Hillrom™

Welch Allyn® iExaminer™ Pro

Welch Allyn iExaminer Pro app

238-3 Welch Allyn MacroView Plus Otoscope

118-3 Welch Allyn PanOptic Plus Ophthalmoscope

118-3-US Welch Allyn PanOptic Plus Ophthalmoscope

11840-IEX Welch Allyn SmartBracket Assembly

11840-IEX-US Welch Allyn SmartBracket Assembly

Instructions for use

Software version 4.0.x for iOS

Professional use only

℞ ONLY

Mode of operation: Refer to appropriate heads IFU

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Welch Allyn Technical Support
https://hillrom.com/en-us/about-us/locations

Notice to Users and/or Patients in EU: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

901161 iEXAMINER PRO SW APP iOS

REF 80028340 Ver. F, Revision date 2023-03

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Device description

The iExaminer application is equivalent to the Welch Allyn iExaminer Pro app.

The iExaminer System with PanOptic Plus consists of PanOptic Plus, SmartBracket, SmartClip, iExaminer Application, one of the following: iPhone X, iPhone 11 Pro, iPhone 11 Pro Max, iPhone 12 Pro), and a case that meets the "Smartphone and case selection guidelines".

The iExaminer System with MacroView Plus consists of MacroView Plus, SmartBracket, SmartClip, iExaminer Application, and a smartphone with case that meets the "Smartphone and case selection guidelines".

Intended use

iExaminer application

The iExaminer application with the appropriate Welch Allyn devices is intended to be used by clinicians and medically qualified personnel to capture and send images on pediatric and adult patients.

The intended use environments for the iExaminer application are professional healthcare facility environments such as general physician's offices, hospitals, specialist, urgent care, clinics, and clinical environment training.

iExaminer system with PanOptic Plus in the U.S.

The iExaminer system with PanOptic Plus is intended to take photographs of the eye and surrounding area.

The intended use environments for the iExaminer system with PanOptic Plus include physician's offices, hospitals, specialty medical offices, urgent care facilities, and clinical training facilities.

Intended users include licensed healthcare professionals trained to use an ophthalmoscope (or trainees under their supervision). The intended patient populations are pediatric and adults.

Indications for use

The iExaminer system with PanOptic Plus, consisting of PanOptic Plus, SmartBracket, SmartClip, iExaminer application, and one of the following: iPhone X, iPhone 11 Pro, iPhone 11 Pro Max, iPhone 12 Pro, is intended to be used to capture images as an aid to clinicians in the evaluation, and documentation of ocular health. The images from the iExaminer System with PanOptic Plus are not intended to be used as a sole means of diagnosis.

iExaminer system with PanOptic Plus outside the U.S.

The iExaminer System with PanOptic Plus is intended to be used by clinicians and medically qualified personnel to capture and send images of the eye on pediatric and adult patients.

The intended use environments for the iExaminer System with PanOptic Plus are professional

healthcare facility environments such as general physician's offices, hospitals, specialist, urgent care, clinics, and clinical environment training.

iExaminer system with MacroView Plus

The iExaminer System with MacroView Plus is intended to be used by clinicians and medically qualified personnel to capture and send images of the external ear, ear canal, and tympanic membrane on pediatric and adult patients.

The intended use environments for the iExaminer System with MacroView Plus are professional healthcare facility environments such as general physician's offices, hospitals, specialist, urgent care, clinics, and clinical environment training.

NOTE Use the smartphone only in environments consistent with the manufacturer's recommendations.

Contraindications

The iExaminer System with MacroView Plus is not intended to be used to examine the eye.

There are no contraindications for the iExaminer app. See the appropriate Welch Allyn device IFU.

Performance characteristics

See the appropriate Welch Allyn device IFU.

Symbols definitions

For information on the origin of these symbols, see the Welch Allyn symbols glossary: welchallyn.com/symbolsglossary.

WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. Warning symbols will appear with a gray background in a black and white document.

CAUTION The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.

NOTE Presents clarification about an instruction or helpful information about a feature or behavior.

7d hillrom.com — Consult instructions for use (IFU). A copy of the IFU is available on this website. A printed copy of the IFU can be ordered from Hillrom for delivery within 7 calendar days.

℞ ONLY — Prescription only or "For Use by or on the order of a licensed medical professional"

REF — Reorder number

— Product Identifier

UDI — Unique device identifier

Manufacturer

Date of manufacture

Warnings and Cautions

WARNING Always use the iExaminer application when sending images or patient files. Do not send patient images from the camera roll to prevent associating patient images incorrectly. Limit use of the camera roll images to training and non-clinical uses only. See Device and patient data and security.

WARNING This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.

WARNING Patient injury risk – magnetic fields. Exercise caution when using a smartphone in close proximity to implanted devices such as, but not limited to, cranial implants, adjustable CSF shunts, and pacemakers.

WARNING The images from the iExaminer System with PanOptic Plus are not intended to be used as a sole means of diagnosis.

WARNING Do not use the iExaminer System with incompatible smartphone models.

CAUTION Evaluate images on the Welch Allyn iExaminer in adequate light. Image evaluation has not been tested in low-light conditions.

CAUTION To ensure your system is providing images of sufficient quality, test the assembly of your system. See Test the assembly.

NOTE See the appropriate Welch Allyn device IFUs for more Warnings and Cautions.

NOTE See the appropriate Welch Allyn device IFUs for information about light-related hazards associated with the system.

Residual risk

This product complies with relevant electro-magnetic interference, mechanical safety, performance, and biocompatibility standards. However, the product cannot completely eliminate potential patient or user harm from the following:

- Harm or device damage associated with electro-magnetic hazards,
- Harm from mechanical hazards,
- Harm from device, function, or parameter unavailability,
- Harm from misuse error, such as inadequate cleaning, and/or
- Harm from device exposure to biological triggers that may result in a severe systemic allergic reaction.

Device and patient data and security

Welch Allyn recommends enabling device level security. Users are responsible for the security of the smartphone.

The iExaminer application allows the user to share patient data, using email and cloud-based storage. When sharing patient data via email or cloud-based storage, it is essential that the user only share the data with other authorized users in accordance with HIPAA regulations. It is the user's sole responsibility to protect patient data. Users must verify patient identity before sending patient records.

To securely share patient data via email, the user must ensure the email application is configured to communicate securely to the email server using Transport Layer Security (TLS). Transport Layer Security (TLS) is cryptographic protocols designed to provide communications security over a computer network. The TLS aims primarily to provide privacy and data integrity between two or more communicating computer applications.

When setting up an email account (e.g. IMAP, POP), the user must select a security method that uses TLS/SSL. The iOS default mail application Mail, when used with the default iCloud email server, is already secured with TLS.

When sending patient data to cloud-based storage, it is essential that the cloud storage method be secured using TLS. In iOS, iCloud Drive is secured using TLS.

First-time use

Visit hillrom.com/getstarted for iExaminer Pro videos.

Confirm that you have completed the following:

1. Select a smartphone that meets the criteria in the Smartphone and case selection guidelines.
2. Download the iExaminer application from the App Store®.
3. If upgrading from a previous version that stored images, follow the instructions on the screen.
4. Select a usage mode.
   - Clinical mode is for use with patients. Exam data must be sent from the app after each exam. No exam data is stored on the phone.
   - Training mode is for training purposes only. By selecting this mode, practice exams can be stored for a user-specified time from 30 days to 180 days, after which you must delete the data from the app. No individually identifiable patient data or personal data should be stored in this mode. The default data retention period is 30 days for practice exams.
5. Agree to Terms and Conditions.
6. Set up app security and smartphone security. Review confidentiality recommendations. See Device and patient data and security.

7. See the **WELCH ALLYN IEXAMINER SMARTBRACKET STARTUP GUIDE** (included in the box) for initial setup. The back of the case must have an area without features or accessories that will inhibit installation of the SmartBracket and SmartClip.
8. Attach the Welch Allyn device to the SmartBracket.
9. Test the assembly of the system using the iExaminer Resolution Test Card (included). See Test the assembly.
10. See videos and other training materials on hillrom.com/getstarted to perform an exam.

NOTE iExaminer 4.0.x is compatible with iOS version 11 through version 15.

NOTE To switch modes, uninstall and reinstall the app. Any stored data will be erased when uninstalling the app.

Smartphone and case selection guidelines

Smartphone case

The back of the case must have an area without features or accessories that will inhibit installation of the SmartBracket and SmartClip. See the **WELCH ALLYN IEXAMINER SMARTBRACKET STARTUP GUIDE** (included in the box).

Smartphone criteria

In the U.S., use one of the following with the PanOptic Plus: iPhone X, iPhone 11 Pro, iPhone 11 Pro Max, iPhone 12 Pro.

For all other uses of the iExaminer system, use a smartphone that meets the criteria below.

- Size: The combined smartphone and case size less than 6.5in (165mm) in length, 3.3in (85mm) in width, and 0.5in (13mm) in thickness.
- Weight: The combined smartphone and case weight less than 9.8oz (280g).
- Optics: Most smartphone cameras with resolution greater than or equal to 8 MP will be acceptable. See Test the assembly on how to test your system.
- Display: A color display that is: ≥4.0in (101mm) screen size
- Hardware: ≥500 MB of internal storage
- Software: Supports JPEG images and is compatible with iOS version 11 through version 15.
- Electrical
  - The smartphone radiated emissions must comply with Part 15 of Title 47 of the Code of Federal Regulations (or equivalent)
  - The smartphone inductive charging must be Qi-certified (or equivalent)
  - The smartphone charging must comply with IEC/UL 60950-1 (or equivalent)
  - The smartphone inductive charging must be Qi-certified (or equivalent)
  - The smartphone charging must comply with IEC/UL 60950-1 (or equivalent)

Test the assembly

Open the iExaminer application then perform the following steps:

1. Attach a handle to the head. If using an ophthalmoscope, turn the handle on and set the diopter to Green 8 with large light spot and without a filter.
2. Attach the head to the SmartBracket. The head can be attached in any 1 of 4 orientations.
3. Place the iExaminer Resolution Test Card (included in the box) on a flat surface.
4. In the Exam screen, tap **Add image** on either the right side or the left side.

NOTE If you installed the app in Training mode, tap + to start an Exam.

5. The recording will begin. The recording will end after 30 seconds. Tap ◉ to restart the recording as needed to complete the steps.
6. Point the scope at a nearby surface to verify that the circle on the screen of the smartphone is a full circle.

NOTE If it is not a full circle, verify the magnification is at 1.0x and the primary lens' aperture is aligned with the SmartBracket. If misaligned, follow the SmartClip removal instructions in the **WELCH ALLYN IEXAMINER SMARTBRACKET STARTUP GUIDE.**

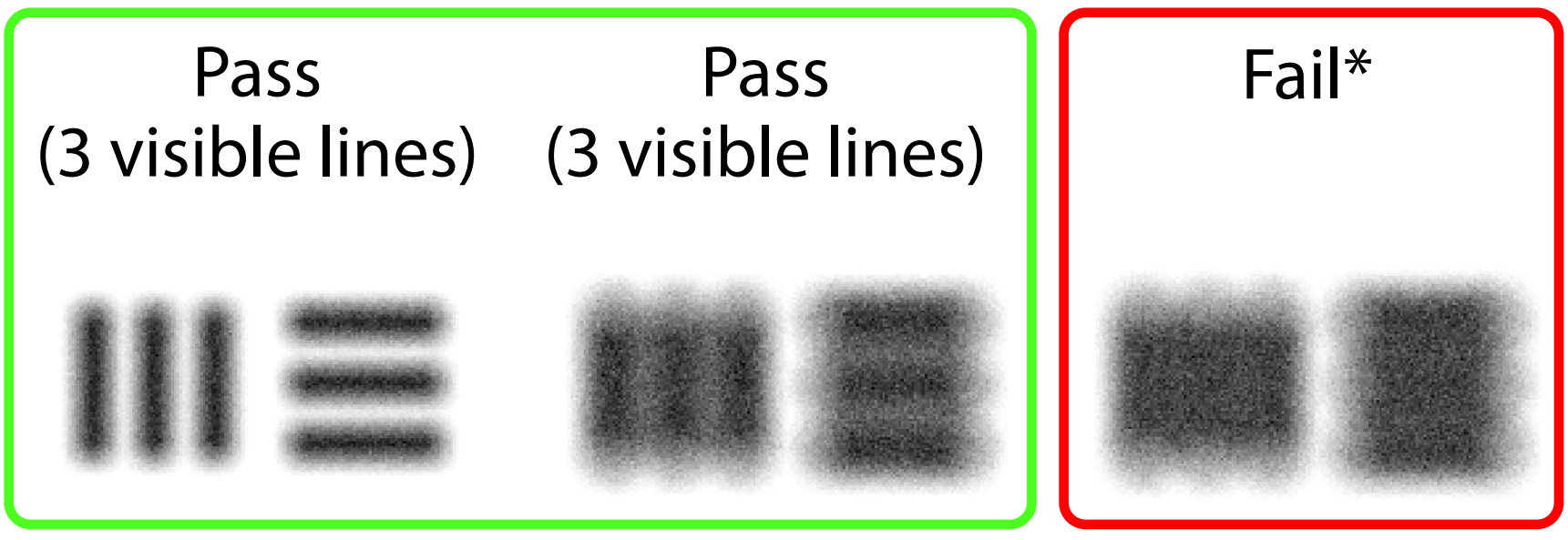
7. Align the circle on the iExaminer Resolution Test Card to the edge of the viewable area. Move the scope closer to or further away from the card as needed. Do not change the magnification.

NOTE If the autofocus does not work, tap the screen on the center target. The autofocus will reset.

NOTE Select the appropriate target circle. There is one for ophthalmoscope and one for otoscope.

8. Review the recording and scroll to select the best image. Pinch to zoom in to the captured image of the resolution targets.

9. Compare all 5 targets to verify that the images have 3 visible lines. If not, repeat the test.



10. Device setup is complete when all 5 targets pass. Return the ophthalmoscope diopter setting to 0 diopters.

11. Begin your patient exam. Refer to the Technique guide (provided in the box) or the Instructions for use (available in the app and at hillrom.com/getstarted).

*Contact Hillrom Technical Support or visit hillrom.com for help.

Using the app features

Use the links below to jump to an action or read the full operating system instructions for your device.

Training mode	Clinical mode
Modify settings (iOS)	Modify settings (iOS)
Set password (iOS)	Not available
Reset password (iOS)	Not available
Login (iOS)	Not available
View an expired exam (iOS)	Not available
Delete expired exams (iOS)	Not available
View exams expiring soon (iOS)	Not available
Add an exam (iOS)	Start a new exam (iOS)
Capture images (iOS)	Capture images (iOS)
Select images (iOS)	Select images (iOS)
View a selected image (iOS)	View a selected image (iOS)
Apply a filter, move, and delete images (iOS)	Apply a filter, move, and delete images (iOS)
Share an image (iOS)	Share an image (iOS)
Save an exam (iOS)	Not available
Update a saved exam (iOS)	Not available
Share an exam (iOS)	Share an exam (iOS)
Delete an exam (iOS)	Discard an exam (iOS)

Go to iOS instructions for using the app

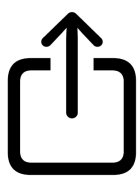
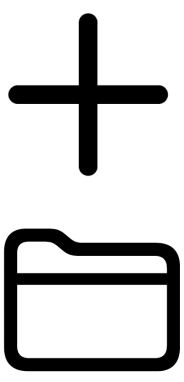
iOS instructions

NOTE Images are shown for illustrative purposes.

NOTE Clinical mode opens to the Exam screen.

Screen elements (iOS)

Applies to: Training mode, Clinical mode

Icon	Definition
	Send/Share
	Delete
	Filter
	Add
	Move

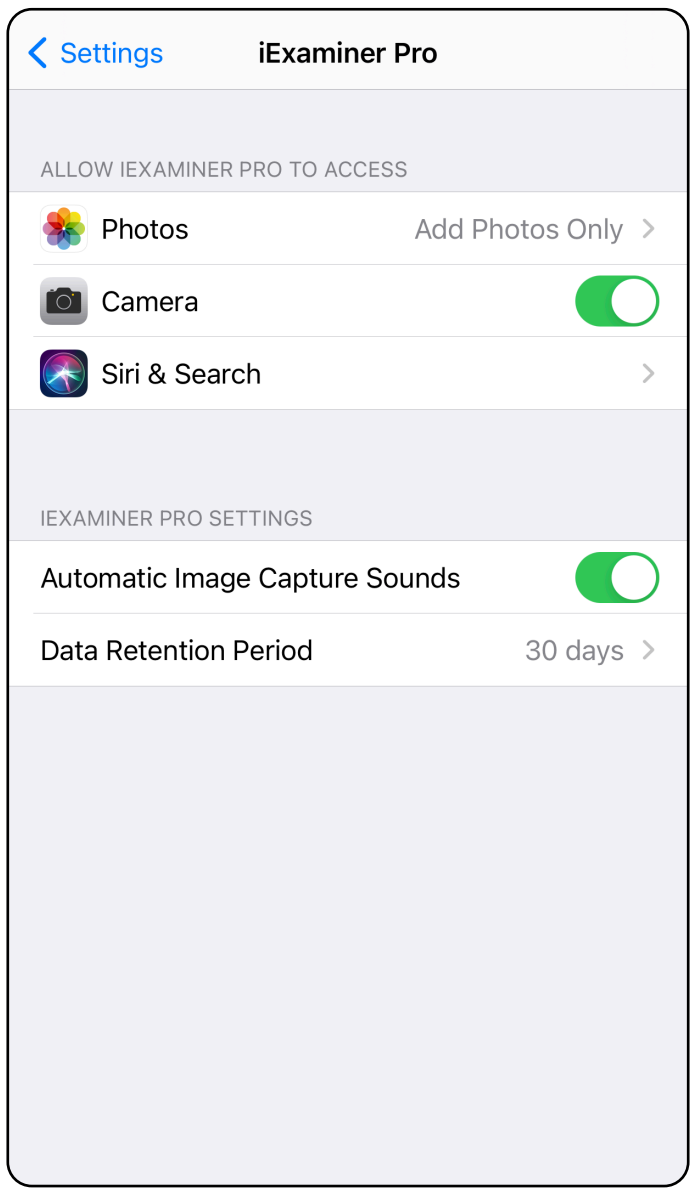
Jump to *Using the app features* list

Modify settings (iOS)

Applies to: Training mode, Clinical mode

Modify settings such as data retention period. Some Settings may be available only in a specific mode.

1. Go to your device settings.
2. Scroll to iExaminer Pro App.
3. Open the app settings.



4. Modify the Settings options.
5. Tap the back arrow in the upper left corner to save settings.
6. Return to the app.

Jump to *Using the app features* list

Authentication (iOS)

Applies to: Training mode

In the Authentication screen, you can

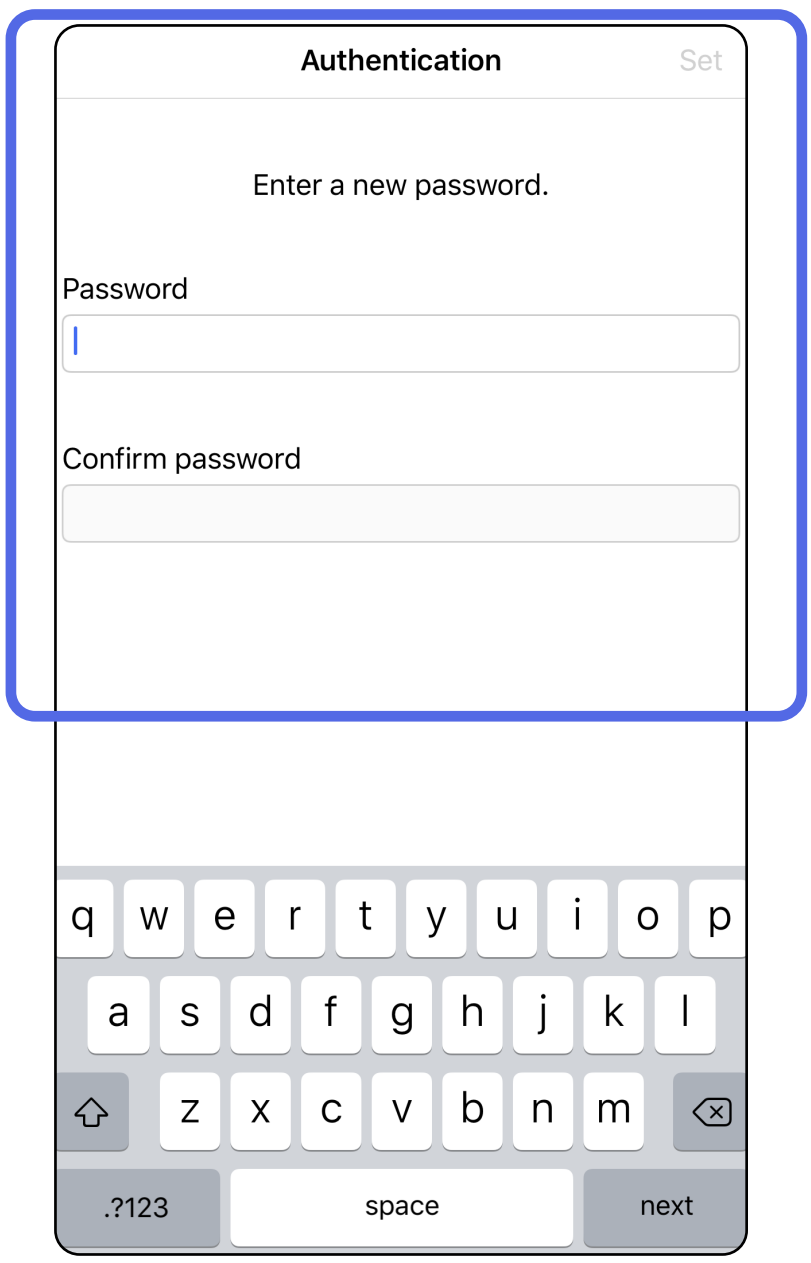
- Set password (iOS)
- Reset password (iOS)
- Login (iOS)

Set password (iOS)

Applies to: Training mode

Set a password that meets validation criteria.

1. In the Authentication screen, enter the new password twice.
2. Tap **Set**.



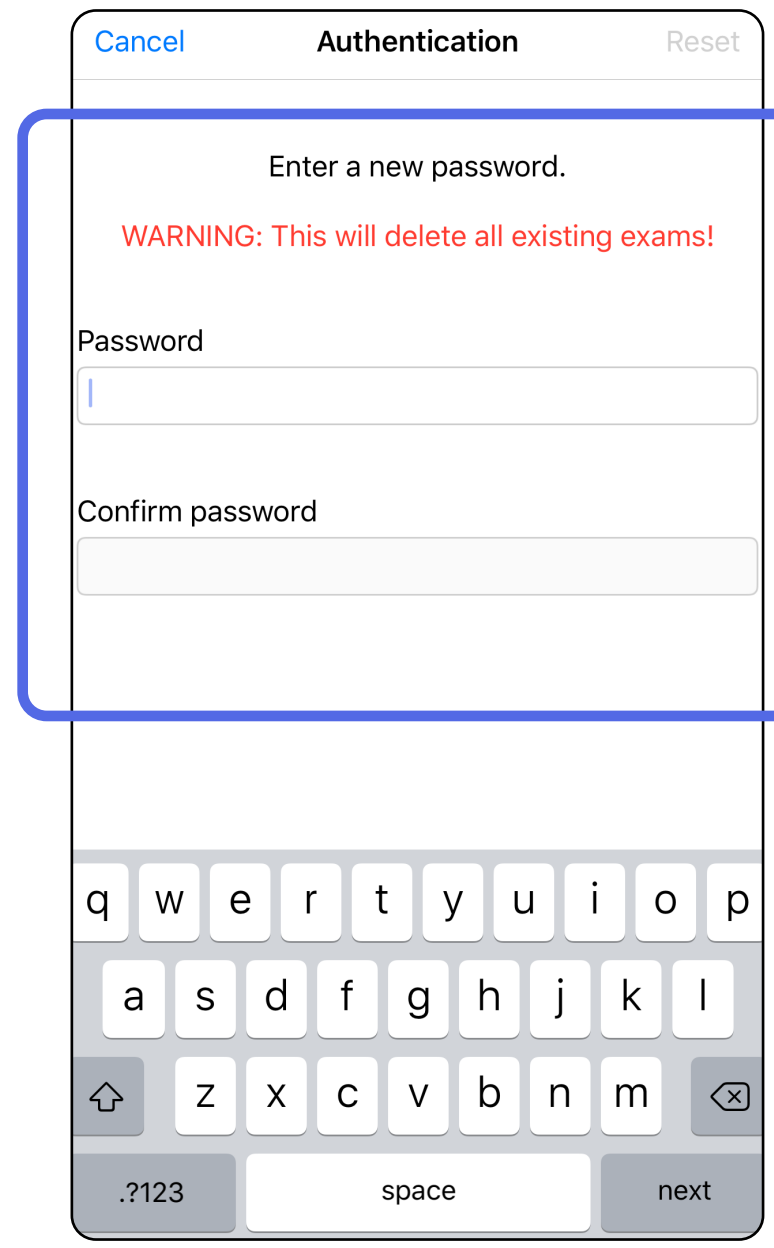
Jump to *Using the app features* list

Reset password (iOS)

Applies to: Training mode

1. To reset your password in the Authentication screen, tap **Reset**.
2. Enter a new password twice.
3. Tap **Reset** to confirm reset of password. This action cannot be undone.

NOTE Reset password will delete all exams from the app.

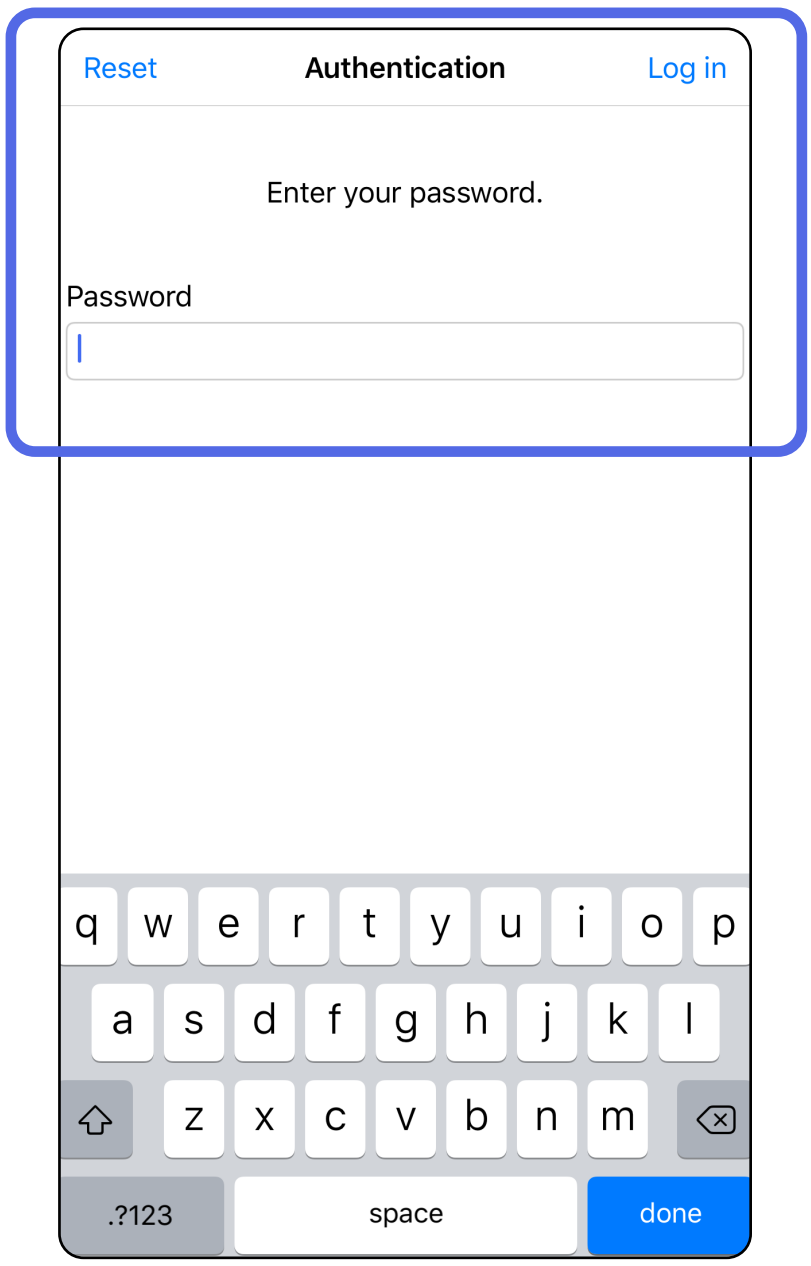


Jump to *Using the app features* list

Login (iOS)

Applies to: Training mode

1. Open the app.
2. Enter your password in the Authentication screen.
3. Tap **Login**.



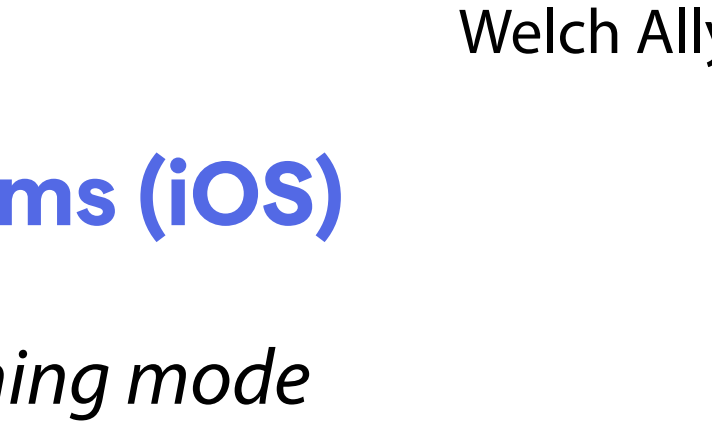
Jump to *Using the app features* list

Expired exams (iOS)

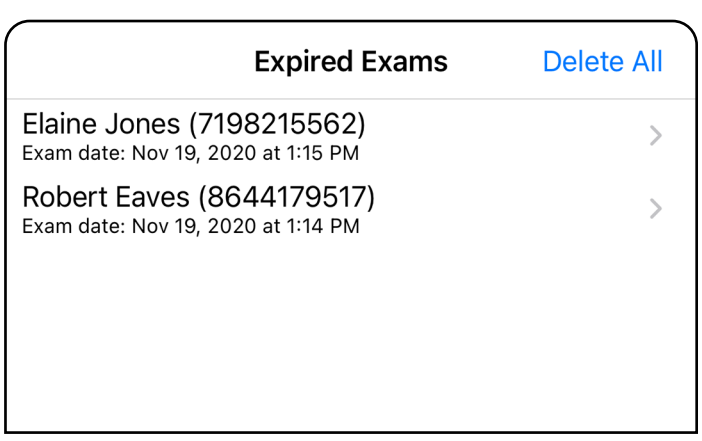
Applies to: Training mode

An exam is expired when it exceeds the data retention period. When the app is opened in Training mode and expired exams exist, the expired exams must be deleted to continue using the App. If any exams are expired, an alert will be displayed.

1. Tap **OK** to acknowledge the alert.



2. Review the list of expired exams that is displayed.



3. View an expired exam (iOS) where you can share or delete the exam and share the images in an exam or Delete expired exams (iOS).

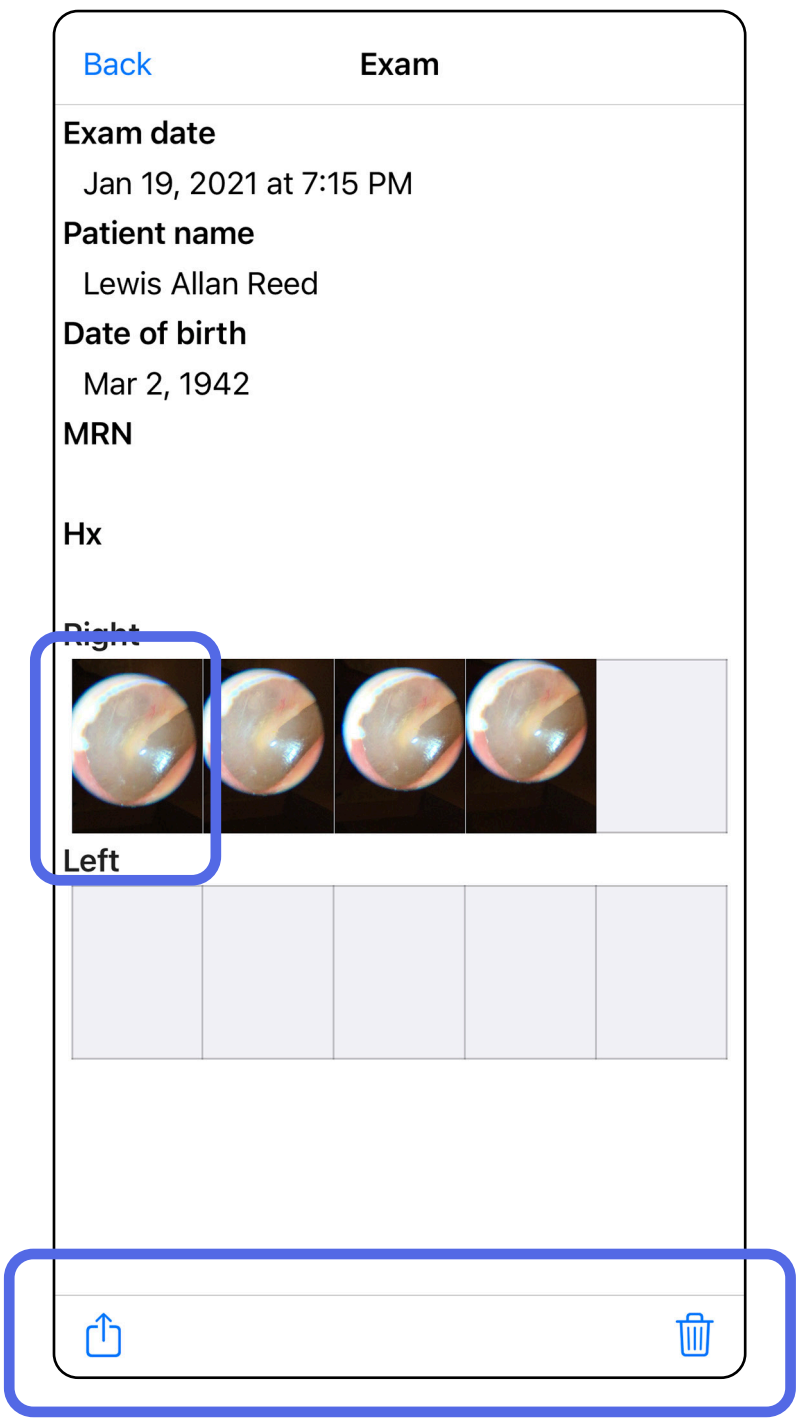
Jump to *Using the app features* list

View an expired exam (iOS)

Applies to: Training mode

Tap on an expired exam from the list. The expired exam is read-only and must be deleted before starting another exam. Before deleting the expired exam, you can:

- Tap on an image to View an image in an expired exam (iOS).
- Tap ⬆ to Share an exam (iOS).



- Delete expired exams (iOS).

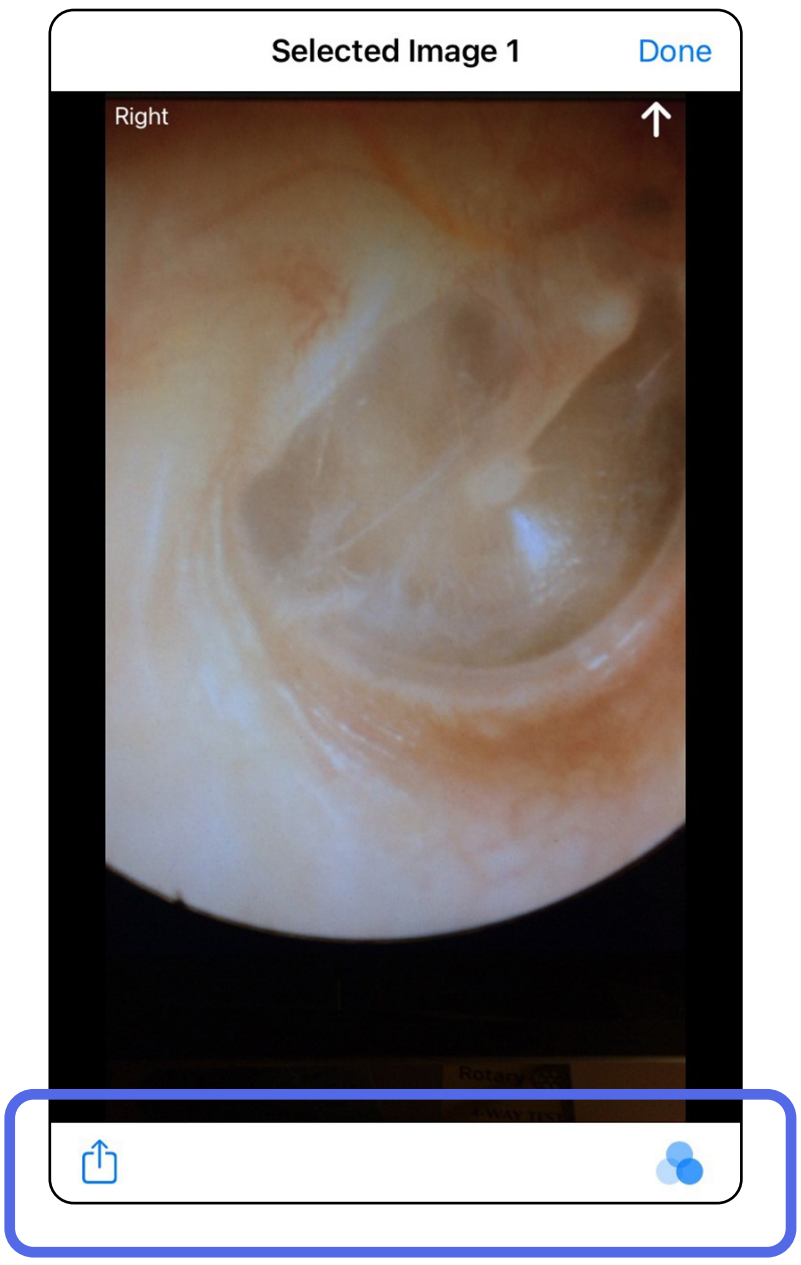
Jump to *Using the app features* list

View an image in an expired exam (iOS)

Applies to: Training mode

In the Expired Exam screen, tap an image to open it.

- Tap to Share an image (iOS) in an expired exam.
- Tap to Apply a filter (iOS) in an expired exam.



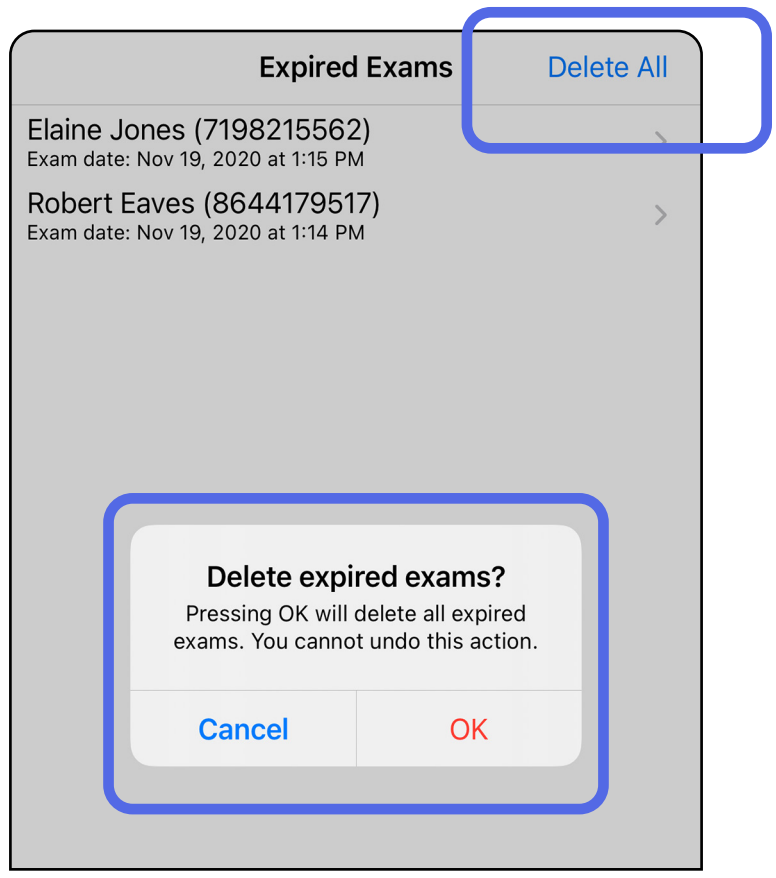
Jump to *Using the app features* list

Delete expired exams (iOS)

Applies to: Training mode

To delete all expired exams,

1. Tap **Delete All**.
2. Tap **OK** to confirm deleting expired exams.

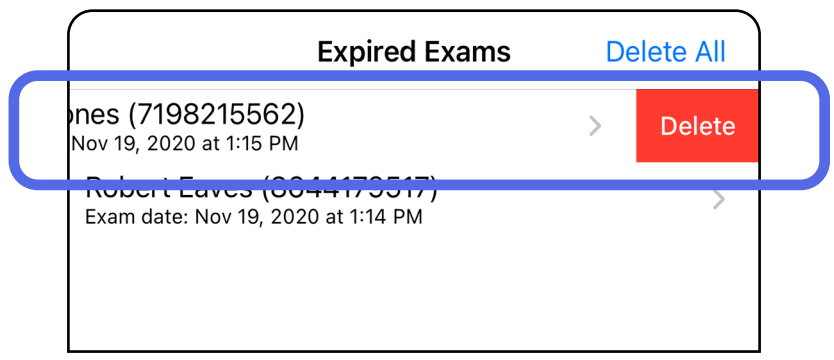


Jump to *Using the app features* list

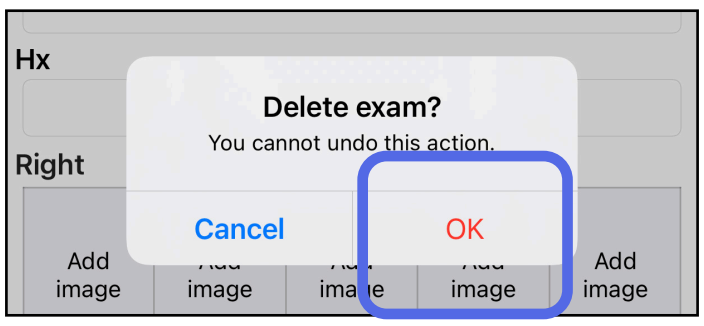
There are 2 options to delete an expired exam.

Option 1: Swipe to delete

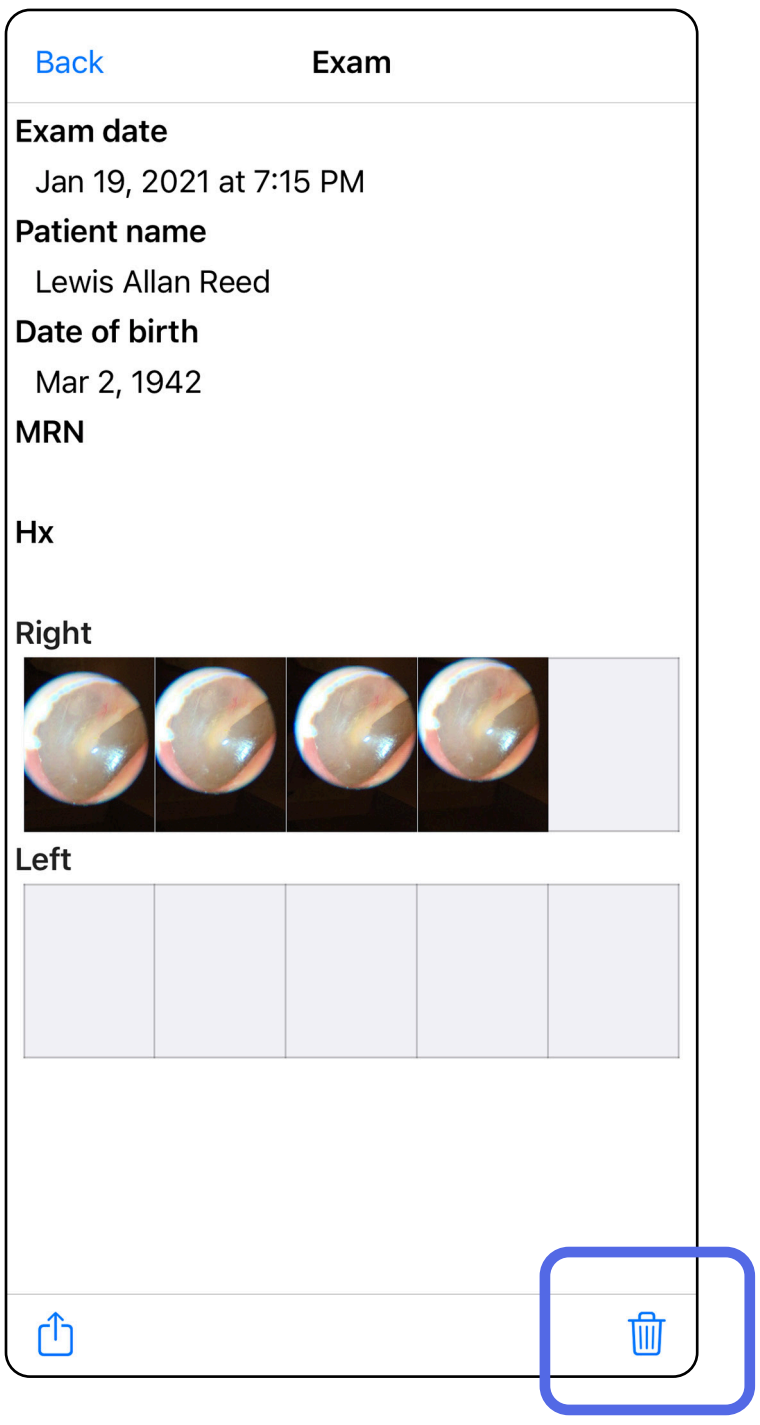
1. Swipe left on the expired exam name.
2. Tap **Delete** to confirm.



3. In the pop up window, tap **OK** to confirm.



Option 2: View the expired exam, then tap 🗑 .



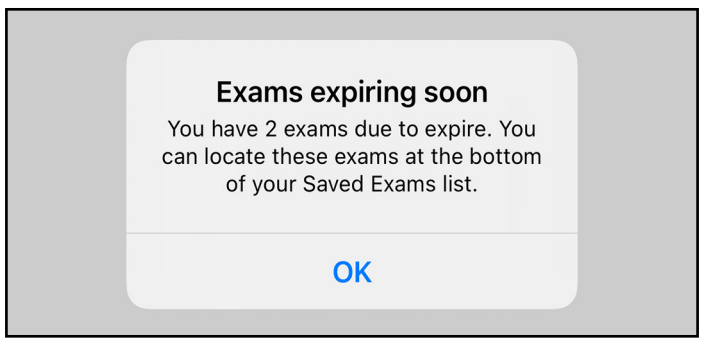
Jump to *Using the app features* list

Exams expiring soon (iOS)

Applies to: Training mode

When you have exams expiring soon, the "Exams expiring soon" dialog appears.

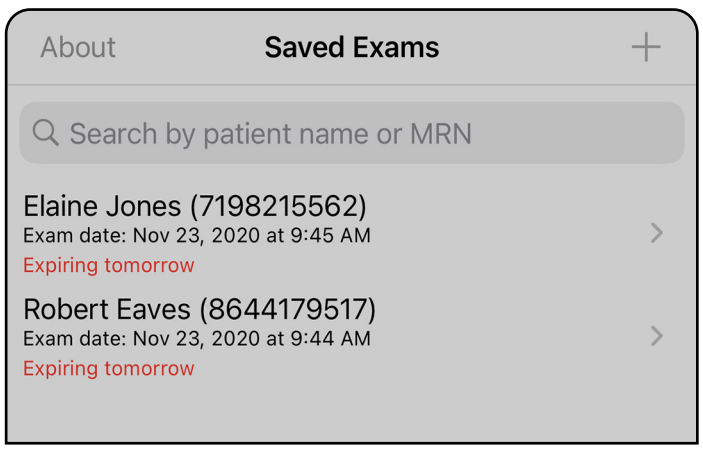
Tap **OK** to review expiring exams.



View exams expiring soon (iOS)

Applies to: Training mode

No action is required until an Exam expires.

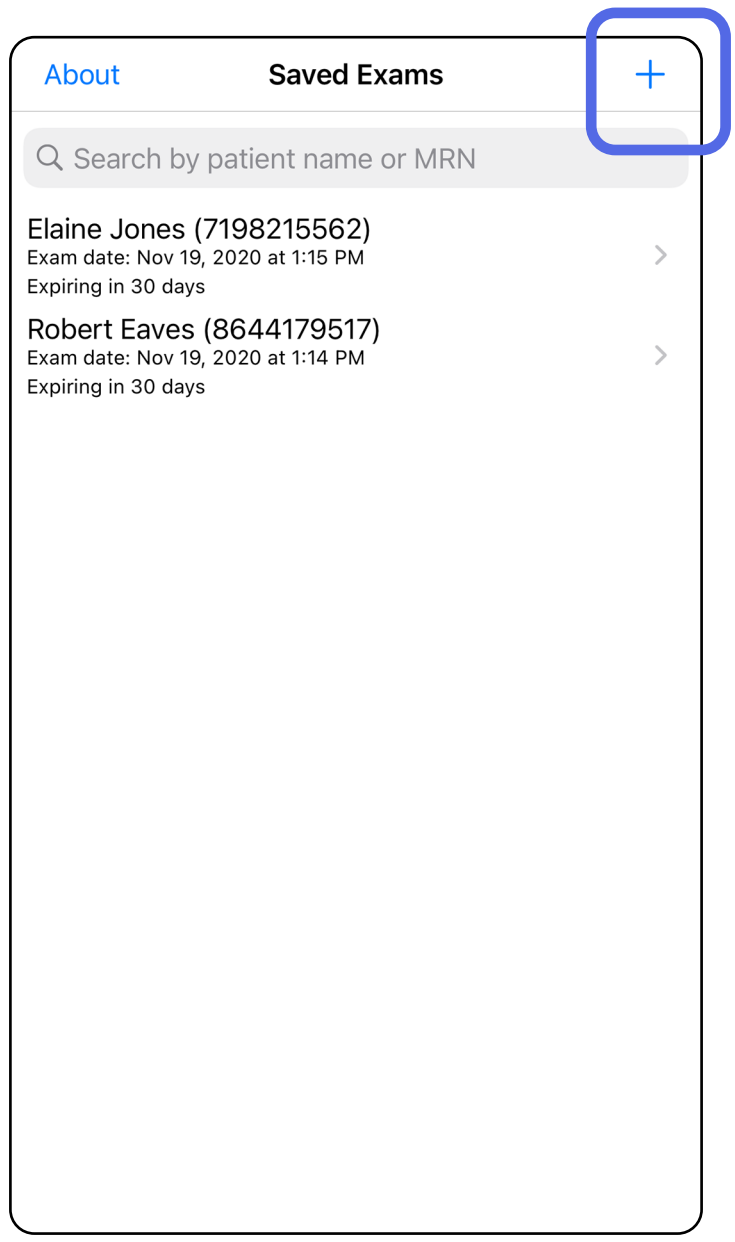


Jump to *Using the app features* list

Add an exam (iOS)

Applies to: Training mode

1. Tap + to add a new exam.
2. See Capture images (iOS).

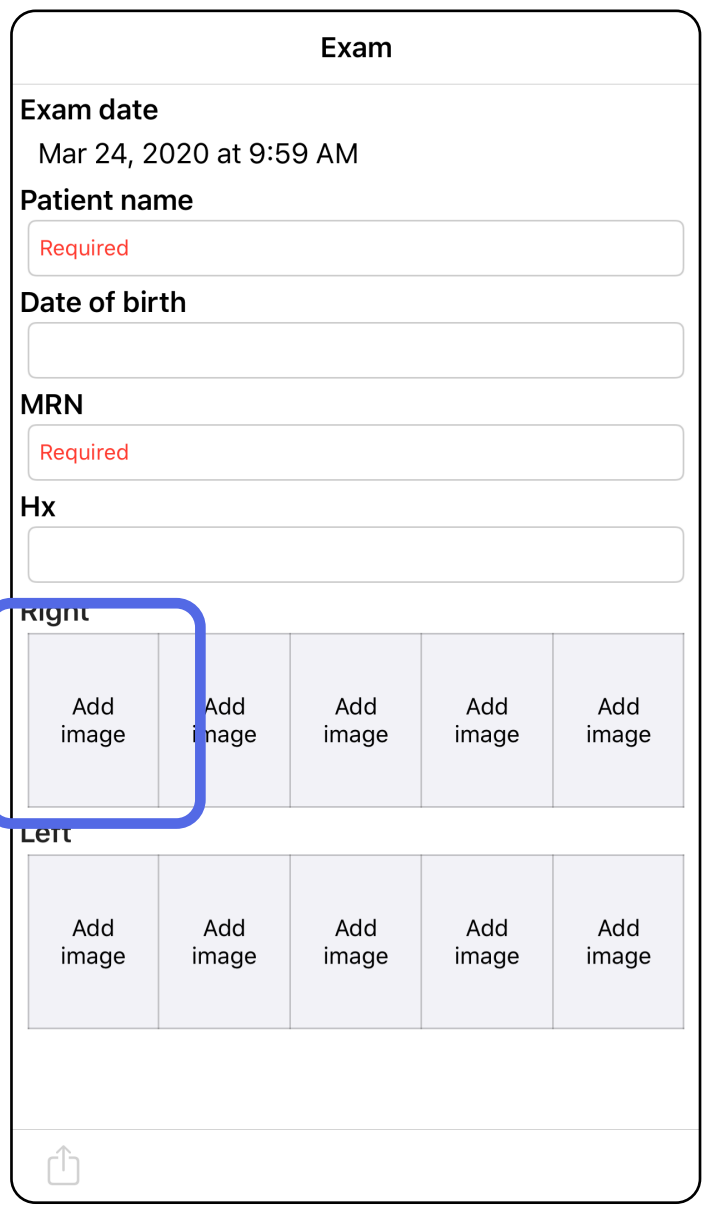


Jump to *Using the app features* list

Capture images (iOS)

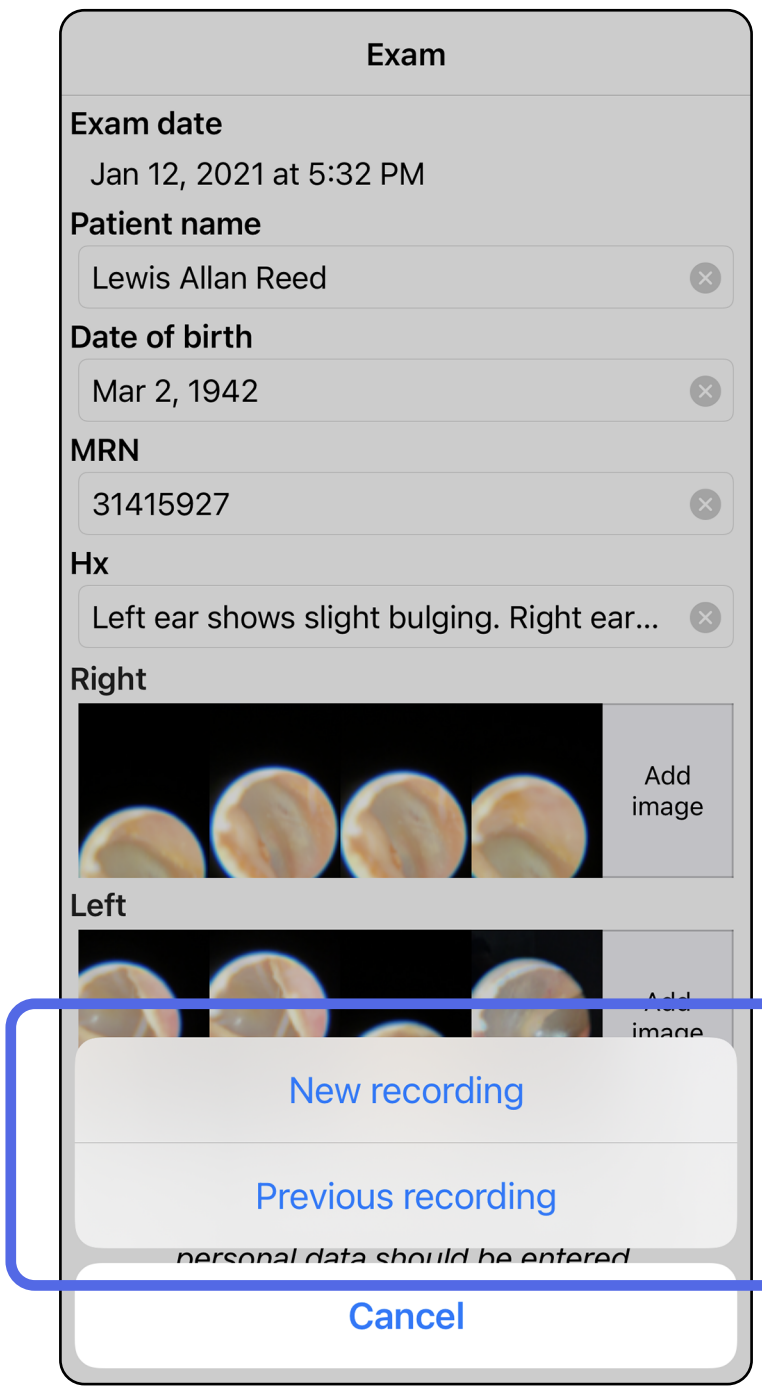
Applies to: Training mode, Clinical mode

1. Position the device in front of the selected side. See videos and other training materials on hillrom.com/getstarted to perform an exam.
2. Tap **Add image** to capture images for the right or left side.



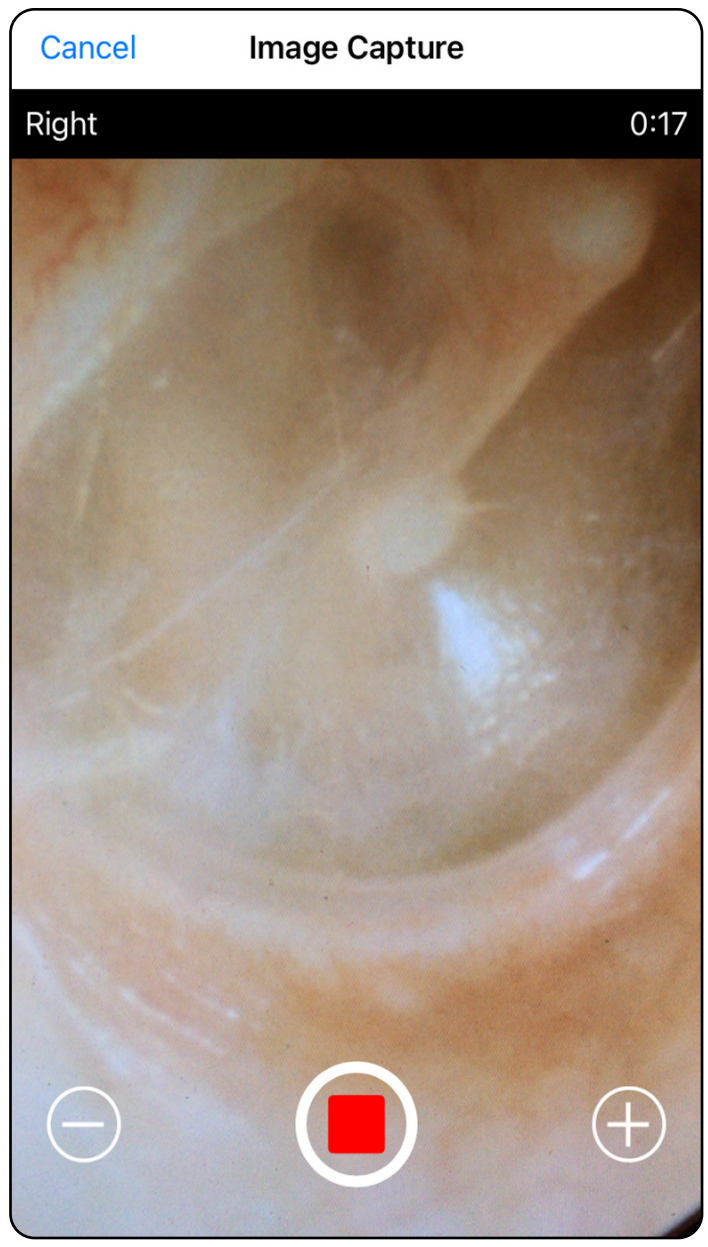
Jump to *Using the app features* list

3. When there is a previous recording, select an option from the pop up menu to start a **New recording** or to select images from a **Previous recording**. See Select images (iOS).



Jump to *Using the app features* list

When there is no previous recording, the recording will start and stop automatically. See Select images (iOS).



Jump to *Using the app features* list

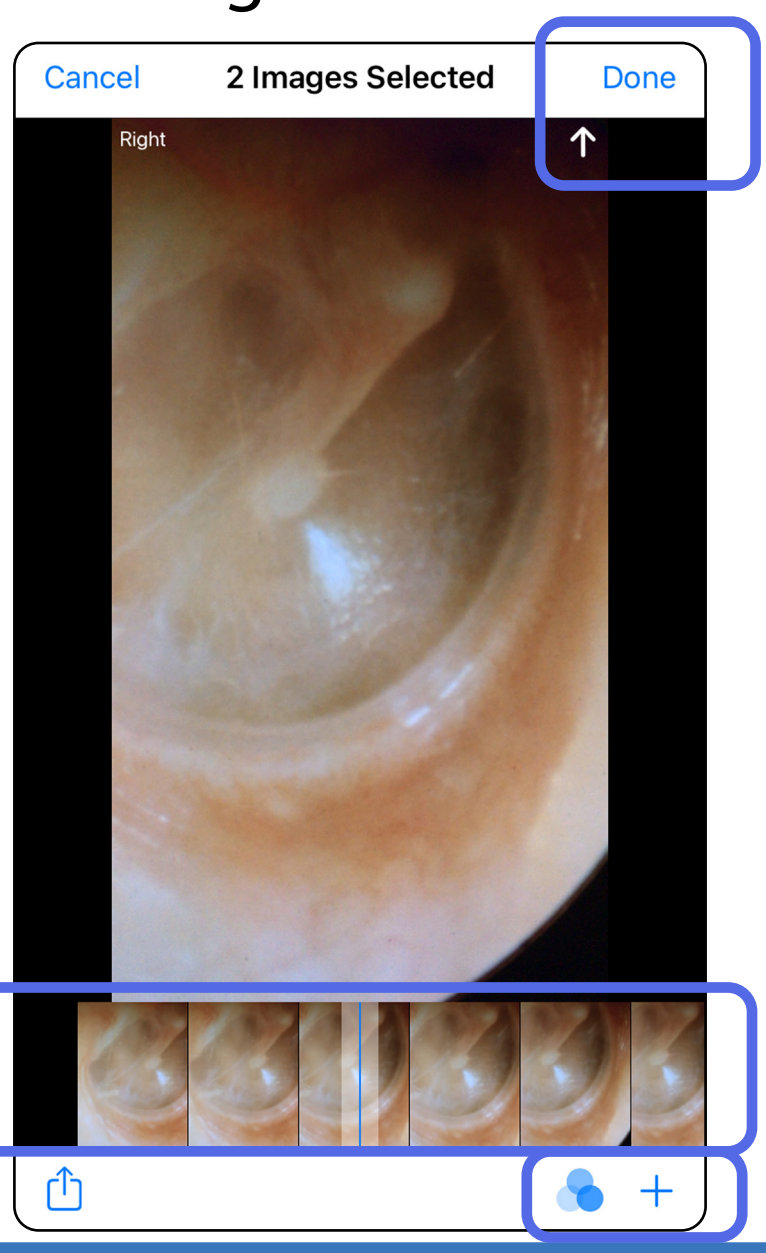
Select images (iOS)

Applies to: Training mode, Clinical mode

1. Select images that you want to keep by using the slider at the bottom and swipe left or right on the image to select images.
2. Tap to apply a filter. Filters are applied to all images currently acquired in the Image selection screen.
3. Tap + for each image that you want to keep.
4. Tap **Done** to return to the Exam screen or to share a selected image from this screen.

NOTE A maximum of 5 images per side may be kept in an exam.

NOTE The arrow in the upper right corner of the image indicates which direction is up on the captured image.



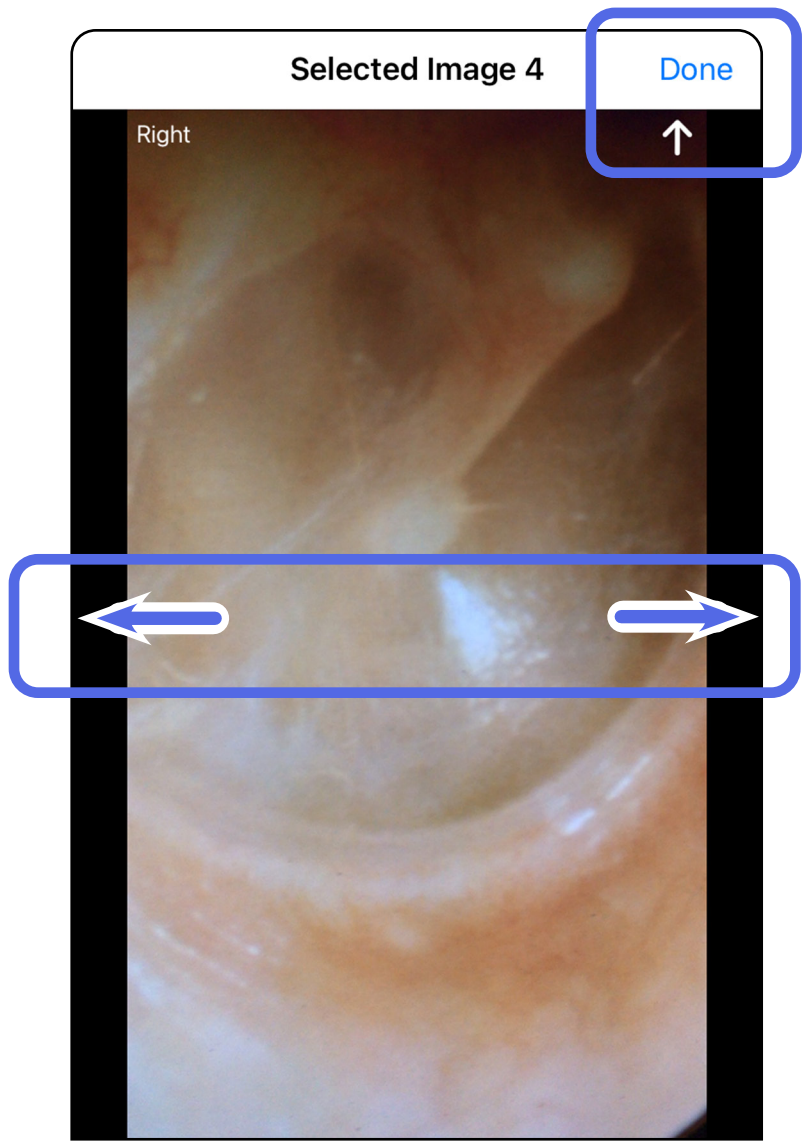
Jump to *Using the app features* list

View a selected image (iOS)

Applies to: Training mode, Clinical mode

1. In the Exam screen, tap an image.
2. In the Selected image screen, swipe left or right to scroll through all images for both sides.

NOTE The arrow in the upper right corner of the image indicates which direction is up on the captured image.



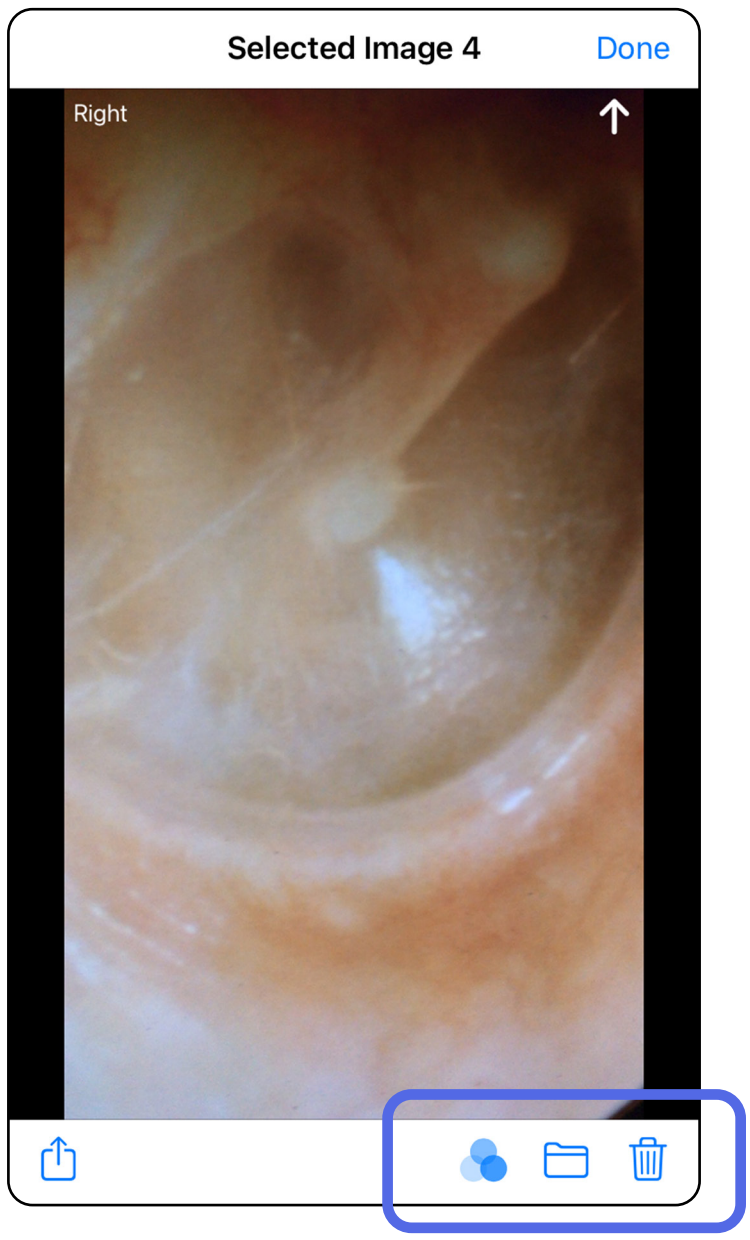
Jump to *Using the app features* list

Apply a filter, move, and delete images (iOS)

Applies to: Training mode, Clinical mode

In the Exam screen, tap an image to open it.

- Tap to apply a filter. Filters are only applied to the current image and when that image is shared. The original unfiltered images are stored.
- Tap to move the image to the other side *(not available in expired exams)*. This feature is useful if you selected the incorrect side when starting the image capture.
- Tap to delete the image, then confirm deletion *(not available in expired exams)*.



Jump to *Using the app features* list

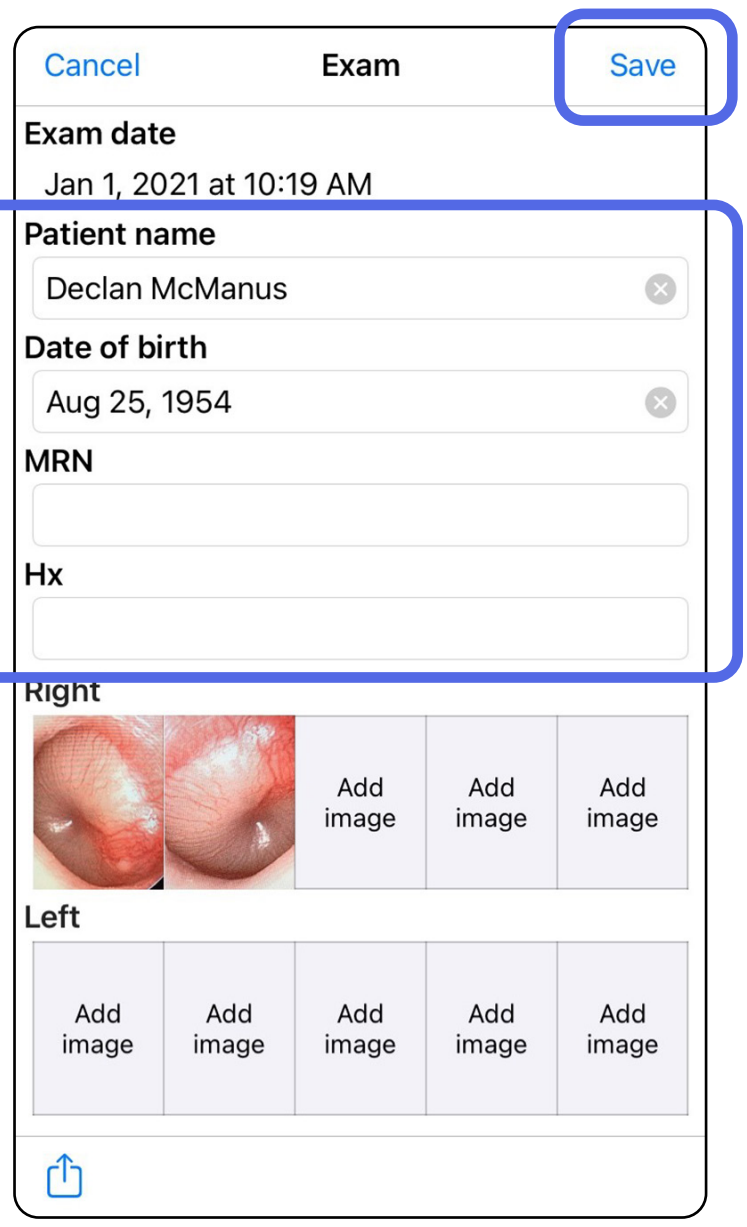
Save an exam (iOS)

Applies to: Training mode

1. Add patient details.
2. Tap **Save**.

NOTE Images are not required to save an exam. Patient details can be added either before or after images are selected.

NOTE An exam can be saved only after entering required details.

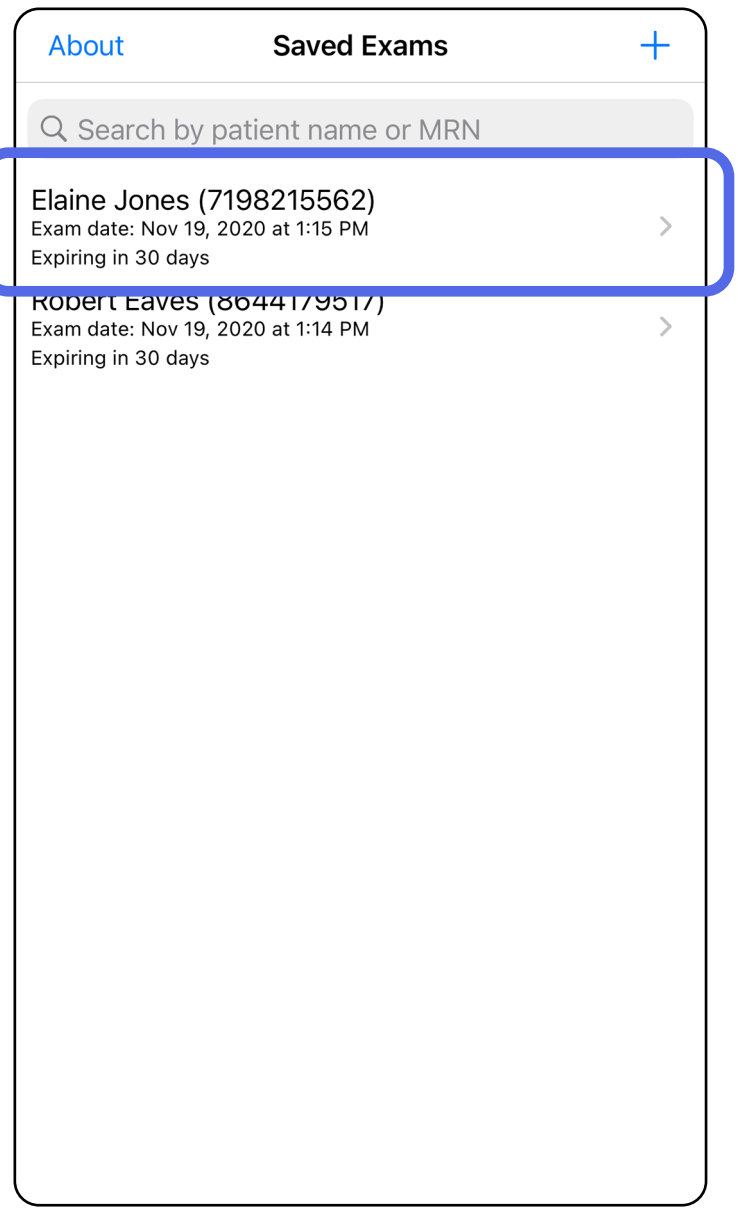


Jump to *Using the app features* list

Update a saved exam (iOS)

Applies to: Training mode

1. To edit the exam, tap on the desired exam name to open the exam.



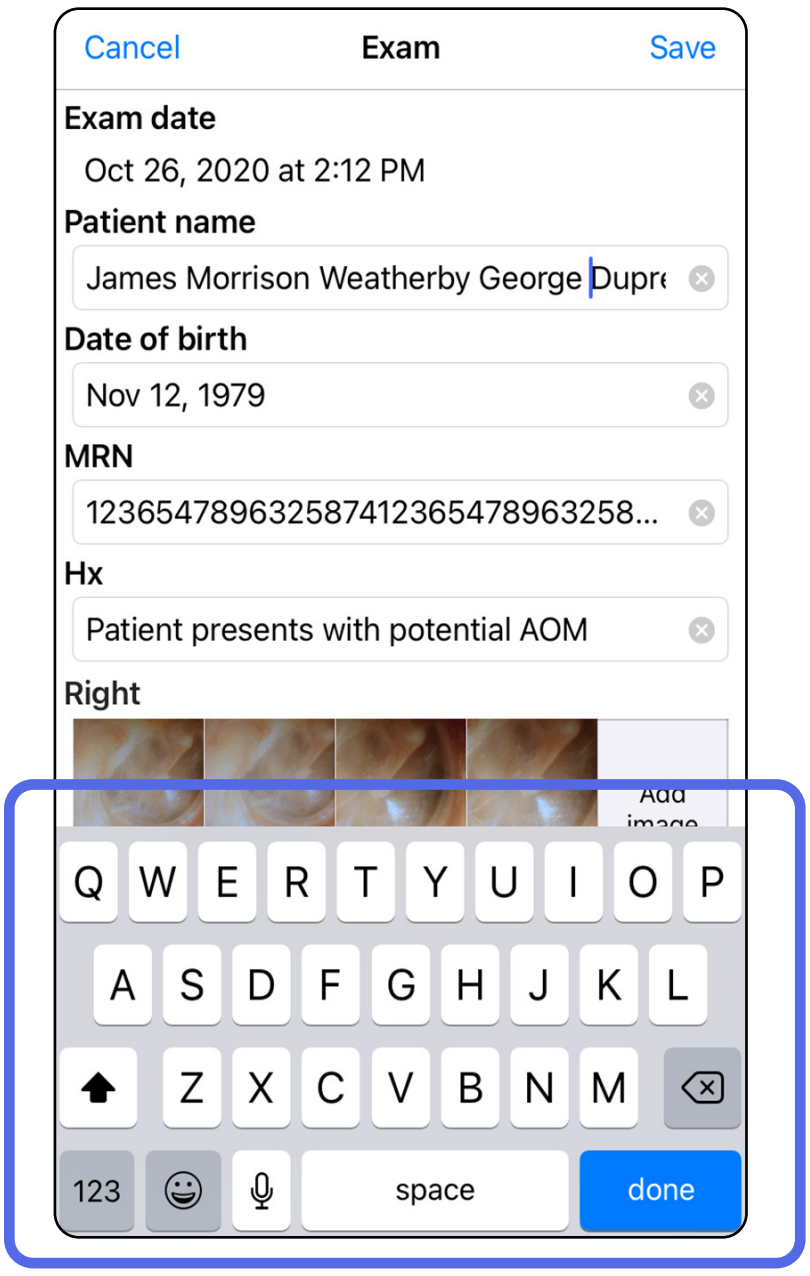
Jump to *Using the app features* list

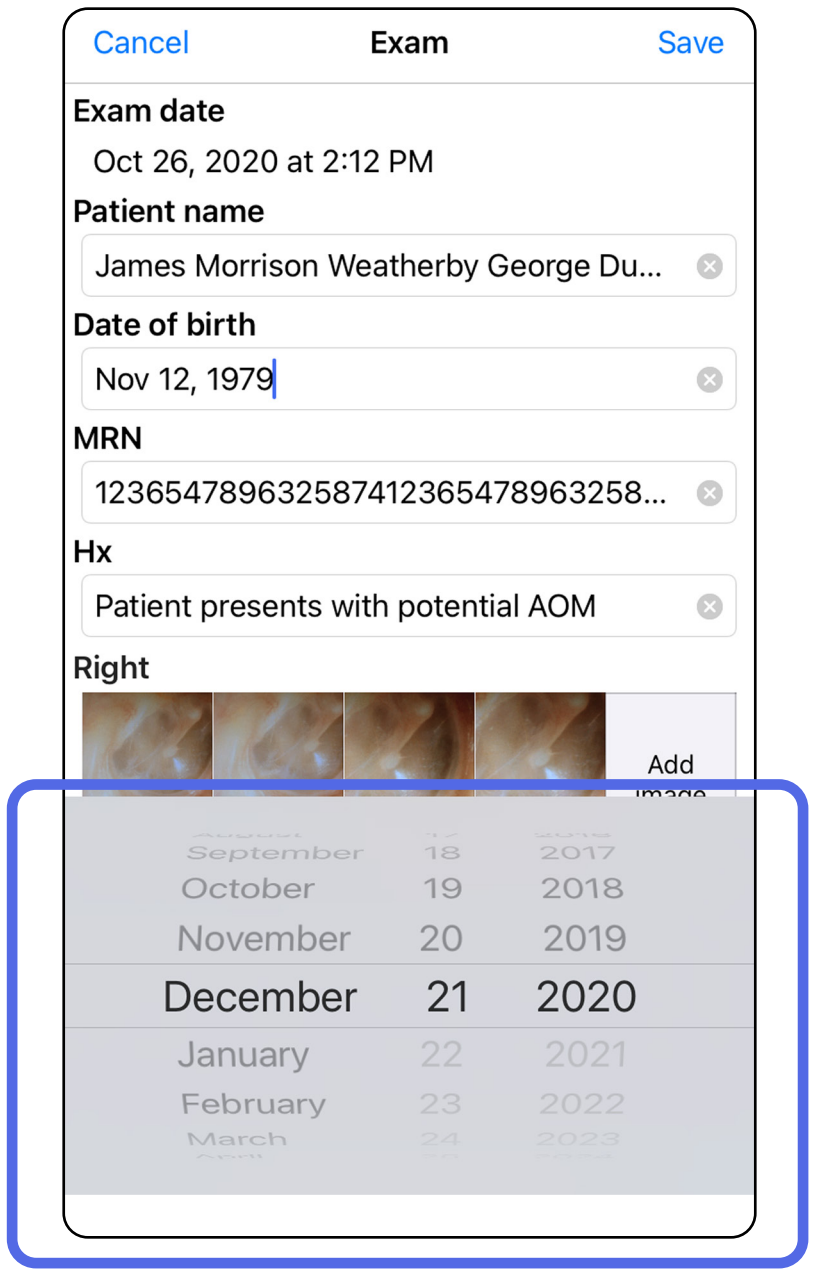
2. In the Exam screen, tap the field that you want to update.

3. Enter the patient information.

   a. Use the pop up keyboard or numeric pad to enter Patient name or MRN (medical record number).

   b. Use the pop up calendar to select a date of birth.





4. Add or remove images. See Capture images (iOS) and Apply a filter, move, and delete images (iOS).

5. Tap **Save**.

NOTE Saving is available only when there are changes and the required patient details are complete.

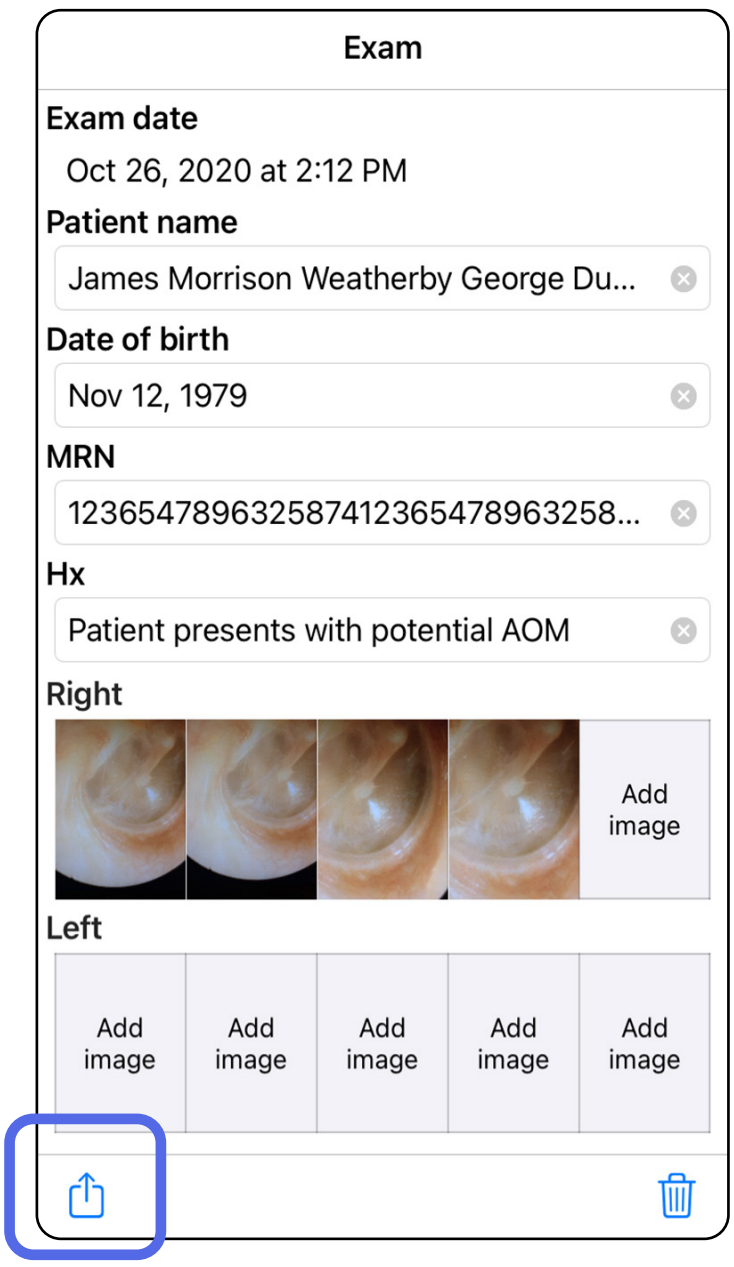
Jump to *Using the app features* list

Share an exam (iOS)

Applies to: Training mode, Clinical mode

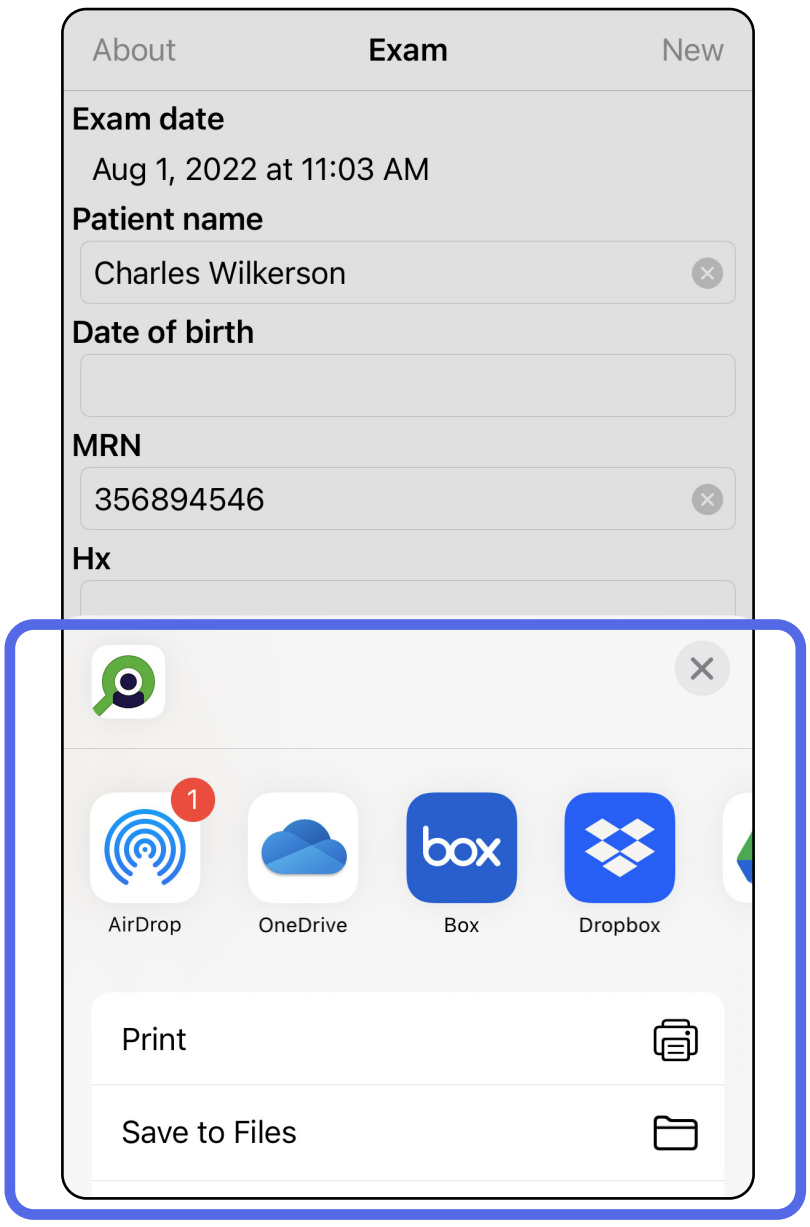
1. In the Exam screen, tap .
2. Follow the prompts to share the exam.

NOTE Sharing is available when there is at least 1 image and the required patient details in the exam.



Jump to *Using the app features* list

3. Select the share method from the pop up menu.



4. Follow prompts to share.

NOTE See Device and patient data and security.

NOTE Shared images from the iExaminer application may have embedded information. Some photo viewing applications do not support embedded information. If the recipient cannot view the photo, then the recipient should verify that the photo viewing application supports viewing images with embedded information or select another photo viewing application.

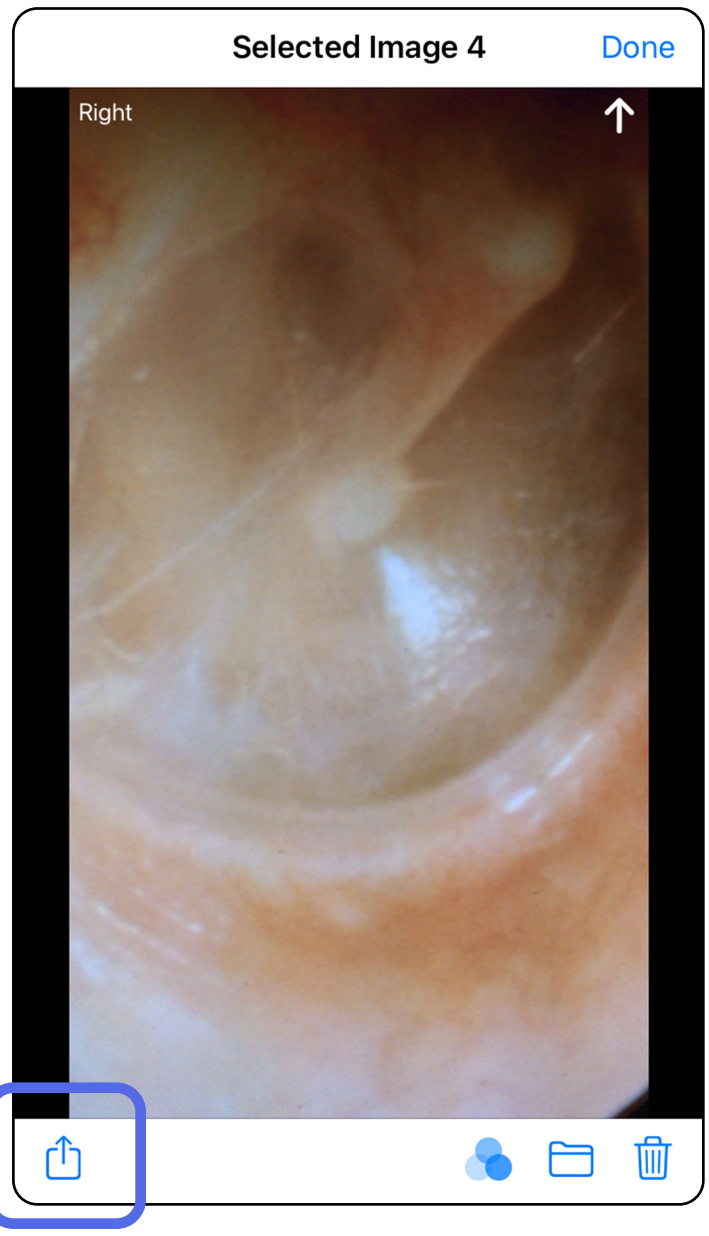
Jump to *Using the app features* list

Share an image (iOS)

Applies to: Training mode, Clinical mode

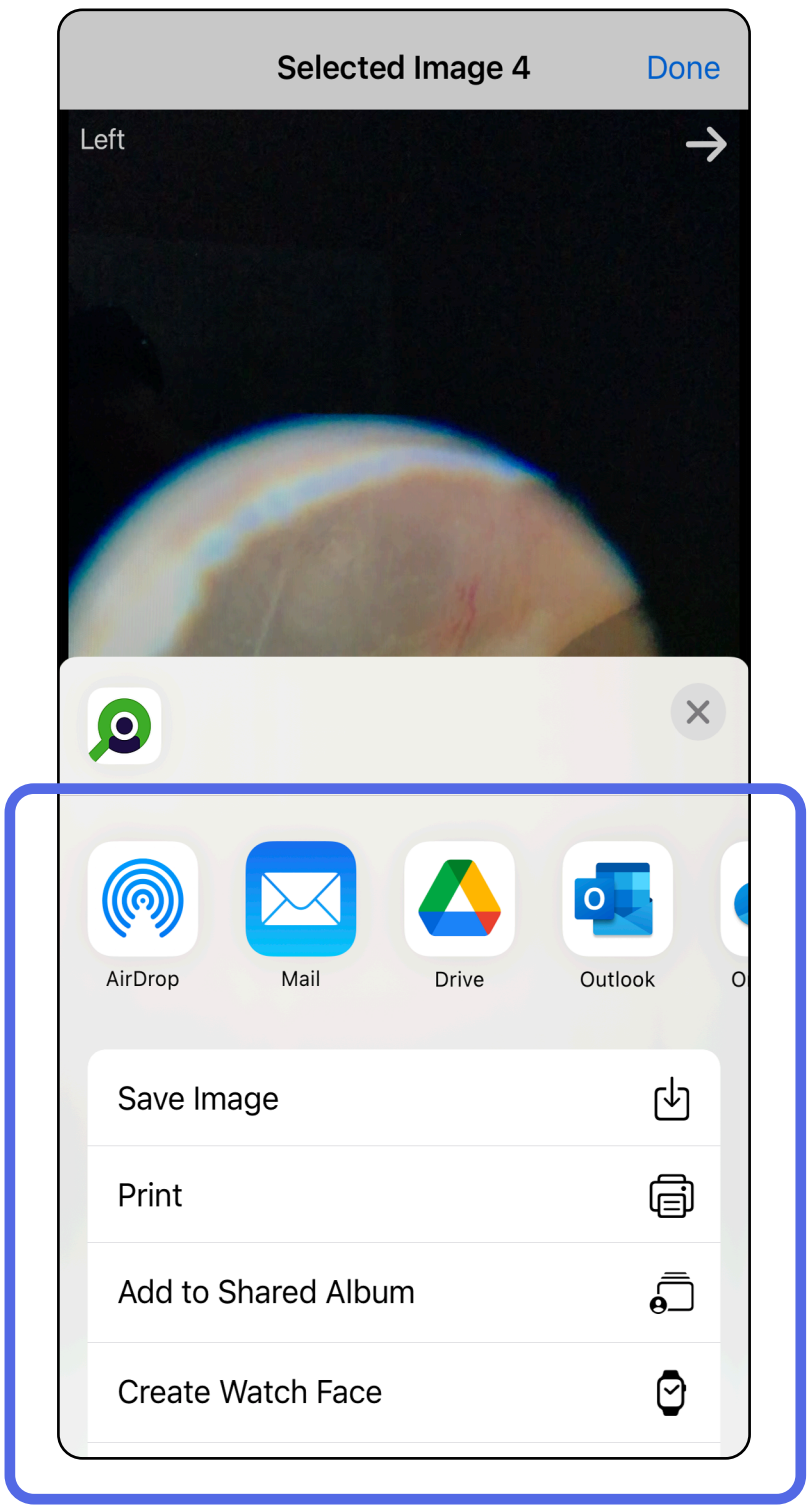
1. In the Exam screen, tap the desired image.
2. Tap ⬆.

NOTE Sharing is only available when the required patient details are in the exam.



Jump to *Using the app features* list

3. Select the share method from the pop up menu and follow prompts to share.



NOTE See Device and patient data and security.

NOTE Shared images from the iExaminer application may have embedded information. Some photo viewing applications do not support embedded information. If the recipient cannot view the photo, then the recipient should verify that the photo viewing application supports viewing images with embedded information or select another photo viewing application.

Jump to *Using the app features* list

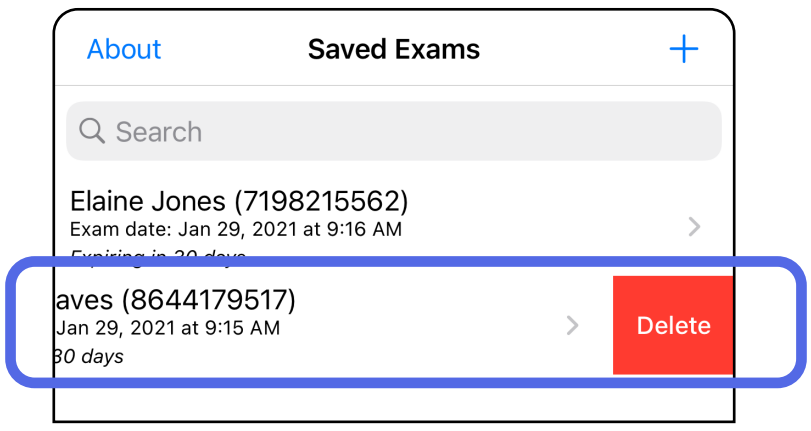
Delete an exam (iOS)

Applies to: Training mode

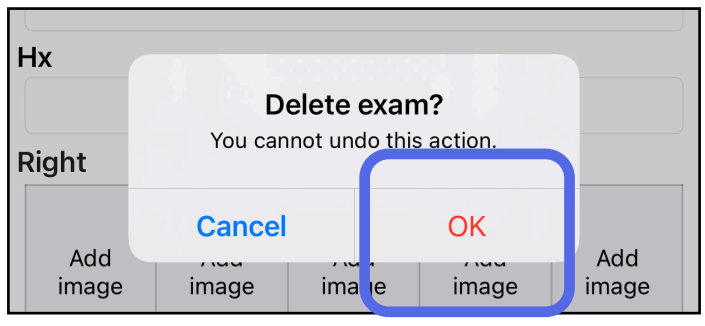
There are 2 options to delete an exam.

Option 1: Swipe to delete

1. To delete a saved exam, swipe left on the saved exam name.
2. Tap **Delete** to confirm.



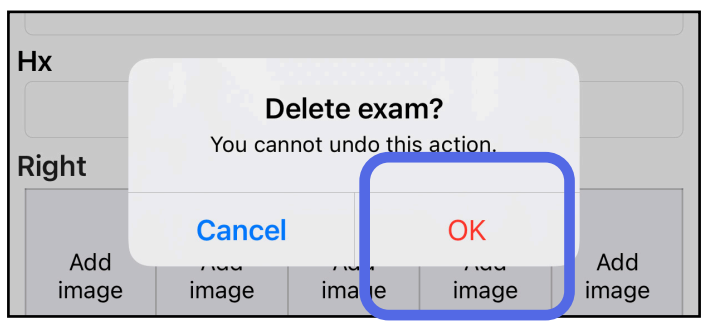
3. In the pop-up window, tap **OK** to confirm.



Option 2: View the exam

1. To delete a saved exam, view the Exam, then tap .

2. In the pop-up window, tap **OK** to confirm.



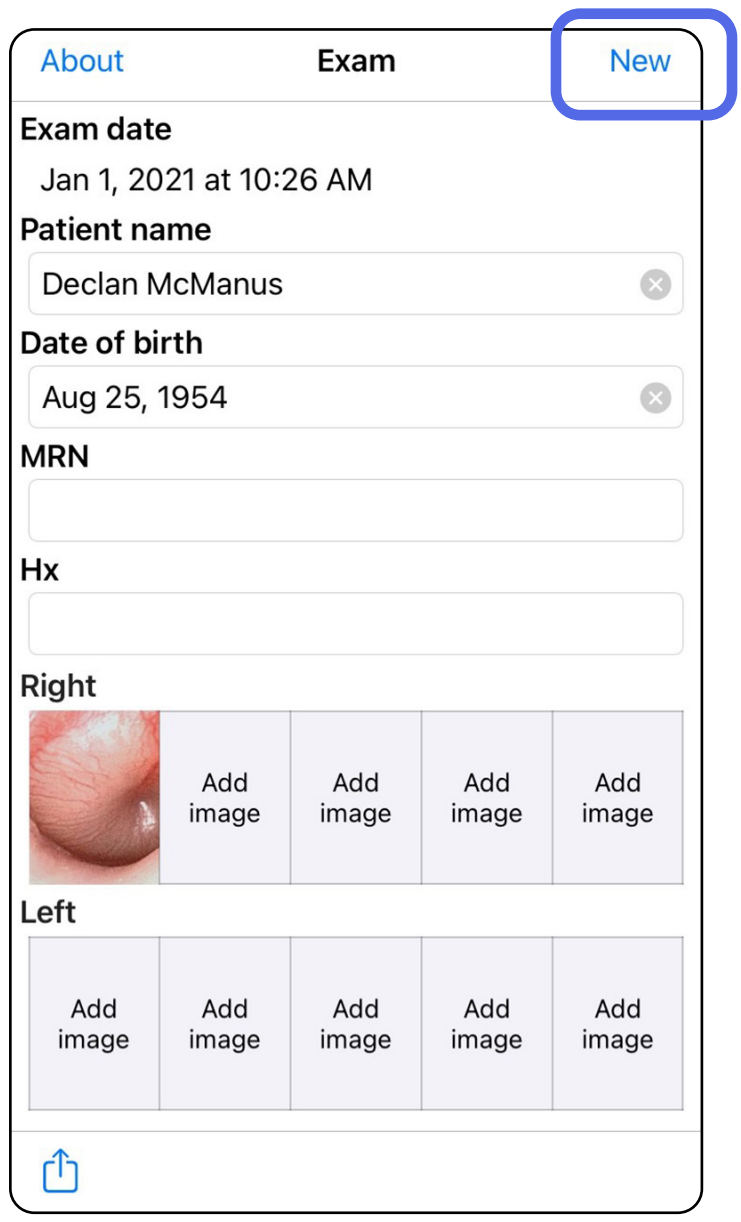
NOTE A deleted exam cannot be recovered.

Jump to *Using the app features* list

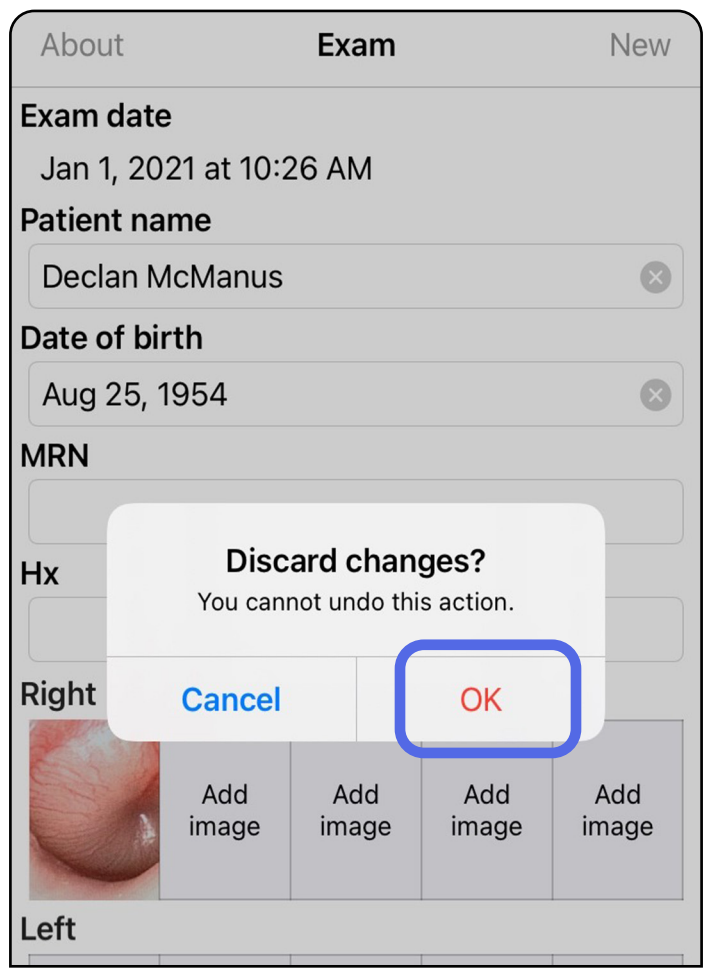
Discard an exam (iOS)

Applies to: Clinical mode

1. To discard the exam, tap **New**.



2. Tap **OK** to discard changes and start a new exam.



Jump to *Using the app features* list

Cleaning

These cleaning instructions are for the SmartBracket and SmartClip. Refer to the appropriate IFU for reprocessing Welch Allyn devices.

⚠ **CAUTION** Do not sterilize the SmartBracket or SmartClip or immerse them in any solution.

No preventive maintenance other than cleaning is necessary for this product.

Approved cleaning chemicals:

- 70% Isopropyl alcohol with 30% deionized water (for example CiDehol® 70 alcohol wipes)
- Metrex™ CaviWipes®
- PDI Super-Sani-Cloth®
- PDI-Sani-Cloth Plus®

1. Remove the SmartBracket from the head and the SmartClip before cleaning. Leave the SmartClip attached to the case.

2. Use approved cleaning chemicals (see above) to wipe the SmartBracket and SmartClip, removing all visible and invisible soil. Frequency: Clean as needed.

3. Allow the cleaning solution to dry.

Safe disposal

Disposal of SmartBracket and SmartClip must be in accordance with the following steps:

1. Follow cleaning instructions per instructions in this user manual section.
2. Segregate material in preparation for the recycling process
    - Components are to be disassembled and recycled based on type of material
        - o Plastic to be recycled as plastic waste
        - o Metal to be recycled as Metals
    - Includes screws and fasteners

See appropriate heads IFU for disposal instructions.

Follow the manufacturer's instructions for smartphone and case disposal. Delete all existing data related to patients/hospital/clinic/doctor to maintain confidentiality. Data backup may be performed prior to deletion.

Users must adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories. If in doubt, the user of the device should first contact Hillrom Technical Support for guidance on safe disposal protocols.

EMC compliance

For information about electromagnetic compatibility (EMC), see the Hillrom website: hillrom.com/getstarted.

Storage and transport

See the appropriate Welch Allyn device IFU.

Pixel pitch

The pixel pitch on fundus for an emmetropic eye with a 17mm focal length varies depending on the smartphone. See the list below.

Pixel pitch	Smartphone
2.02 microns	iPhone X
2.01 microns	iPhone 11 Pro
2.02 microns	iPhone 11 Pro Max
2.06 microns	iPhone 12 Pro

Compliance

Complies with ISO 10940:2009.

Accessories

See the appropriate Welch Allyn device IFU for accessories and applied parts.

Compatible devices

See the appropriate Welch Allyn device IFU.

Warranty

Welch Allyn, Inc. warrants the Welch Allyn iExaminer SmartBracket and SmartClip to be free of original defects in material and workmanship and to perform in accordance with the manufacturer's specifications for a period of one year from the date of purchase. If this instrument is found to be defective or at variance with the manufacturer's specifications during the warranty period, Welch Allyn will repair or replace the instrument or component at no cost to the purchaser. This warranty only applies to Welch Allyn iExaminer SmartBracket and SmartClip purchased new from Welch Allyn or its authorized distributors or representatives. The purchaser must return the SmartBracket and SmartClip directly to Welch Allyn or an authorized distributor or representative and bear the cost of shipping.

This warranty does not cover breakage or failure due to tampering, misuse, neglect, accidents, modification, or shipping. This warranty is void if the instrument is not used in accordance with the manufacturer's recommendations or if repaired.