content in this user manual does not and will not form part of any contract between UltraSight and any user of the ULTRASIGHT FOR IMPELLA software. No person has the authority to bind UltraSight to any representation or warranty except as specifically set forth above and/or in the UltraSight User Agreement.

The content of this user manual is provided for informational purposes only and is subject to change by UltraSight without notice. Any modifications and amendments hereto will be deemed included in subsequent versions of the UltraSight user manual. Additionally, the content in this user manual does not purport to cover all details or variations of the ULTRASIGHT FOR IMPELLA software and does not address every possible contingency related to its use.

This user manual contains proprietary information that is protected by international copyright. No part of this document may be photocopied, reproduced, or translated without the prior written consent of UltraSight. UltraSight is protected by the following patents: US11593638B2, EP3793447B1, D1046893, and US11478226B2. Any unauthorized use of information and content from the UltraSight user manual is strictly prohibited and may result in prosecution by UltraSight Ltd.

Please read this user manual thoroughly and feel free to contact our product support team with any questions at: **support@ultrasight.co m**.

License Agreement

All computer programs copyrighted in 2025 by UltraSight Ltd. or its suppliers are licensed under the following software agreement.

UltraSight Ltd. or its suppliers retain ownership of and title to any computer program supplied with the Device and the trade secrets embodied in such computer programs. Subject to the Buyer’s acceptance and fulfillment of the obligations in this paragraph.

UltraSight Ltd. grants the Buyer a personal, non-transferable, non-exclusive license to use any computer program supplied with the Device that is necessary to operate the Device solely on the medium in which such program is delivered for the purpose of operating the Device in accordance with the instructions set forth in the operator's manuals supplied with the Device and for no other purpose whatsoever. Buyer may not reverse-assemble, reverse-compile, or otherwise reverse-engineer such computer programs, nor may Buyer make a copy of such program or apply any techniques to derive the trade secrets embodied therein. In the event of a failure by Buyer to comply with the terms of this license, the license granted by this paragraph shall terminate. Further, because unauthorized use of such computer programs will leave UltraSight Ltd. without an adequate remedy at law, Buyer agrees that injunctive or other equitable relief will be appropriate to restrain such use, threatened or actual. Buyer further agrees that (i) any of UltraSight Ltd. suppliers of software is a direct and intended beneficiary of this end-user sublicense and may enforce it directly against Buyer with respect to software supplied by such supplier, and (ii) no supplier of UltraSight shall be liable to Buyer for any general, special, direct, indirect, consequential, incidental or other damages arising out of the sublicense of the computer programs supplied with the Device.

Table of Contents

Chapter 1 Introduction 1-1

1.1 About this Guide 1-1

1.2 Device Labels 1-1

Chapter 2 System Requirements 2-1

2.1 UltraSight Guidance (version 1.6.0) 2-1

2.2 PVAD IQ (version 1.1.0) 2-1

2.3 Tablet Requirements and Settings 2-1

Chapter 3 The ULTRASIGHT FOR IMPELLA Application 3-1

3.1 Installing the Application 3-1

3.2 Configuring Lumify 3-2

3.3 Launching the ULTRASIGHT FOR IMPELLA Application 3-2

3.4 Registration and Entitlement 3-6

3.4.1 Activating the Application 3-6

3.4.2 Functional Check 3-8

3.5 The UltraSight Guidance Application 3-10

3.6 The PVAD IQ Software 3-11

Chapter 4 ULTRASIGHT FOR IMPELLA Workflow 4-1

4.1 Launching the Application 4-1

4.2 Starting an Exam 4-5

4.3 Performing an Exam 4-7

Chapter 5 Appendices 5-1

Appendix A. Configuring Lumify 5-1

A.1. Configuring the Export Destination 5-1

A.2. Configuring the Connectivity Default Profile 5-7

Chapter 1
Introduction

1.1 About this Guide

The ULTRASIGHT FOR IMPELLA software comprises two applications: the UltraSight Guidance software, which assists medical professionals in performing cardiac ultrasound scans, and the PVAD IQ software for patients with a Percutaneous Ventricular Assist Device (PVAD).

This Quick User Guide (QUG) provides essential instructions for the proper installation and operation of the ULTRASIGHT FOR IMPELLA software. It is not intended to replace the user manuals for the UltraSight Guidance software or PVAD IQ application software.

Please review the User Manuals of each application thoroughly, including detailed instructions, warnings, and precautions, before first use to ensure safe and effective operation in alignment with regulatory guidelines and intended use.

Link 1

Link 2

1.2 Device Labels

Symbol	Definition
MD	The medical device symbol.
CE	The CE Marking symbol.
Rx only	Federal (United States) law restricts this product from sale by or on the order of a physician.
UDI	The unique device identification number symbol.
MR	MR unsafe symbol.
EC REP	The symbol for Authorized Representative.
	The product manufacturer, including the address.

Chapter 2
System Requirements

Below are the system requirements applicable to the ULTRASIGHT FOR IMPELLA application. For a complete list of system requirements, please refer to each software application's user manuals.

2.1 UltraSight Guidance (version 1.6.0)

- Philips Lumify S4-1 ultrasound transducer, Lumify Power Module (LPM) Philips, Philips part number 453561998451.
- Philips Lumify application - Philips Lumify, software number/version: 4.0 453562133201 21-11-16 or 4.0.1 453562163981 22-09-15.

2.2 PVAD IQ (version 1.1.0)

- PVAD IQ currently supports only DICOM files that contain ultrasound clips of images encoded with JPEG (8 bits per color channel, lossy).

2.3 Tablet Requirements and Settings

The following are the supported tablets and their specifications:

- Supported tablet devices:
  - Samsung Galaxy Tab S9, S9+, and S11.
- Tablet software:
  - Tablet OS - Android version 14 and above.
- Memory Storage:
  - Minimum 6GB of RAM.
  - Minimum storage space for installation: 1GB.

> ***Note***
>
> The ULTRASIGHT FOR IMPELLA application uses only the device's processing power and does not require internet connectivity (except for the registration process).

- Required Android OS Configuration:
  - The screen zoom of Android tablets must be set to its default level.

  - If you are using an MDM (Mobile Device Management) system to manage the device, it must allow Screen Recording.
- Recommended Android OS Configuration:
  - Set the Screen timeout to at least 5 minutes.
  - For Android 16 and above, we recommend to disable all the options in the Multi window settings

Chapter 3
The ULTRASIGHT FOR IMPELLA Application

3.1 Installing the Application

Downloading and installing the ULTRASIGHT FOR IMPELLA Application requires an internet connection.

> ***Note***
>
> Using the ULTRASIGHT FOR IMPELLA software application requires installing the Lumify Ultrasound System application.

To connect the tablet to the internet:

1. Tap the tablet **Settings** icon and select **Connections** .
2. Ensure the **Wi-Fi** sliding button is switched on and tap the **Wi-Fi** field. A list of available Wi-Fi networks within range is displayed.
3. Select your network. If the network is secured, enter the password and tap **Connect** .

To download the UltraSight App:

1. Open the **Google Play Store** on the tablet.
2. Search for the **UltraSight ™** App and its logo.
   The App is free of charge.
3. Tap **Install** to install the UltraSight™ App. The App is installed automatically after downloading from the Google Play Store.

> ***Note***
>
> Software updates will be available on the Google Play Store.

3.2 Configuring Lumify

Before launching the ULTRASIGHT FOR IMPELLA application, Lumify must be configured to operate with ULTRASIGHT FOR IMPELLA.

> ***Note***
>
> It is essential to configure the Lumify before launching the ULTRASIGHT FOR IMPELLA.

1. Verify that the "**Lumify Ultrasound System** " application is installed on the tablet.
2. Configure Lumify, as described in Appendix A.

3.3 Launching the ULTRASIGHT FOR IMPELLA Application

1. Connect a compatible ultrasound probe to the tablet so that the application can function fully and display the cardiac scan.

> ***Note***
>
> If the cardiac probe is not connected to the tablet's USB-C port, the Cardiac scan mode will not be available.

2. Tap the **ULTRASIGHT FOR IMPELLA** application icon on your device.

   The application opens, and a window opens with the terms of use agreement and an analytics data dialog.

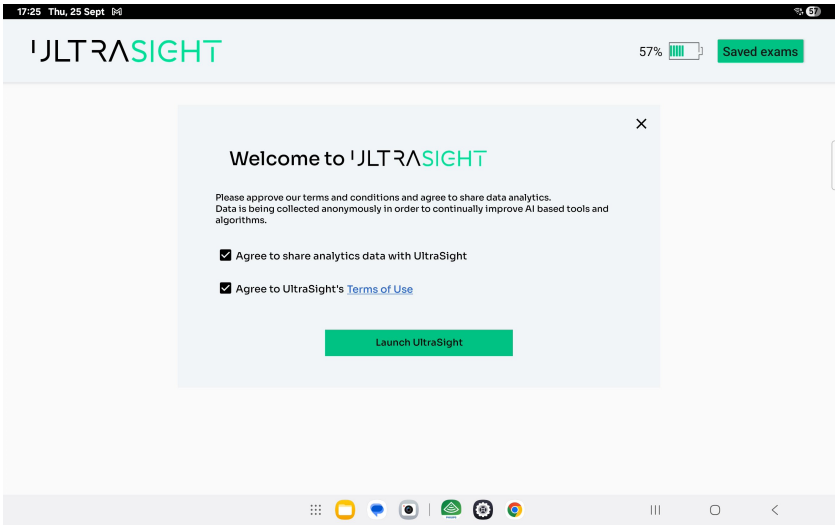


Figure 3-1. Terms of use agreement and analytics data

3. Mark the checkbox next to "Agree to UltraSight's Terms of Use".
4. Tap the **Launch UltraSight** button.

The permission to show things on top of other apps is displayed.

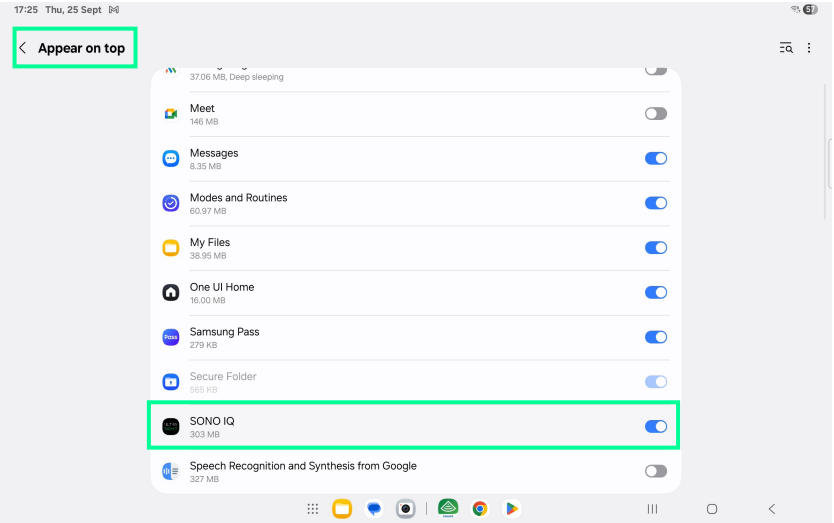


Figure 3-2. ULTRASIGHT FOR IMPELLA overlay permission

5. Scroll down and select the ULTRASIGHT FOR IMPELLA to enable the application.
6. Tap back to return to the UltraSight application.

   The request to enable ULTRASIGHT FOR IMPELLA to send notifications appears.

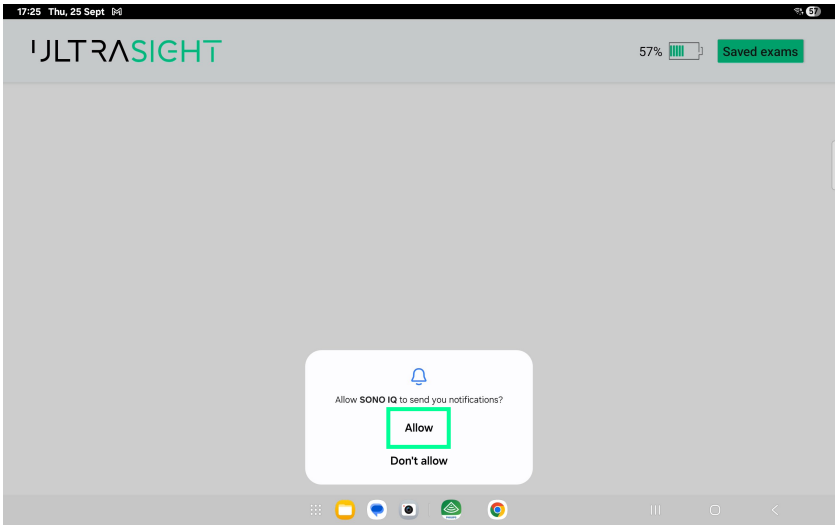


Figure 3-3. UltraSight notification permission

7. Tap **Allow**.

   The battery usage notification message appears.

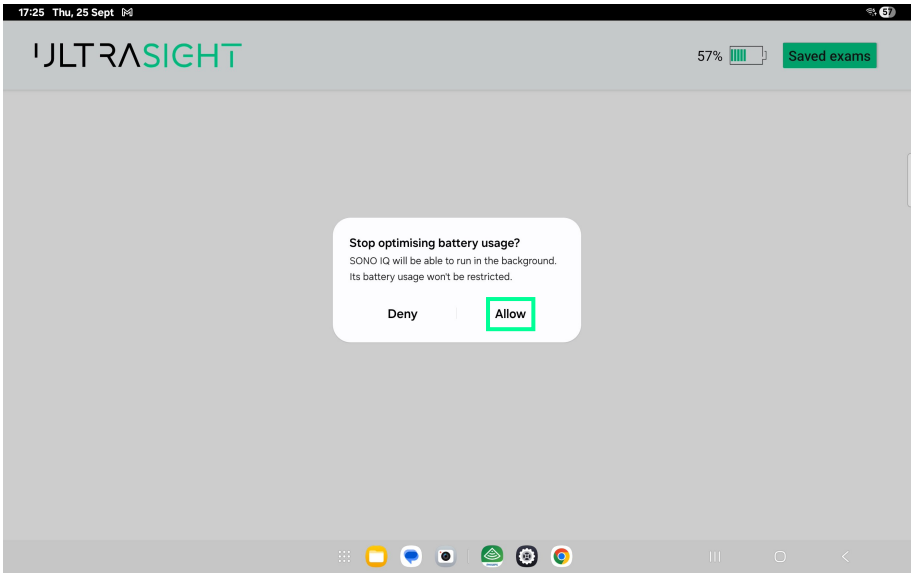


Figure 3-4. Stop optimi sing battery usage

8. Tap **Allow**.

   The PVAD folders screen opens.

   Choose the same folder that was defined in Lumify's App Export Destination (see Appendix A.1).

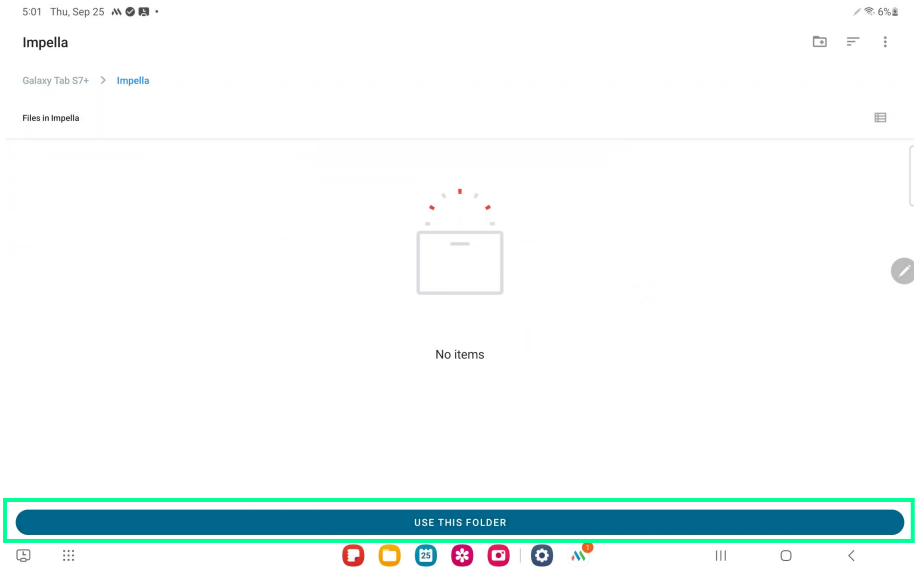


Figure 3-5. Folder selection

3.4 Registration and Entitlement

Using the ULTRASIGHT FOR IMPELLA application requires registering an account with UltraSight. Once UltraSight approves the account, an activation key per the acquired license is received.

The activation key must be inserted and activated on the tablet device running the ULTRASIGHT FOR IMPELLA application to enable its functionality. This action requires the tablet to be connected to the internet.

> ***Note***
>
> The activation key has an expiration date, requiring renewal for the application to continue functioning.

3.4.1 Activating the Application

1. Insert the activation key in the displayed activation key screen. The Activation key should have been supplied to you with the purchase of the license for the ULTRASIGHT FOR IMPELLA application.

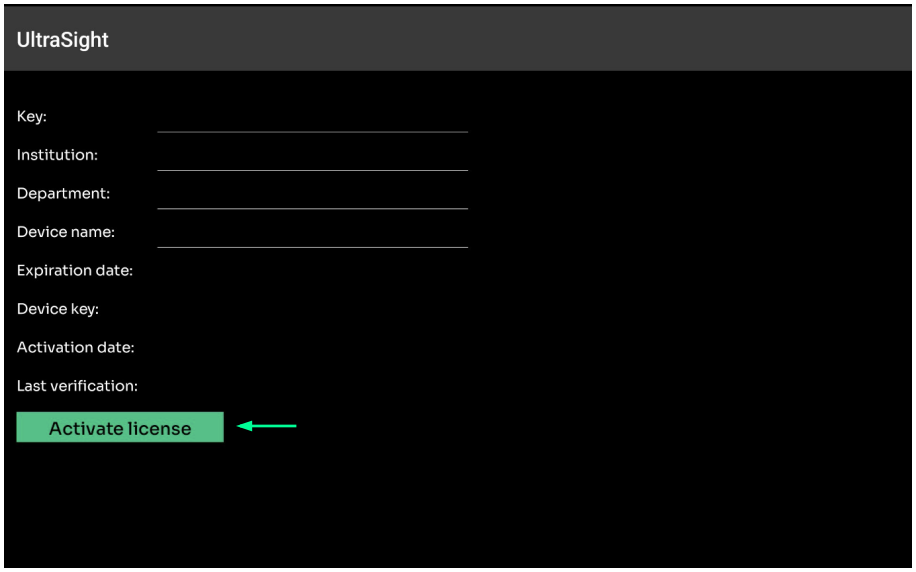


Figure 3-6. UltraSight activation key screen: Activate license

2. Fill the required fields.
3. Tap **Activate license** .

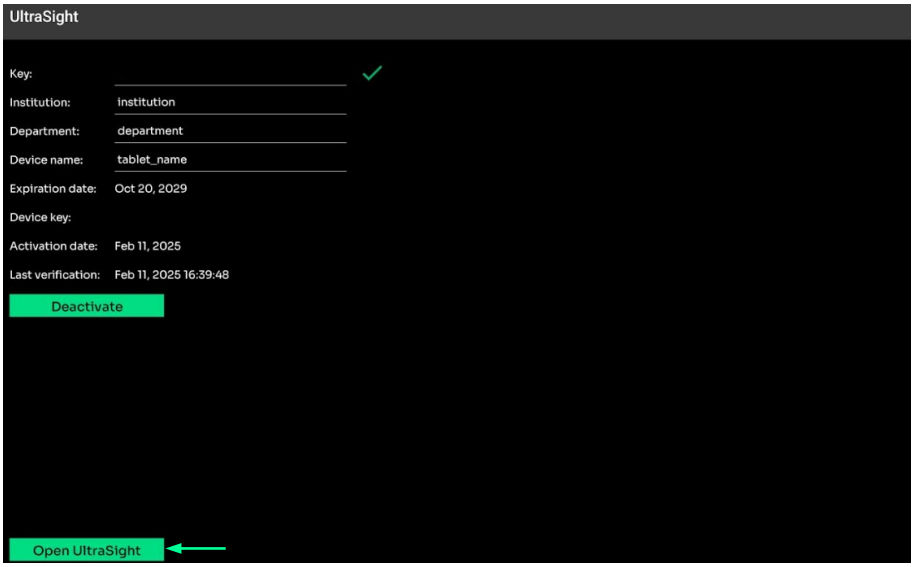


Figure 3-7. UltraSight activation key screen: Open UltraSight

4. Tap **Open UltraSight** .

> ***Notes***
>
> Launching the UltraSight Guidance application automatically opens the basic ultrasound operating application, if it is not already open, with the UltraSight software overlay.
>
> The UltraSight Guidance user interface appears differently depending on the hosting Ultrasound device.

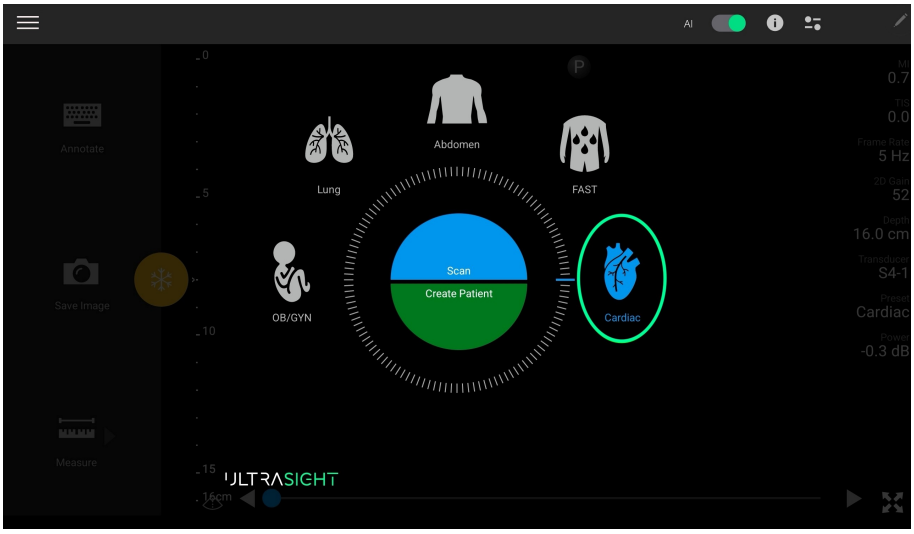


Figure 3-8. Main screen

3.4.2 Functional Check

Purpose:
To ensure correct installation and configuration of the UltraSight application within the managed device environment (MDM).

Functional Check Procedure:

1. **Verify Lumify Transducer Functionality**
   a. Confirm that the Lumify transducer operates as expected by following the steps outlined in the *Philips Lumify User Manual*, Testing Transducers section.

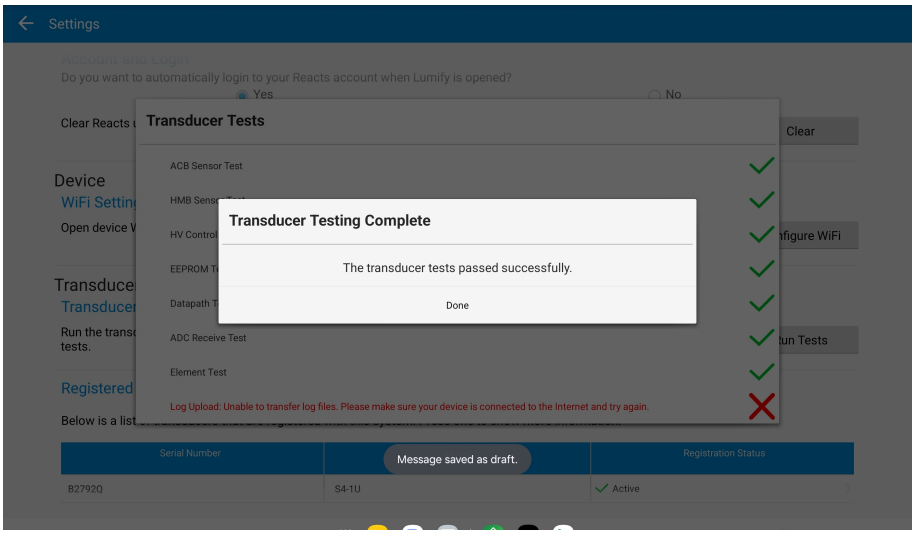


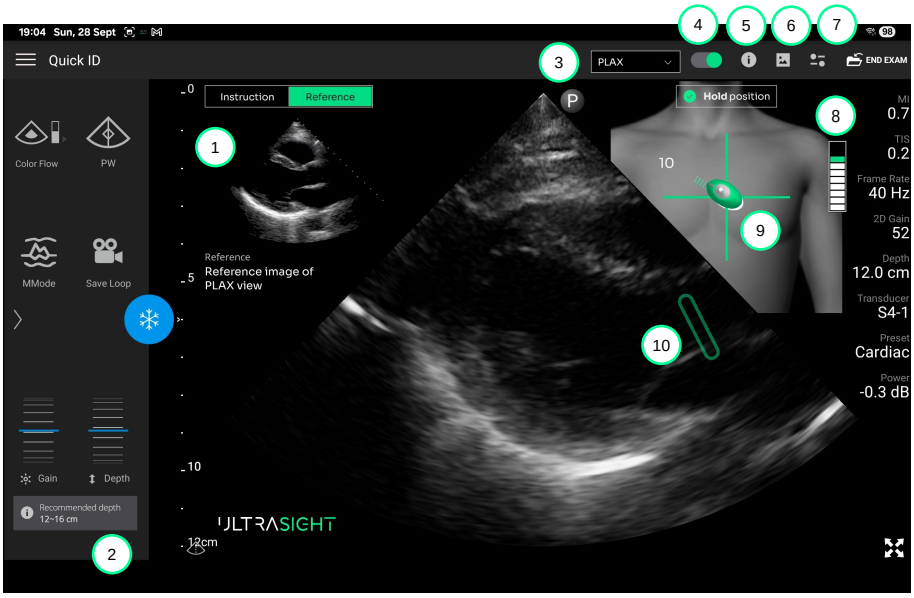
Figure 3-9. Philips Lumify Transducer Testing screen

2. **Verify UltraSight Application Operation**
   a. Open the **UltraSight** app and confirm that it launches **without notifications or restrictions from the MDM (Mobile Device Management) system**, such as:
      i. *"Your IT Administrator has restricted access to System UI."*
      ii. *"Your administrator is blocking screen recording."*
      iii. *"There is a problem with results processing."*
   b. These unexpected messages may indicate that MDM settings are inhibiting functionality.
   c. Select **Cardiac → "Start Scan"** and confirm that **UltraSight guidance activates as expected** (e.g., the **guidance UI** appears in the **top right corner** of the screen).

Next Step (Recommendation):
Each site is encouraged to perform an optional **end-to-end workflow confirmation** in a test or sandbox environment (EHR and PACS) prior to go-live. This ensures that data routing, storage, and system behavior align with institutional configurations and expectations.

3.5 The UltraSight Guidance Application

The UltraSight application has the following displays and functions.



1.	Static guidance: Instructions / Reference image	6.	Clip icon - review saved loops
2.	Static guidance: Recommended depth	7.	Main menu
3.	View selection menu	8.	Quality bar
4.	Guidance master switch	9.	Active real-time guidance
5.	Tutorial button	10.	Impella Inlet and Aortic Annulus markings

Figure 3-10. Guidance screen

For a detailed description of the various buttons, refer to the UltraSight Guidance User Manual.

3.6 The PVAD IQ Software

When launching the PVAD IQ software, the Saved exams table is displayed.

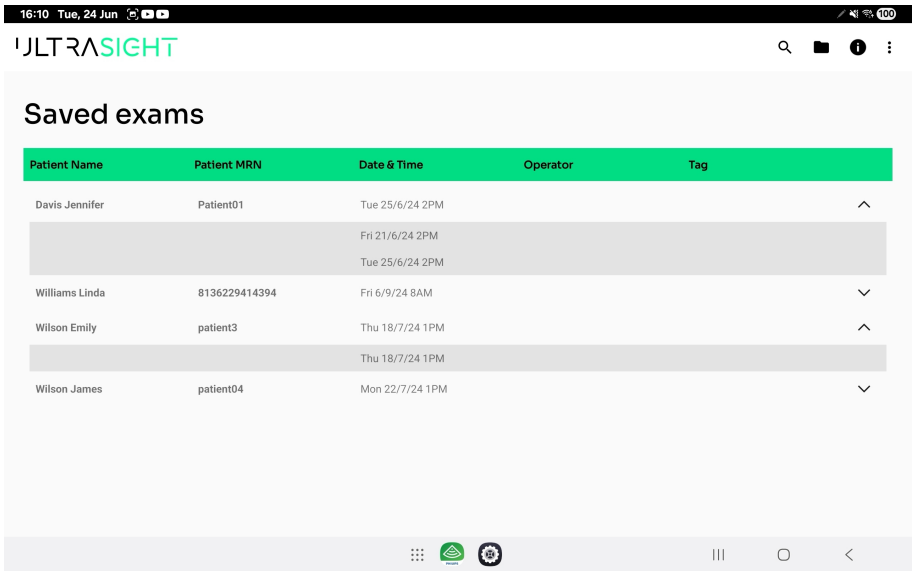


Figure 3-11. Saved exams table

The table lists patients by Patient Name, MRN, Date & Time of the performed echo exams, and the operator who performed the exam.

Selecting a particular exam opens the “Exam Viewer” screen.

For a detailed description of the various buttons on the Saved exams screen, refer to the PVAD IQ software User Manual.

Chapter 4
ULTRASIGHT FOR IMPELLA
Workflow

4.1 Launching the Application

1. Tap the **UltraSight** application icon on your device.

   The “Start recording” window appears.

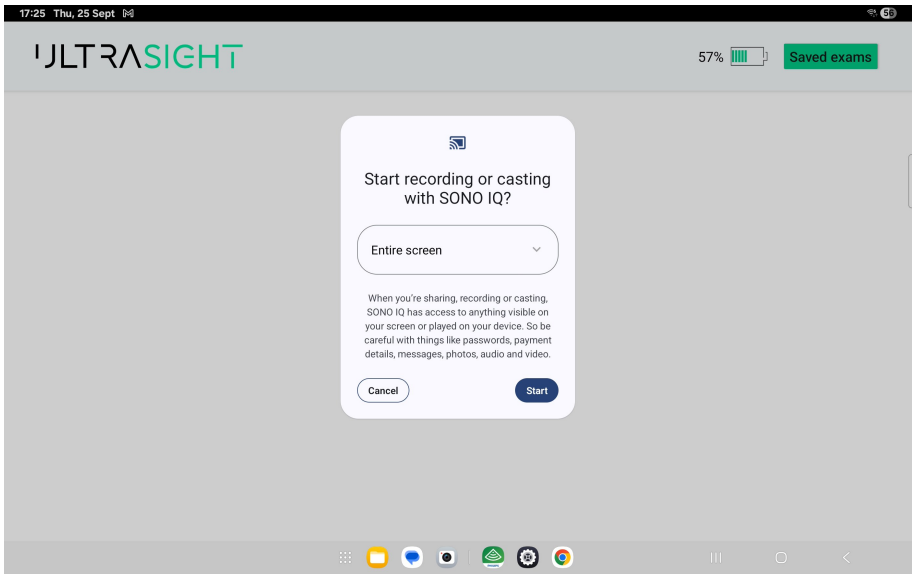


Figure 4-1. Start recording window

   The UltraSight Guidance application uses the screen recording capability of the tablet’s Android OS to capture the stream of images from the ultrasound system. This requires screen recording permissions from the Android OS

2. Select **Entire screen** from the drop-down list.
3. Tap **Start**.

   The “Connect ultrasound probe to start exam” screen is displayed.

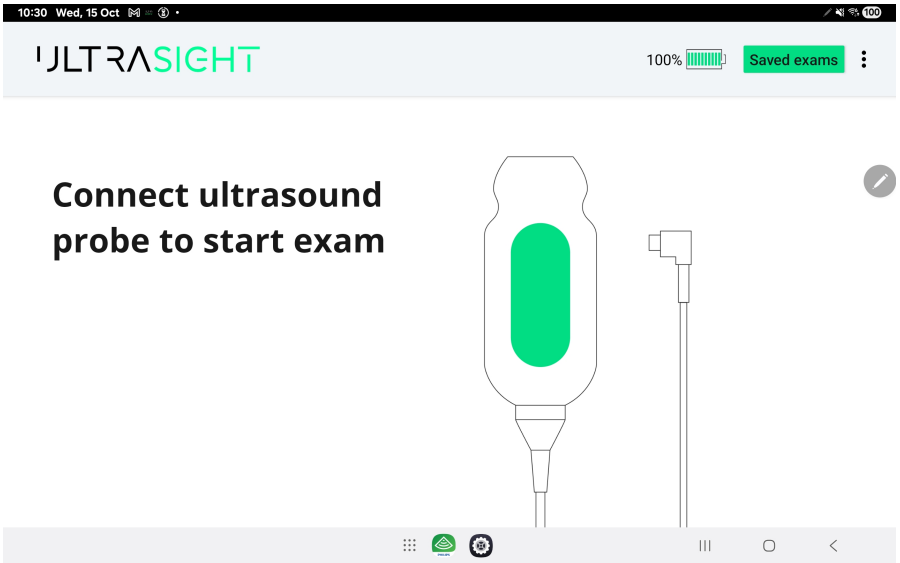


Figure 4-2. Connect the ultrasound probe

4. Connect the ultrasound probe.
   If this is the first time the probe is connected to the tablet you might see a pop up **"Open Lumify to handle PiUSB "**, click OK. The Lumify application might require registering the probe with Philips.

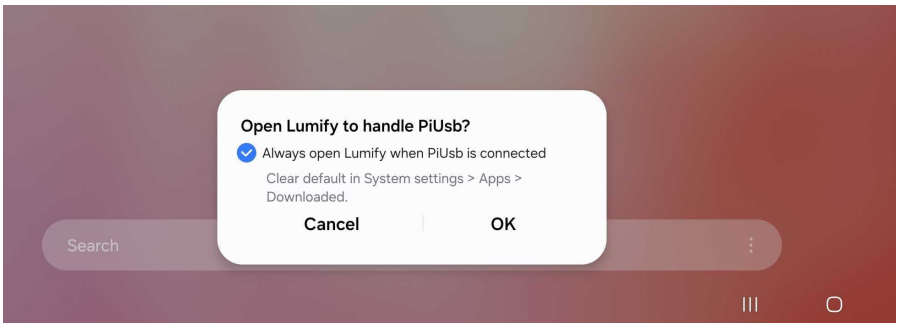


Figure 4-3. Open Lumify to handle PiUsb

5. The Lumify screen and the UltraSight Guidance main screens are displayed momentarily.

   The Add Impella Serial Number screen is displayed.

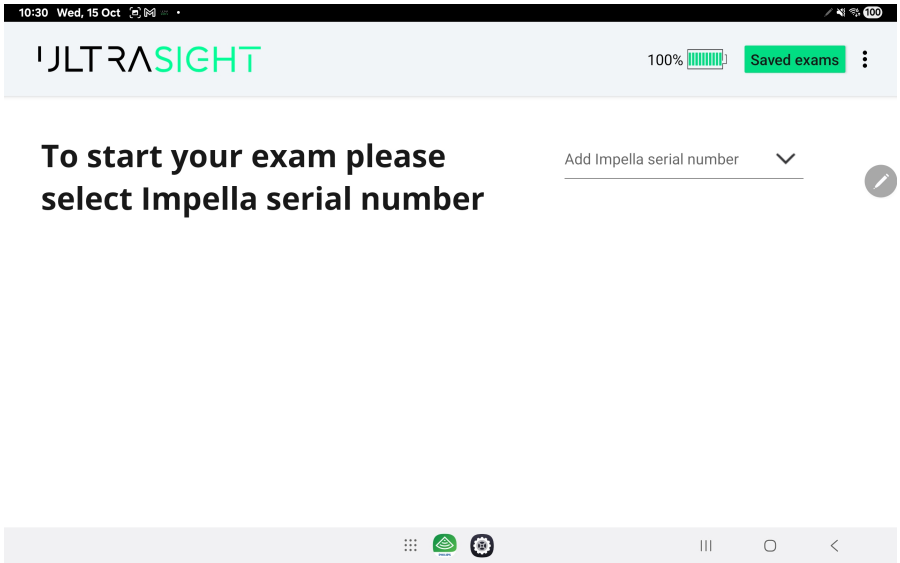


Figure 4-3. Add the Impella Serial Number screen

6. Add the **Impella Serial Number** to start an exam, as follows:
   - Select from the drop-down list.

     Or
   - Type the Impella Serial Number.

     The **Impella Serial Number** can be found on the top left corner of the AIC (Automated Impella Controller) screen.

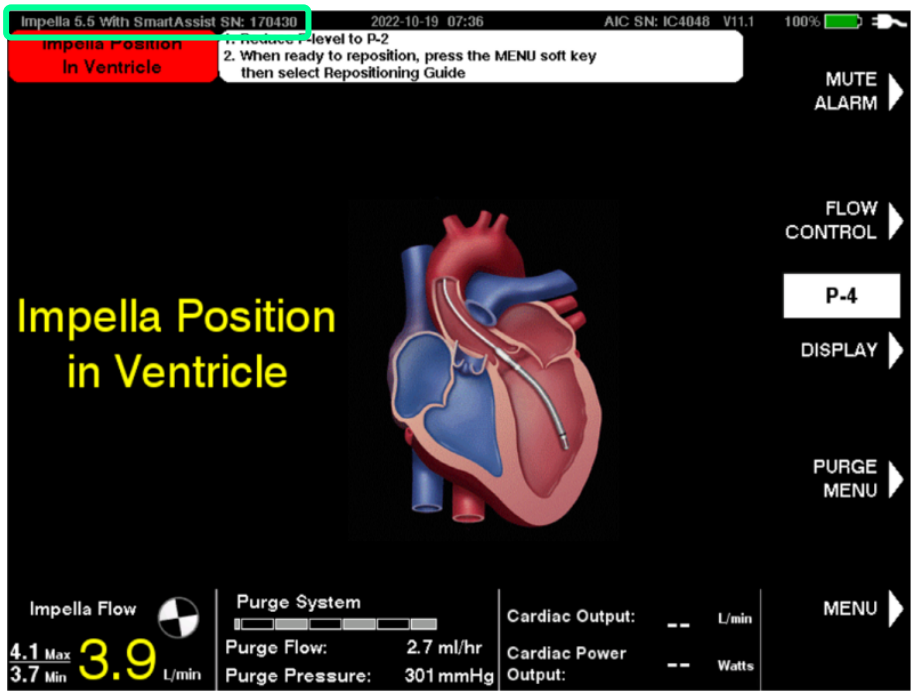


Figure 4-5. Impella Serial Number on the AIC screen

If the serial number is not already in the system, a message "**Impella Serial Number doesn't exist**" is written (in red), and the user can select "To Start exam and add manually".

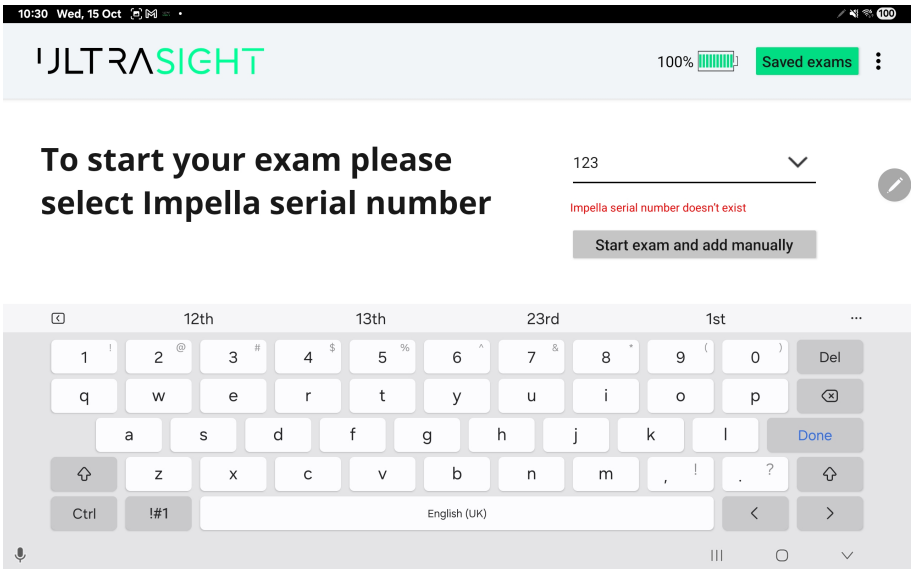


Figure 4-4. Start exam and add manually

4.2 Starting an Exam

Starting an exam requires selecting the correct Impella serial number.

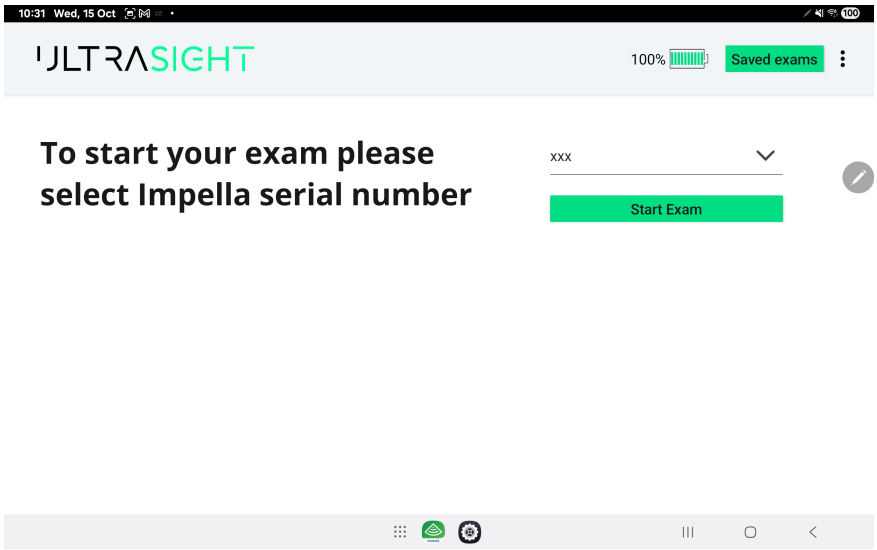


Figure 4-7. Start Exam screen

1. Tap **Start Exam** .

   The Guidance screen appears (see Figure 3-8).
2. Tap **Create Patient** on the Lumify application screen.

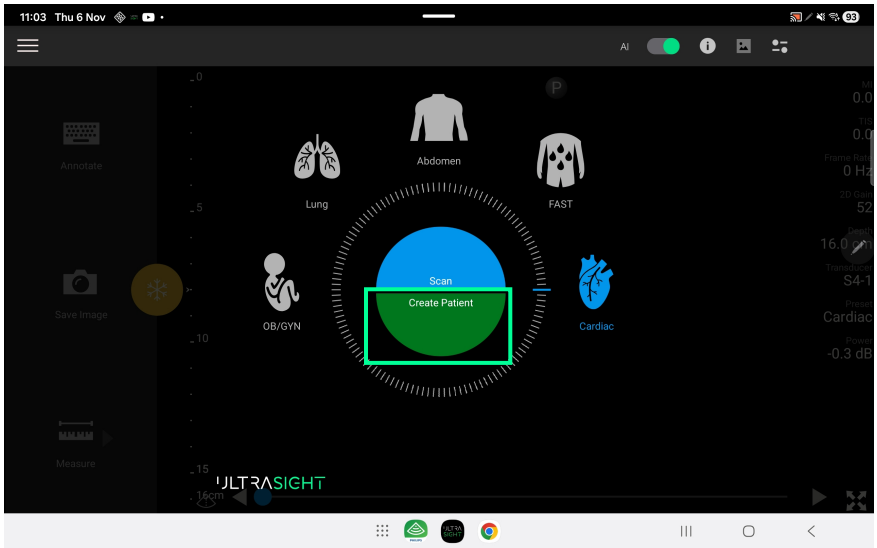


Figure 4-8. Lumify screen (Create Patient)

3. Enter the patient details in the **Patient Info** screen. Click **START EXAM** when done.

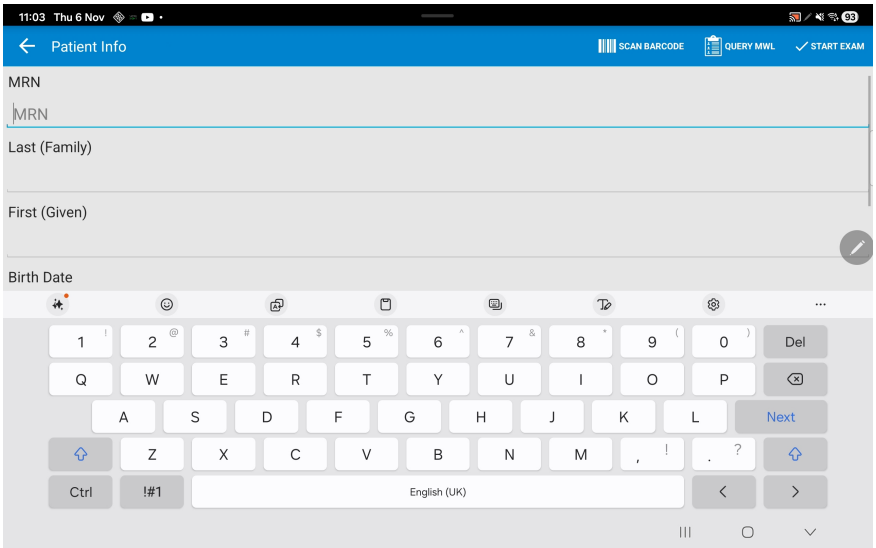


Figure 4-9. Patient Info screen

4. The Approve Impella serial number screen is displayed.

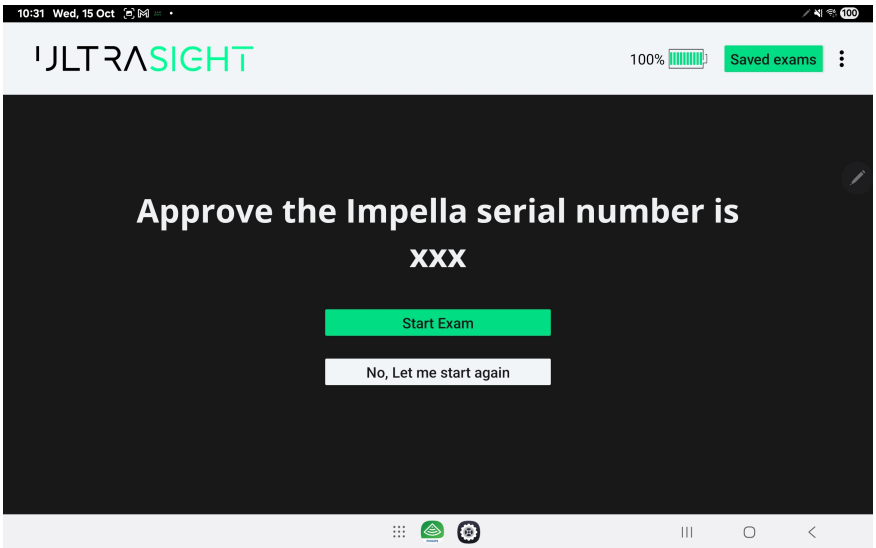


Figure 4-10. Approve Impella serial number screen

5. Tap **Start Exam**.

4.3 Performing an Exam

For detailed instructions on using the UltraSight Guidance software to perform an exam, see the UltraSight Guidance User Manual.

1. Begin the exam with the guidance of the **Instructions** for initial probe placement on the patient's chest.

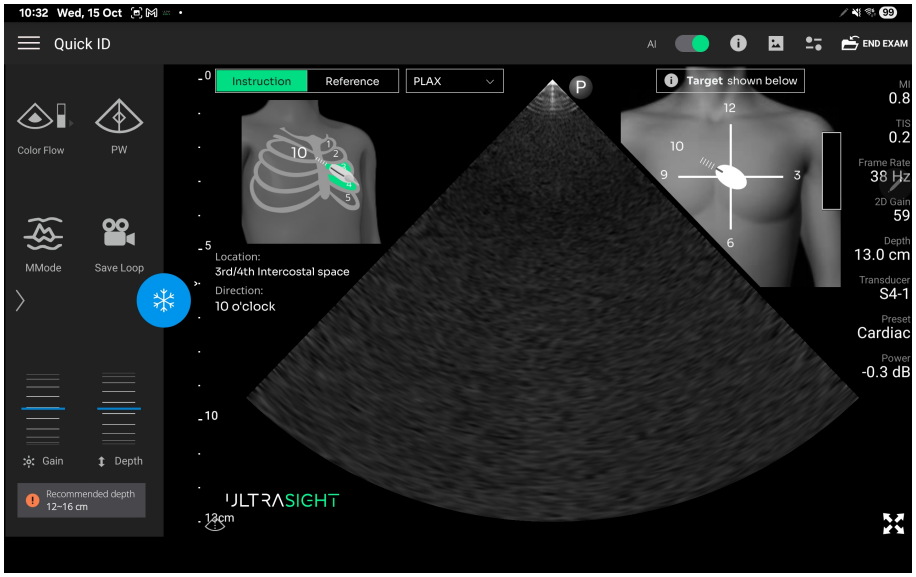


Figure 4-11. Guidance instructions

2. Select the cardiac **View** from the drop-down list.

   PLAX (Parasternal Long Axis) view will show markings for the Aortic Annulus and the Impella inlet, while Apical 3, 4, and 5 chambers will only show the guidance and quality indications.

3. Continue the exam in **Reference** mode, which provides the image of the selected cardiac view for a better visual reference.

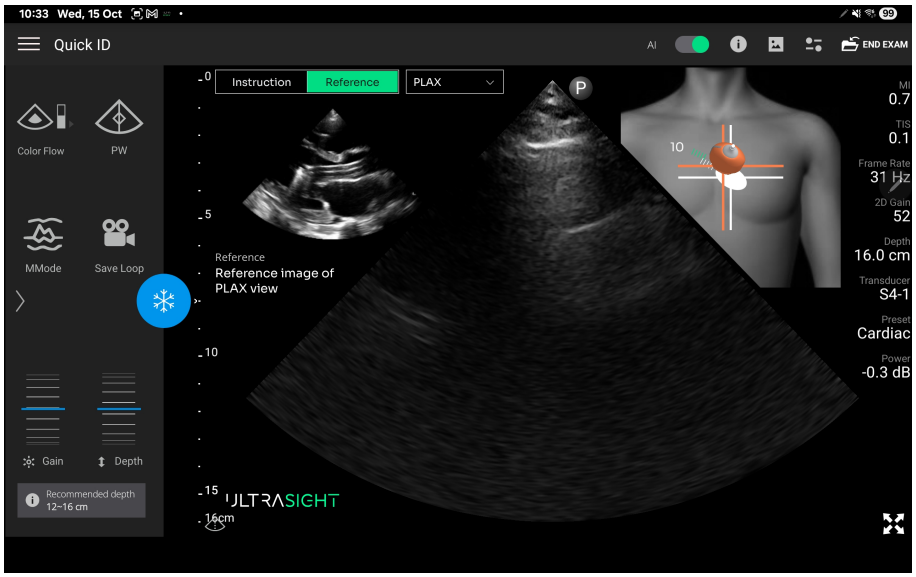


Figure 4-12. Reference mode

4. Follow the on-screen Guidance cues until the Guidance parameters are positive (probe tail and image crosshairs are green) and the Quality bar is green.

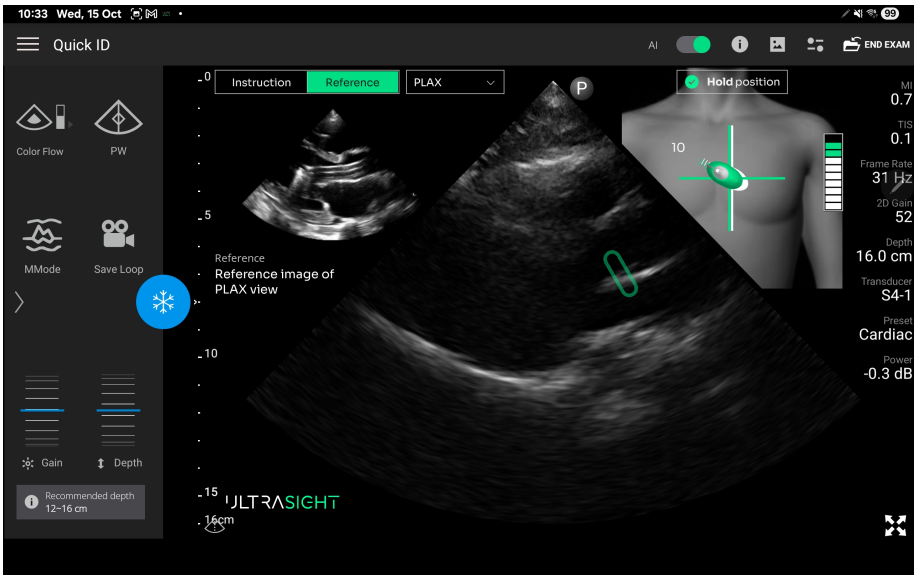


Figure 4-13. Reference mode

The Guidance cues and Quality bar disappear when the:

- PLAX is visible, and the average quality bar over the last 4 seconds is at least 7 bars.
- The Aortic annulus is visible at least 70% of the time during the last 4 seconds.

When this is achieved, the additional "**Impella**" tab is added to the static Guidance instructions side, the reference image is PLAX with landmarks, and a message appears notifying the user that the Guidance cues and Quality bar are hidden at this stage.

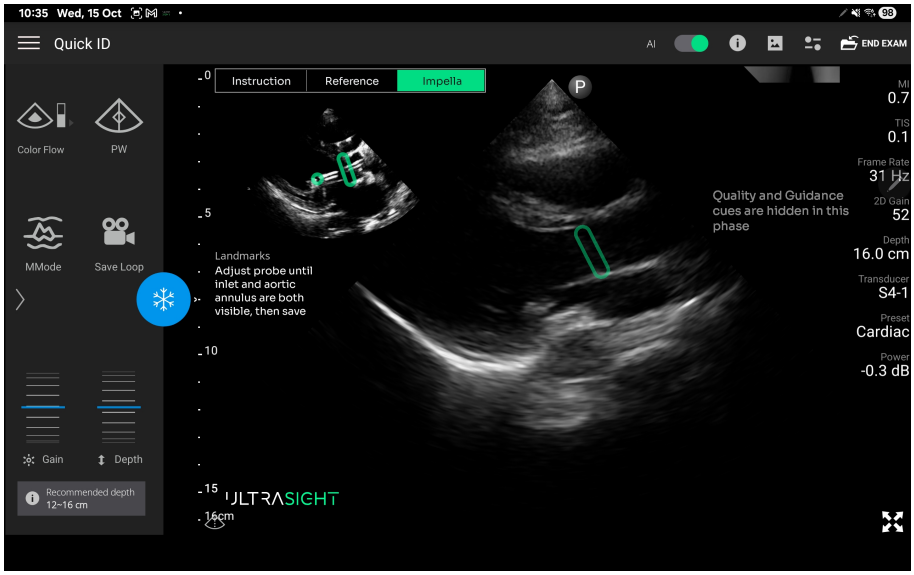


Figure 4-14. Impella mode (with message)

After a couple of seconds, the message that the Guidance cues and Quality bar are hidden disappears.

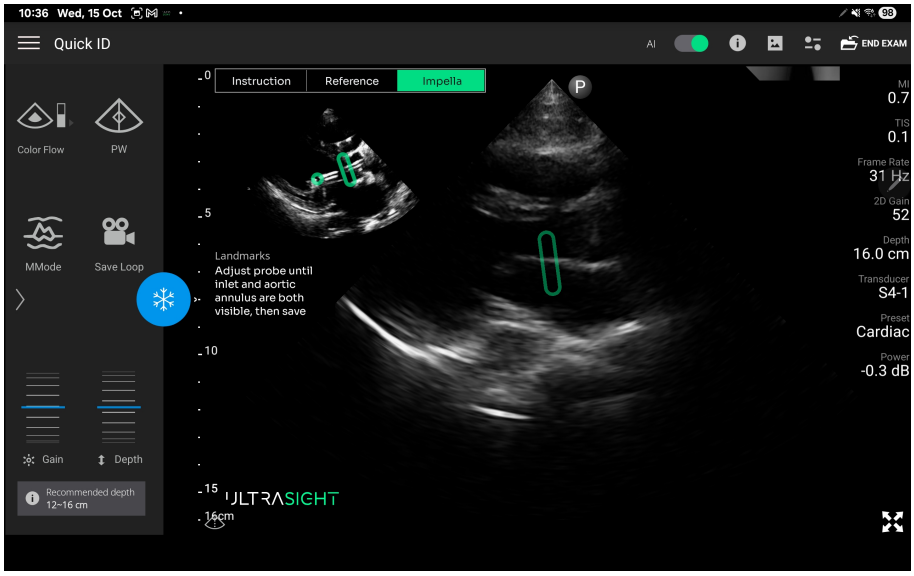


Figure 4-15. Impella mode (with out message)

The Guidance cues and Quality bar will be visible again when the Aortic annulus is not visible in 90% of the last 4 seconds.

5. If required, change the probe orientation to achieve a good view of the two green marks of the Impella device inlet and the aortic annulus in the ultrasound clip.

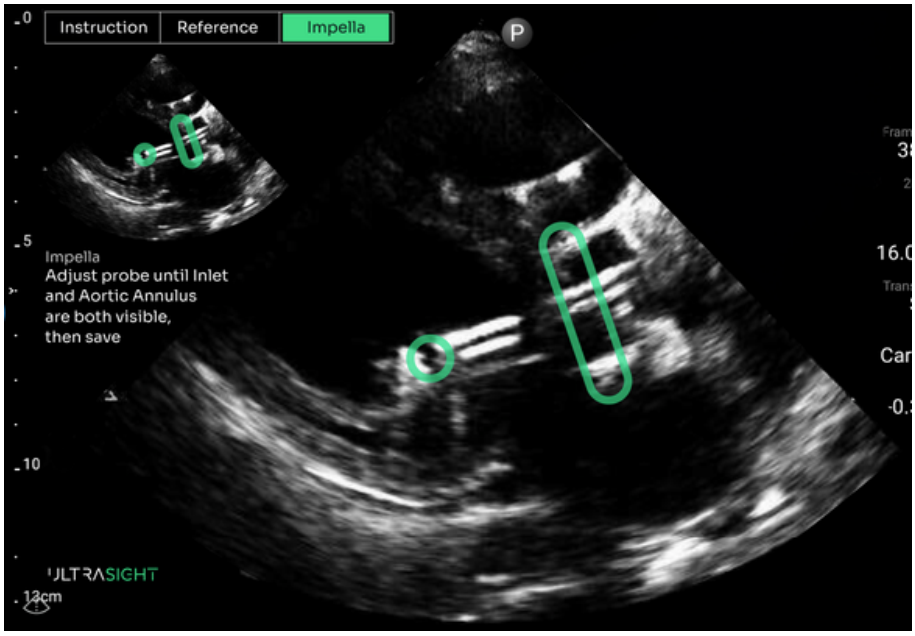


Figure 4-16. Impella Inlet and Aortic Annulus markings

6. Tap the **Save Loop** icon on the Lumify user interface to save the media (clip duration is set within the Lumify user interface).
   a. Once the application identifies that the new DICOM file has been saved, it checks that the file has sufficient PLAX quality. If it does, it runs the inlet and annulus distance detection algorithm and shows a progress indicator in the top right corner of the viewer icon.
   b. Once the clip distance is available, the application will show the distance for 3 seconds on the top bar, and the **Clip** button color will change to green. If the algorithm could not find the inlet-annulus distance, a “Distance not found” message will appear on the top bar.
7. To review the saved clip, click on the **Clip** button, which opens the PVAD IQ component for the recently saved clip. For detailed instructions on using the PVAD IQ software to review exams, see the PVAD IQ User Manual.
8. Continue acquiring all the required cardiac views.
9. When complete, tap the **END EXAM** icon to end and **save** all the acquired views.

   The “End Current exam” window appears.

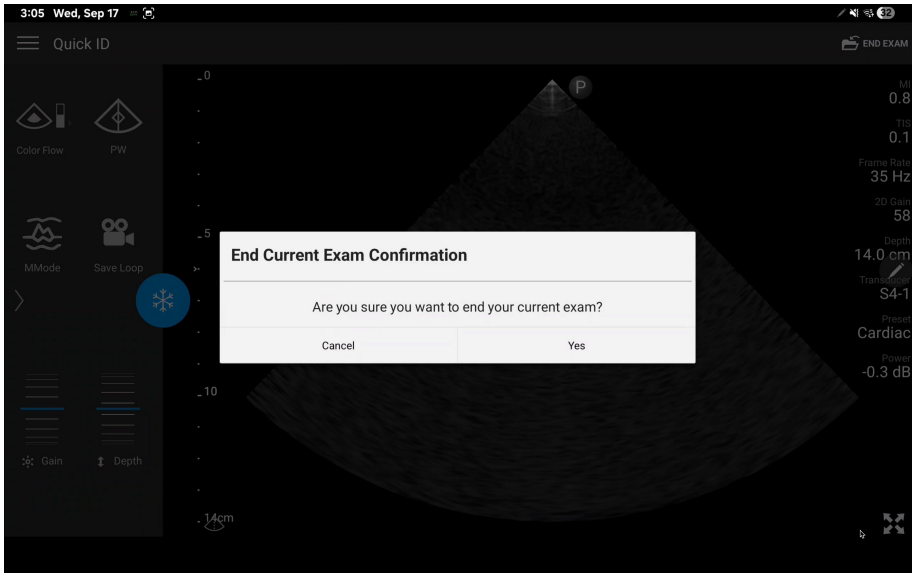


Figure 4-17. End Current Exam Confirmation window

10. Tap **Yes** to end the current exam.

    The exam is saved, and the “Connect to power source” screen is displayed.

11. To review the saved exams, click on the **Saved Exams** button, which opens the PVAD IQ component. For detailed instructions on using the PVAD IQ software to review exams, see the PVAD IQ User Manual.

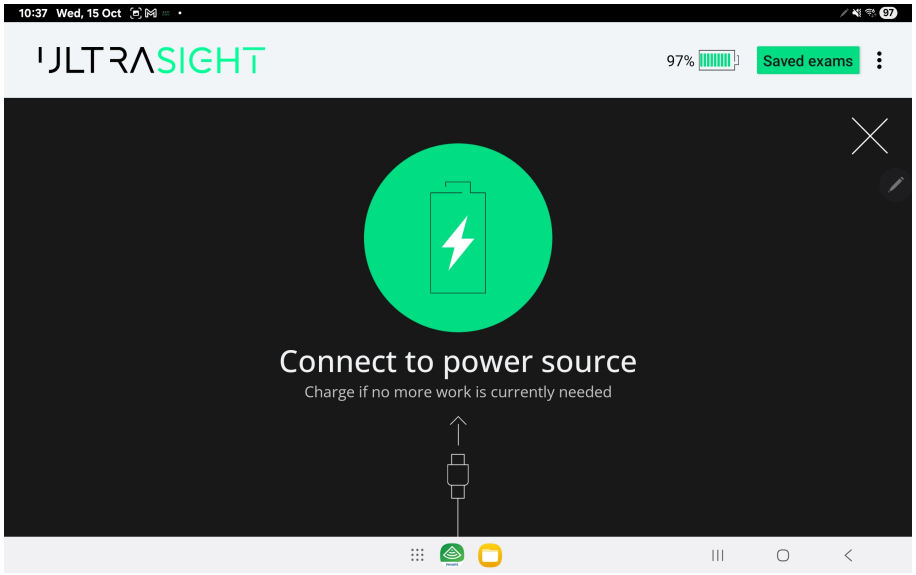


Figure 4-18. Connect to power source screen

12. If the work is completed and no further work is required, charge the tablet.

Chapter 5
Appendices

Appendix A. Configuring Lumify

1.1. Configuring the Export Destination

1. Tap the Lumify Menu icon (upper left corner) and select **Export Destination** from the Lumify menu.

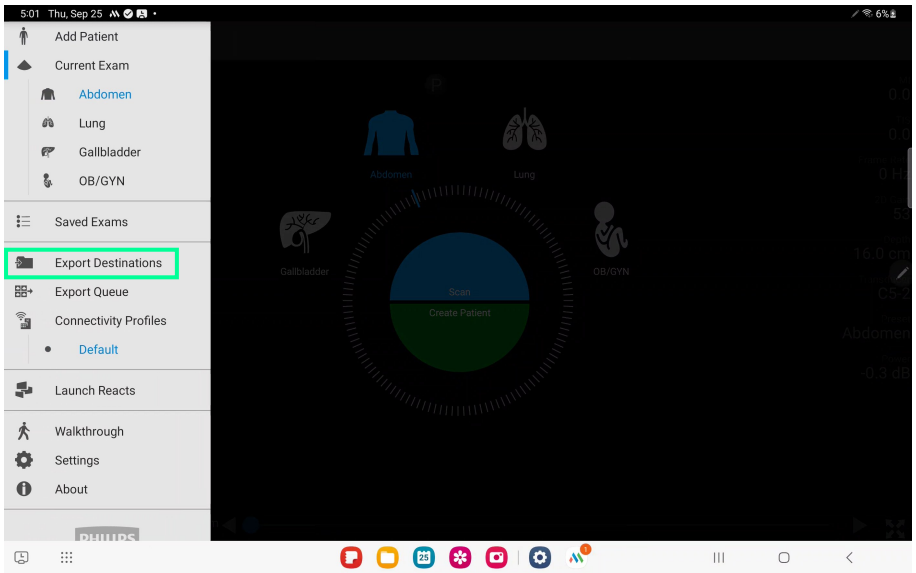


Figure 5-1. Lumify menu (Export Destination)

The Add New Destination dialog box opens.

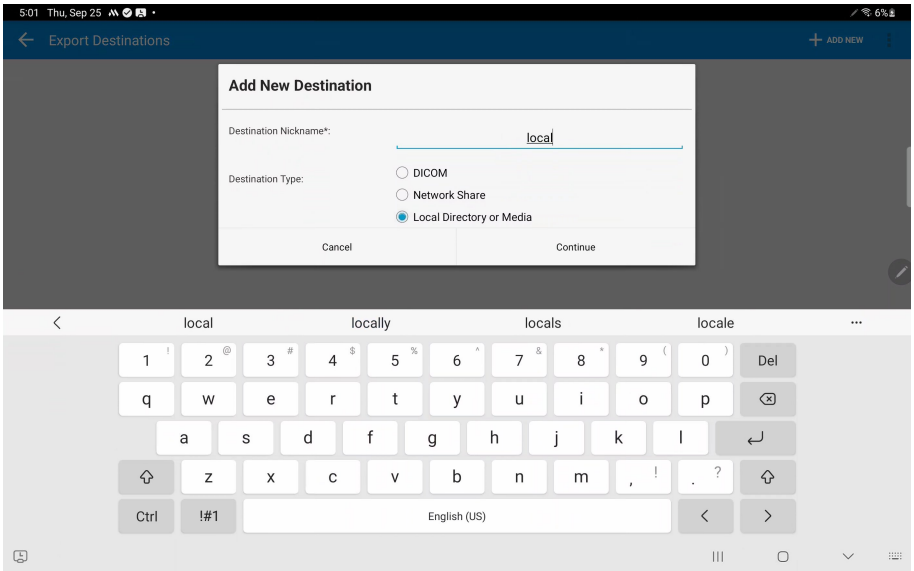


Figure 5-2. Add New Destination dialog box

a. Tap the **Destination Nickname** field and use the virtual keyboard to type a name (e.g., local).

b. Mark the **Local Directory or Media** radio button.

2. Tap **Continue**.

   The **local** dialog box opens.

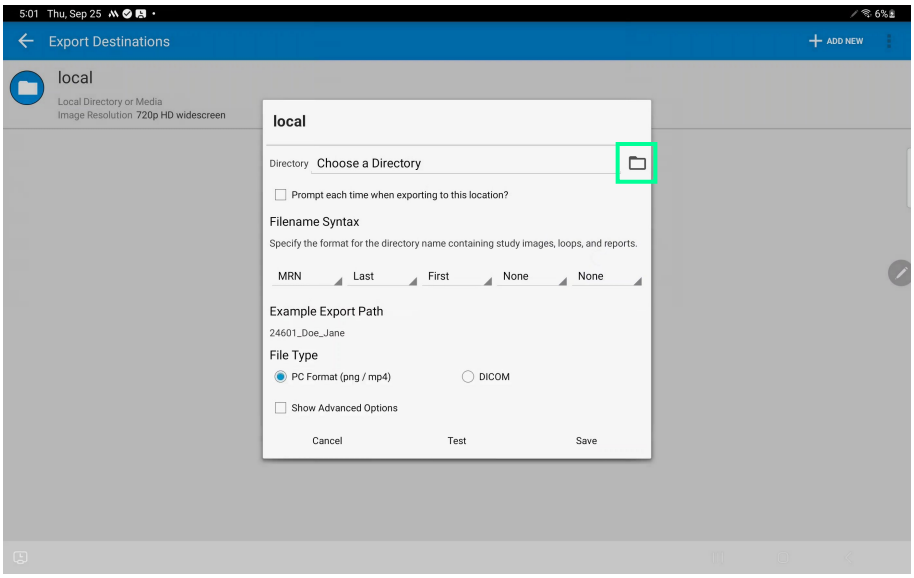


Figure 5-3. Local dialog box

3. Tap the Directory icon.

   The folders screen opens.

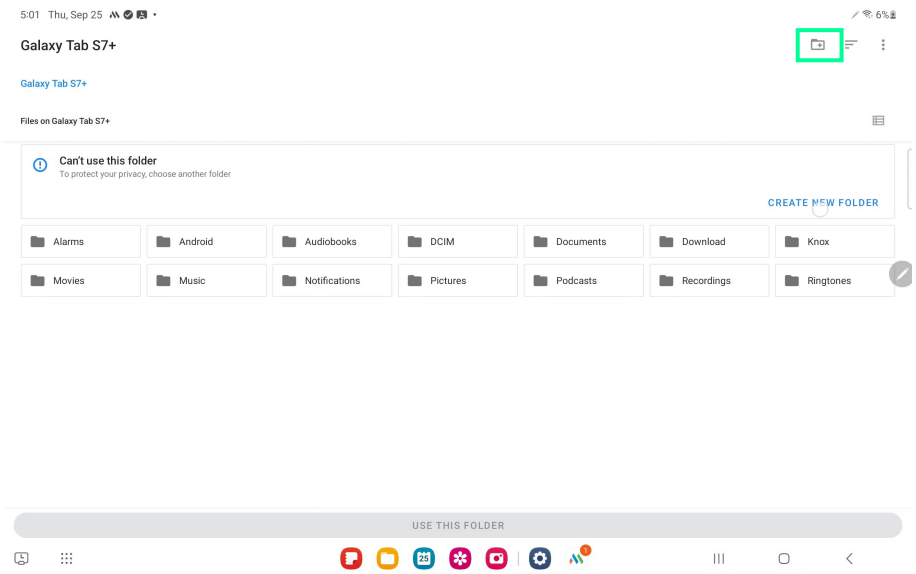


Figure 5-4. Folders screen

4. Tap **Create New Folder icon** .

   The New folder dialog box opens.

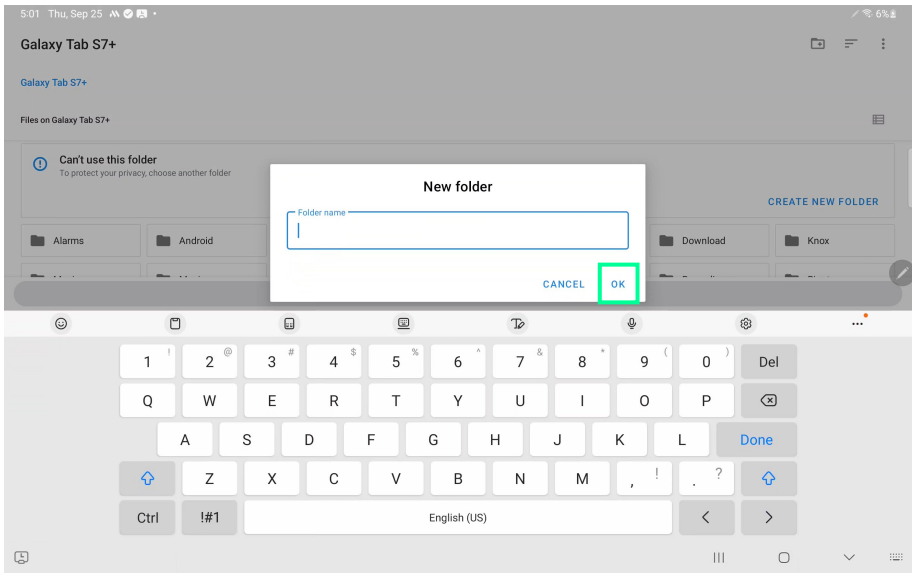


Figure 5-5. New folder dialog box

5. Type a Folder name (e.g., Impella) and tap **OK**.

   The created folder opens.

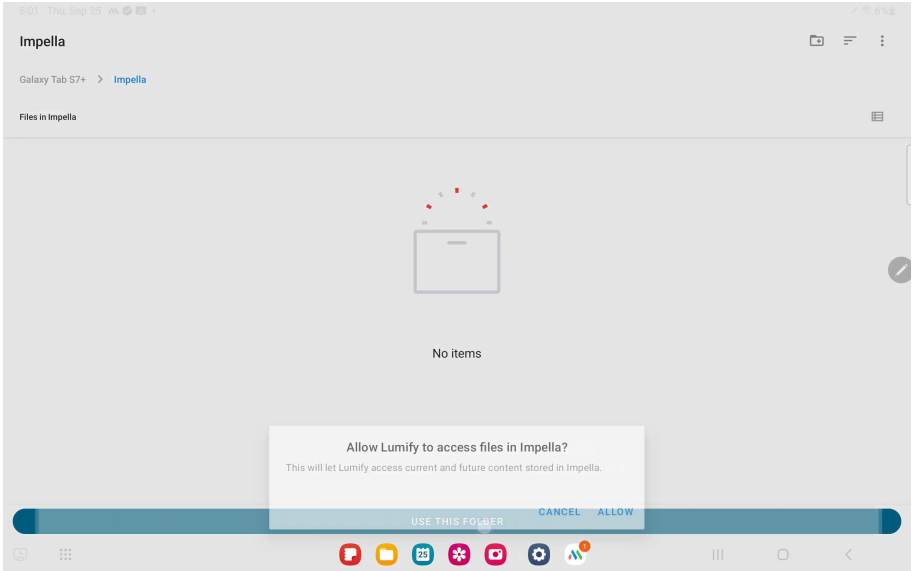


Figure 5-6. Created folder

6. Tap the **Use this Folder** line at the bottom of the screen and tap **Allow** on the “Allow Lumify to access files in Impella” message.

   The **local** dialog box opens (see Figure 5-3).

7. Ensure the **Prompt each time when exporting to this location** checkbox is not marked.

8. Configure the **Filename Syntax** .

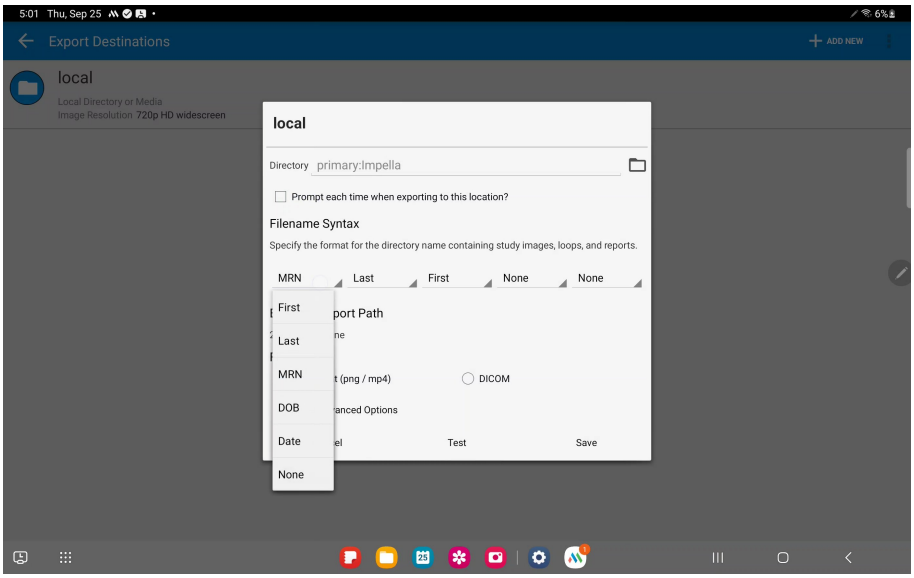


Figure 5-7. Filename Syntax

a. Tap the first part of the file name and select **Date**.

b. Tap the second part of the file name and select **MRN**.

c. Tap the third part of the file name and select **None**.

9. Select the **File Type** as **DICOM**.

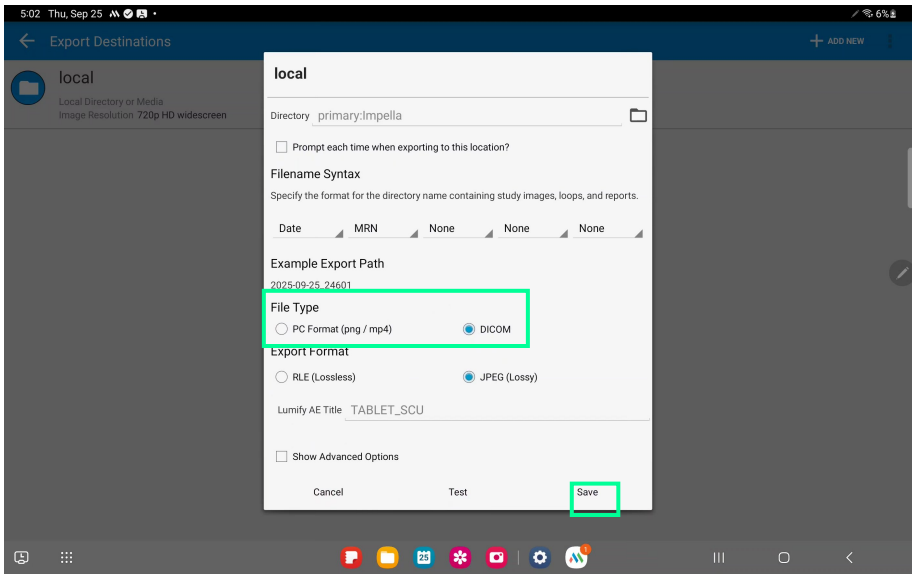


Figure 5-8. File Type (DICOM)

10. Tap the **Lumify AE Title** field and use the virtual keyboard to type a title (e.g., “tablet”), then tap **Save**.

    A Warning message appears. Read it and tap **Okay**.

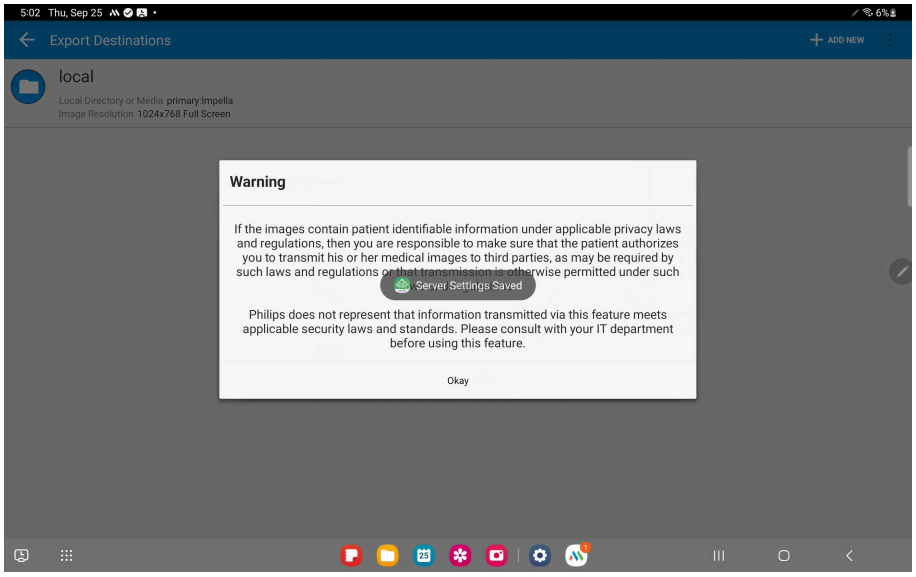


Figure 5-9. Warning message

    The Server Settings are Saved.

11. Tap the left arrow in the upper left corner of the screen (Export Destinations) to return to the Lumify main screen.

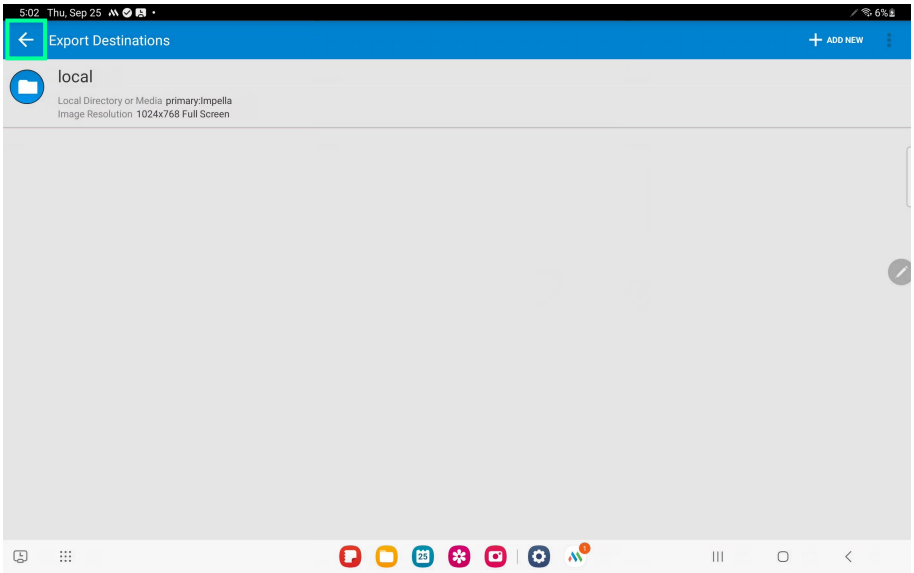


Figure 5-10. Return arrow

1.2. Configuring the Connectivity Default Profile

1. Tap the Lumify menu icon and select **Connectivity Default Profiles**.

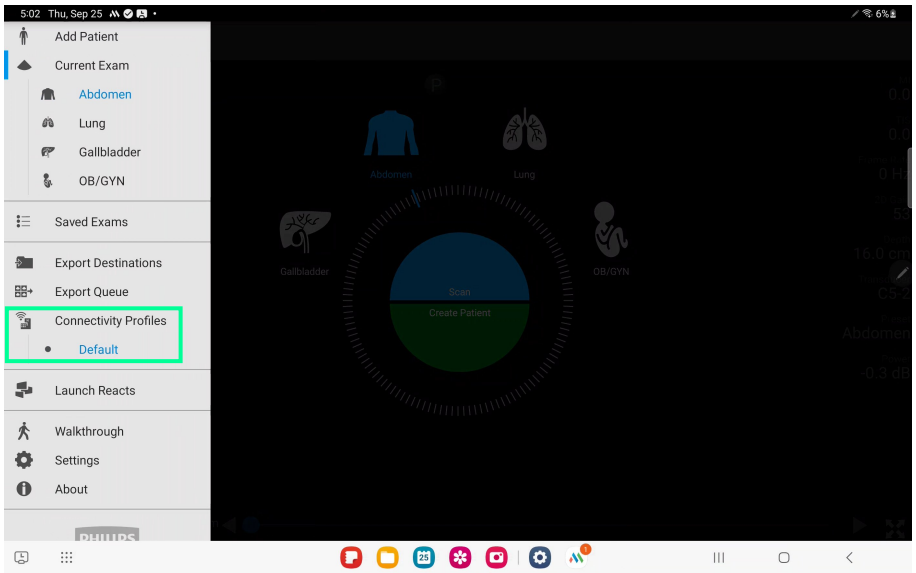


Figure 5-11. Lumify menu (Connectivity Profiles)

The Connectivity Profiles Window opens.

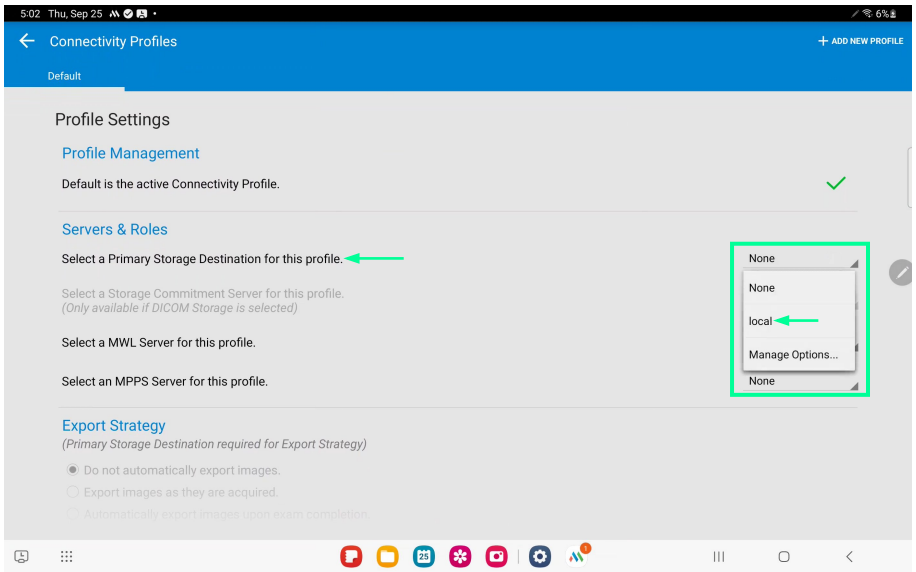


Figure 5-12. Connectivity Profiles (Server & Roles)

2. Tap the arrow for the “Select a Primary Storage Destination for this profile” line and select **local**.
3. Scroll down, select the **Export images as they are acquired** radio button, and tap **Save**.

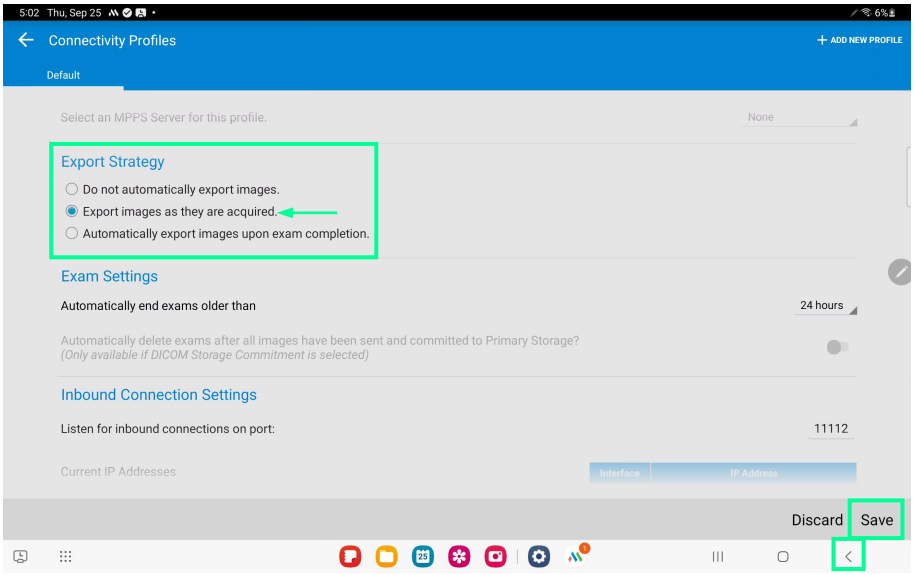


Figure 5-13. Export Strategy

4. Tap the return < arrow in the bottom right corner of the screen. The Lumify main screen is displayed.

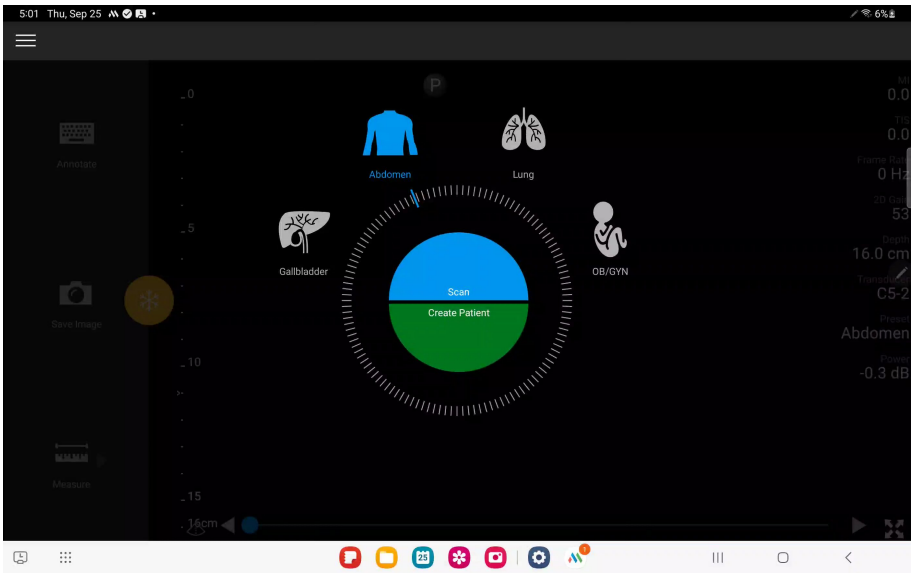


Figure 5-14. Lumify main screen

5. Go to section 3.3 for launching the ULTRASIGHT FOR IMPELLA application.

ULTRASIGHT

UltraSight Ltd.
UM-0003

September 2025

Email: Info@ultrasight.com
Info: https://www.ultrasight.com/