Modus IR

User Manual

MAN-0742 Revision C

Synaptive

User Manual

Synaptive™ Modus IR

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Synaptive

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Table of Contents

1.0 Introduction

Modus IR is an accessory to the Synaptive surgical exoscope for fluorescence imaging. For complete information about the Synaptive surgical exoscope and how to use it, see the user manual accompanying your system.

2.0 Indication for Use

Modus IR used with the Synaptive Surgical Exoscope is indicated for fluorescence imaging in conjunction with indocyanine green to aid in the visualization of vessels (micro- and macro-vasculature) and blood flow in the cerebrovasculature before, during, and after neurosurgery, plastic, and reconstructive surgeries.

3.0 Warnings and Precautions

CAUTION

Federal law (U.S.A.) restricts this device to sale by or on the order of a surgeon.

WARNING: Risk of Patient Death or Permanent Disability Due to Improper Use of the System

Use the system for the indications specified in this user manual only.

Failure to follow the instructions for use and understand system behavior may result in unexpected system performance, procedure delay and patient or operator injury.

WARNING: Risk of Patient Death or Permanent Disability Due to Malfunctioning Equipment

Sources of infrared light in the operating room will interfere with the Modus IR optical system when it is using an infrared (IR) optical preset. This interference can cause flickering in the video field which may interfere with the view of the surgical field or trigger an epileptic seizure in susceptible persons.

WARNING: Risk of Patient Injury Due to Light Sources

Although it is very unlikely, the Synaptive surgical exoscope light sources are capable of producing light intense enough to cause tissue burns and blindness. The risk of tissue burns is affected by factors such as:

- The length of exposure (longer surgical procedures increase the risk)
- Materials adjacent to the surgical site (such as incision drapes) and local vasoconstrictive medications
- The location of the procedure (some areas of the body may be more sensitive than others)
- The patient's skin type and general health
- Medications that affect sensitivity to light
- The distance between the end effector and the body.

To reduce the risk of injury to the patient, take protective measures such as:

- Regularly irrigating the illuminated surgical field to keep it moist
- Covering illuminated areas with moistened sterile gauze
- Regularly re-moistening any drapes in use in illuminated areas

Do not leave active light sources unattended.

During certain electromagnetic compatibility (EMC) events, the auxiliary light source may be influenced by RF energy. Use external light sources if the performance of the Synaptive surgical exoscope is insufficient or leads to patient discomfort.

WARNING: Risk of Patient Death or Permanent Disability Due to Obscured View of Surgical Site

Clip recording playback will partially or completely obscure the view of the surgical site on the monitor(s). Use the advanced playback controls to control how clip recording playback is displayed.

WARNING: Risk of Patient Injury Due to Improper Treatment

Clearing the video clip recordings list will result in the clip recordings being unavailable for playback on the external monitor. The inability to play back a clip recording may result in improper treatment for the patient, or a delay in completing the procedure.

Operating outside of the recommended fluorescence mode parameters may result in unreliable visualization of the fluorescent areas. If the visualization of the fluorescent area is not sufficient, try reducing working distance and/or the zoom level.

The fluorescence optical presets have been designed to optimize viewing of the fluorescence signal. Any changes to the optical settings, including light intensity, when using the fluorescence optical presets may result in unreliable visualization of the fluorescent areas.

False positive and false negative fluorescence can occur. Evaluate tissue using other methods as necessary.

WARNING: Risk of Procedure Delay Due to Loss of the Synaptive Surgical Exoscope Function

Only the main light source can emit infrared light. If the main light source is turned off or is not functioning, infrared light will not be available and the infrared (IR) optical presets will not function as intended.

If there is insufficient data storage space available on the Synaptive surgical exoscope, the system will not be able to record video or capture still image snapshots. Export and/or delete unneeded videos and snapshots regularly to ensure that sufficient data storage space is available.

CAUTION: Risk of Procedure Delay

There is a risk of photobleaching of the fluorophores if high intensity fluorescence light is used for an extended period of time.

If the Ethernet cable connecting Modus X to the monitor is disconnected when the Modus IR picture in picture (PIP) feature is in use, the monitor will continue to display the PIP window and you will not be able to stop viewing the PIP window until you reconnect the Ethernet cable.

CAUTION: Risk of Poor Quality Images of the Surgical Field

The Synaptive surgical exoscope should only be used with monitors provided by Synaptive Medical. The use of a monitor other than that provided by Synaptive Medical could impact color, tissue differentiation or image quality. If using a monitor other than that provided by Synaptive Medical, image quality must be validated by surgical staff. Ensure that the image quality on the monitor is adequate for performing surgery.

Using picture-in-picture display may obstruct the view of the surgical overlay or the surgical site. See 1.0 Monitors on page 1 for information on how to toggle the picture-in-picture feature on or off.

Damaged or malfunctioning equipment may produce an inadequate surgical image.

Always use the designated Modus IR drape for procedures that will use a Modus IR optical preset. Using the incorrect drape may result in a reduction of the IR signal.

4.0 Synaptive Customer Service Information

For 24-hour access to clinical and technical support, contact Synaptive customer service.

Phone: 1-844-462-7246 (North America)
1-647-925-3435 (International)
Email: service@synaptivemedical.com

5.0 Modus IR

5.1 Modus IR Features in the Synaptive Surgical Exoscope User Interface

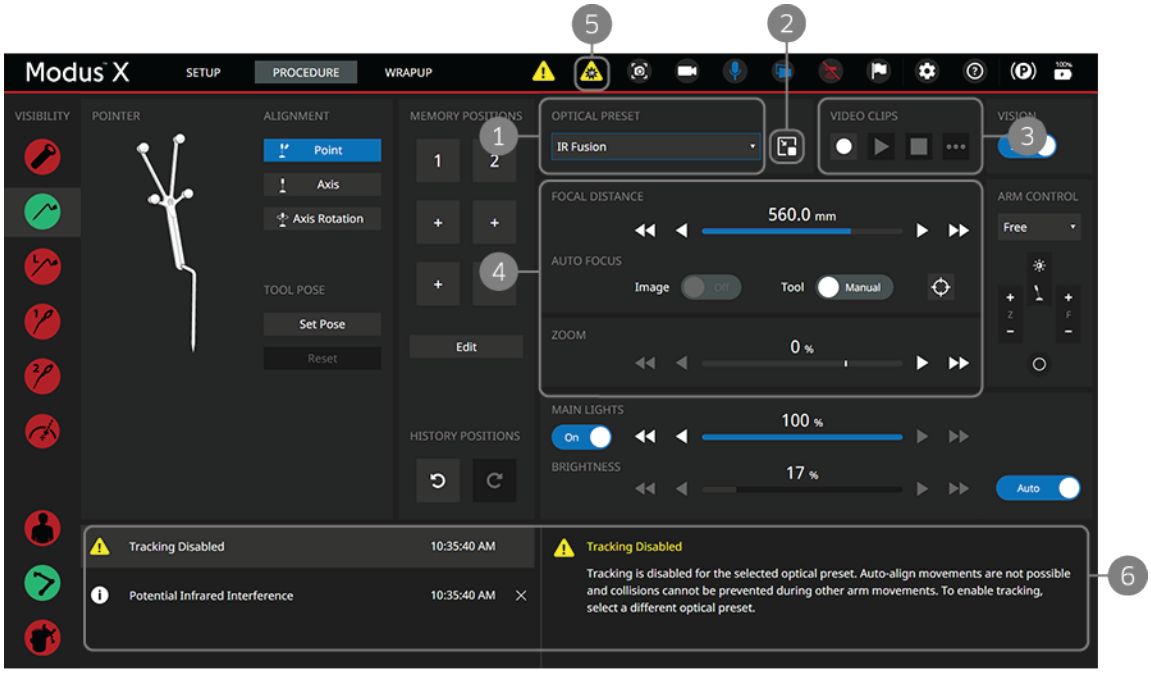

Figure 1 Modus IR features

1 To use Modus IR, select one of the IR presets from the OPTICAL PRESET list.
2 Picture in picture icon. Tap to display a second view of the surgical field on the monitors(s). For more information, see Using the Picture in Picture Feature with Modus IR on page 10.
3 Use the VIDEO CLIP features to record video from the surgical cameras after administering the fluorescence medium to the patient. For more information, see 5.5 Video Clips on page 11.
4 Make sure the focal distance and zoom level are set to the recommended values for Modus IR.
5 The IR notification icon indicates when the illuminators on the end effector are emitting infrared light.
6 Other important information relevant to using Modus IR appears in the notification area.

5.2 Modus IR Light Source

Modus IR uses the Synaptive surgical exoscope main light source to emit infrared light from the illuminators on the end effector.

NOTE: To avoid patient discomfort, do not position the end effector so that the light from the illuminators is shining directly into the patient's eyes.

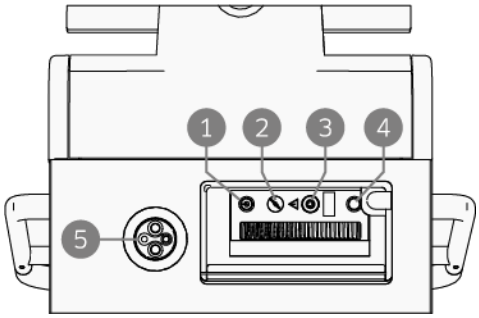

Figure 2 Synaptive surgical exoscope light source connectors

1 Main light source power button

NOTE: The light source powers on automatically when the Synaptive surgical exoscope starts up. Do not use this power button.

2 Main light source control key

3 Main light source connector

4 Main light source interlock reset button

5 Auxiliary light source connector

To use Modus IR, the light guide coming from the Synaptive surgical exoscope positioning arm must be plugged in to the main light source. If you need to access the light guide (for example to switch from the auxiliary light source to the main light source) open the panel on the front of the Synaptive surgical exoscope mobile base and unplug the light guide.

NOTE: When a light guide is not connected to a light source, the light source is in an interlock state. To reset the main light source, plug the light guide into the main light source connector and press the interlock reset button (item 4 in Figure 2). If the main lights are still not available, verify that the light guide is properly connected to the main light source.

The main light source provides light modes appropriate to the optical presets available in the Synaptive surgical exoscope. When you select an optical preset on the Procedure screen, Synaptive surgical exoscope automatically switches to the light mode appropriate for that preset.

NOTE: The main light source has a control key that must be inserted and turned to the "ON" position in order for the light source to function (item 2 in Figure 2). Do not remove the control key from the main light source. If the control key is misplaced, contact Synaptive customer service for assistance.

5.3 Modus IR Arm Drape

Always use the infrared fluorescence arm drape (part number SYN-01013) when performing a procedure with Modus IR. Note that the IR arm drape is designated by the IR symbol on the drape label.

To order IR arm drapes, contact salesorders@synaptivemedical.com or call 1-844-462-7246.

5.4 Using Modus IR

Use Modus IR to make fluorescing areas visible. Modus IR is designed for excitation in the wavelength range of 748 to 802 nm and observation in the wavelength range of 820 to 1000 nm.

Factors Which Influence the Fluorescence Signal

The visualization of the fluorescence signal is influenced by several factors, including:

- The fluorescence medium and its concentration in the tissue
- The illumination intensity of the light source in the defined wavelength range
- The transmission of the optical system

- The total magnification and the aperture setting
- The working distance and the illuminated field diameter

Standard Conditions of Use

When using Modus IR in conjunction with a fluorescence substance, the medical contraindications apply as in the use of suitable marker substances.

Lights in the operating room should be dimmed for optimal viewing of the fluorescent light.

Recommended Modus X Parameters

For optimal visualization when using Modus IR, the Modus X focus distance and zoom level must match the recommended parameters defined in the instructions below. If you select a Modus IR optical preset and the current focus distance and zoom level do not match its recommended parameters, a notification appears on the surgical overlay and on the Procedure screen. These notifications disappear when you adjust the focus distance and/or zoom level to match the recommended parameters. The notification on the surgical overlay will also disappear automatically after a few seconds, and you can dismiss the notification on the Procedure screen by tapping **Acknowledge**.

Instructions for Normal Use

When an IR optical preset is selected, if the Synaptive surgical exoscope is connected to a tracking camera, the tracking function is disable to prevent IR interference with the Synaptive surgical exoscope video feed.

Before using an IR optical preset with a fluorescence medium, check whether there are any other sources of IR interference in the operating room. If any are found, turn them away from the surgical site while using the IR optical preset to prevent interference with the Synaptive surgical exoscope video feed.

To use the Modus IR fluorescence module:

1. Verify that the excitation and observation wavelengths of the Modus IR module are sufficient to detect and display the fluorescence medium for visualization.
2. Select the **IR Fusion** or **IR Monochrome** optical preset from the OPTICAL PRESET drop-down list.

   NOTE: When an IR optical preset is active and the Synaptive surgical exoscope main lights are on, the illuminators on the end effector are emitting invisible infrared light. This is indicated by the IR icons that appear on the touchscreen monitor and the surgical overlay.
3. On the Synaptive surgical exoscope Procedure screen, set an appropriate zoom and focus distance for the optical preset you are using:
   - **IR Fusion**
     - Focus distance: 300-550 mm
     - Zoom: 0-50%
   - **IR Monochrome**
     - Focus distance: 300 mm
     - Zoom: 40%
4. Administer the fluorescence medium to the patient.
5. Use the VIDEO CLIPS controls to record and play back video of the surgical field. For more information, see the Video Clips section below.

Using the Picture in Picture Feature with Modus IR

NOTE: To use this feature, at least one monitor must be connected to Modus X by an Ethernet cable. For more information, see your Synaptive surgical exoscope user manual.

CAUTION: Risk of Procedure Delay

If the Ethernet cable connecting Modus X to the monitor is disconnected when the Modus IR picture in picture (PIP) feature is in use, the monitor will continue to display the PIP window and you will not be able to stop viewing the PIP window until you reconnect the Ethernet cable.

Use the picture in picture (PIP) feature to display a second view of the surgical field when using an IR optical preset.

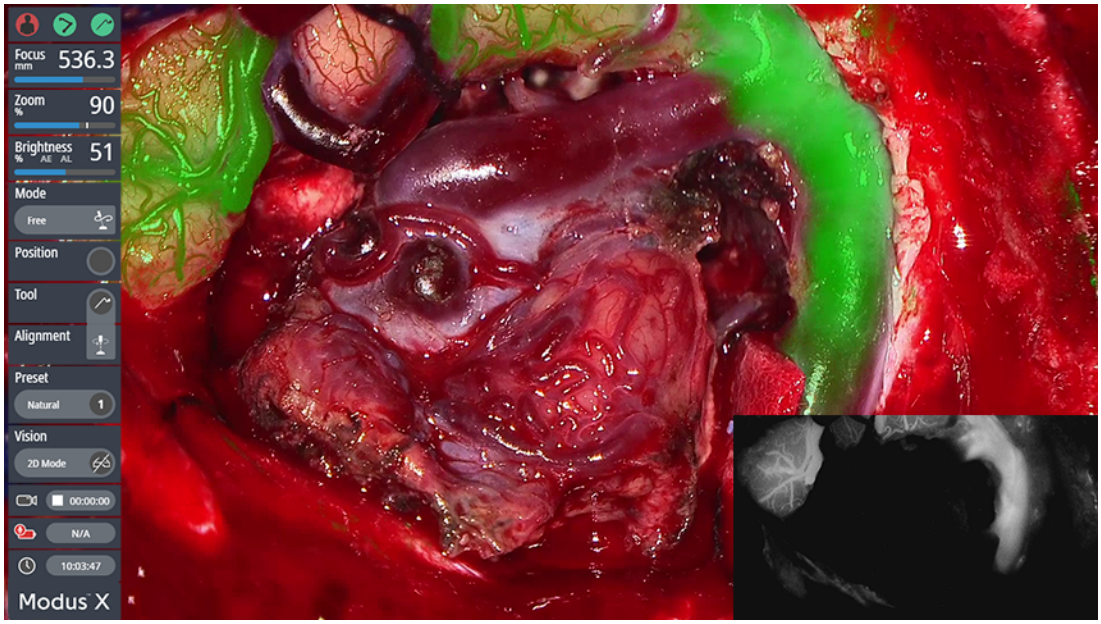

Figure 3 Picture in picture window for IR Fusion optical preset

When the IR Fusion optical preset is selected, the PIP window displays the IR monochrome view. When the IR Monochrome optical preset is selected, the PIP window displays the white light view.

To display the PIP window, tap the PIP icon beside the OPTICAL PRESET drop-down list. The position of the PIP window is determined by the **PIP Position** setting on the Monitors settings page. For more information, see 1.0 Monitors on page 1.

To stop displaying the PIP window, tap the PIP icon again. Modus X also stops displaying the PIP window if you switch to a different optical preset, or if the PIP window would interfere with another function (such as suction tool calibration).

NOTES:

- **The IR PIP feature can only be displayed in 2D. If you are viewing the video in 3D, it will switch to 2D when you enable the IR PIP feature, but will automatically switch back to 3D when you turn the IR PIP feature off.**

- The PIP window is not displayed when video clips are being played back. You can distinguish between the clip playback window and the PIP window by the time stamp information, which is only displayed on the clip playback window.
- The IR PIP feature will replace Modus Nav if Modus Nav is currently being displayed in the PIP window or if Modus Nav is being displayed on a secondary monitor. However, your previous view of Modus Nav will be restored when you stop using the IR PIP feature.

5.5 Video Clips

Use the VIDEO CLIPS controls on the Procedure screen to record and play back short video clips.

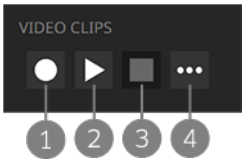

Figure 4 VIDEO CLIPS controls on the Procedure screen

1 Start/stop recording. Tap this icon to start recording a video clip, or to stop recording if recording is already in progress.

NOTE: Clip recording is not available when a clip is being played back or if there is insufficient data storage space for new clips.

2 Play/pause video clip. Tap this icon to play the most recently recorded video clip on the surgeon monitor(s), or to pause the playback if the clip is currently playing.

NOTE: Clicking this Play icon will play the most recently recorded clip. If you want to play an earlier clip, use the advanced clip recording playback controls (see below).

3 Stop playback. Tap this icon to stop a video clip that is currently playing and stop showing the video clip on the surgeon monitor(s).

4 Advanced playback controls. Tap this icon to access the advanced playback controls. For more information, see Using the Advanced Playback Controls below.

NOTE: The surgical overlay components are not included in clips.

Using the Advanced Playback Controls

Tap the advanced playback controls icon ••• on the VIDEO CLIPS controls to access the advanced playback controls.

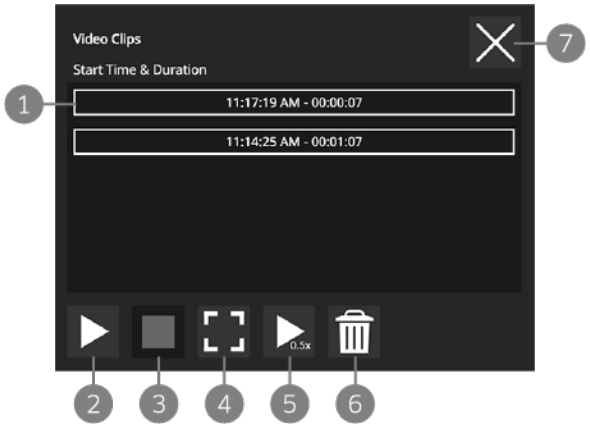

Figure 5 Advanced video clip playback controls

1 Clip list. Tap on a clip to start playing it on the surgeon monitor(s).

2 Play/pause video clip. Tap this icon to play the selected clip on the surgeon monitor(s), or to pause the playback if the clip is currently playing.

3 Stop playback. Tap this icon to stop a video clip that is currently playing and stop showing the video clip on the surgeon monitor(s).

4 Full screen mode. Tap this icon to toggle between displaying the video clip in full screen mode and picture-in-picture mode on the surgeon monitor(s).

5 Playback speed. Tap this icon to toggle between playing the video clip at 50% or full speed.

6 Clear clip list. Tap this icon to clear all the clips in the clip list.

NOTE: Cleared clip recordings are no longer available for playback but can still be exported (see below). To prevent clip recordings from accidentally being viewed in a subsequent procedure, always clear the clip list at the end of each procedure.

7 Close. Tap this icon to close the advanced playback controls dialog.

NOTE: This will also stop playback if a clip is playing.

NOTE: Clips are always recorded and played back in the standard monitor orientation, even if they are played on a monitor that has been set to flip and mirror the images from the Modus X surgical cameras.

5.6 Exporting Clips

To view the list of clips available for export, tap the video export icon on the right side of the Setup or Wrapup screen.

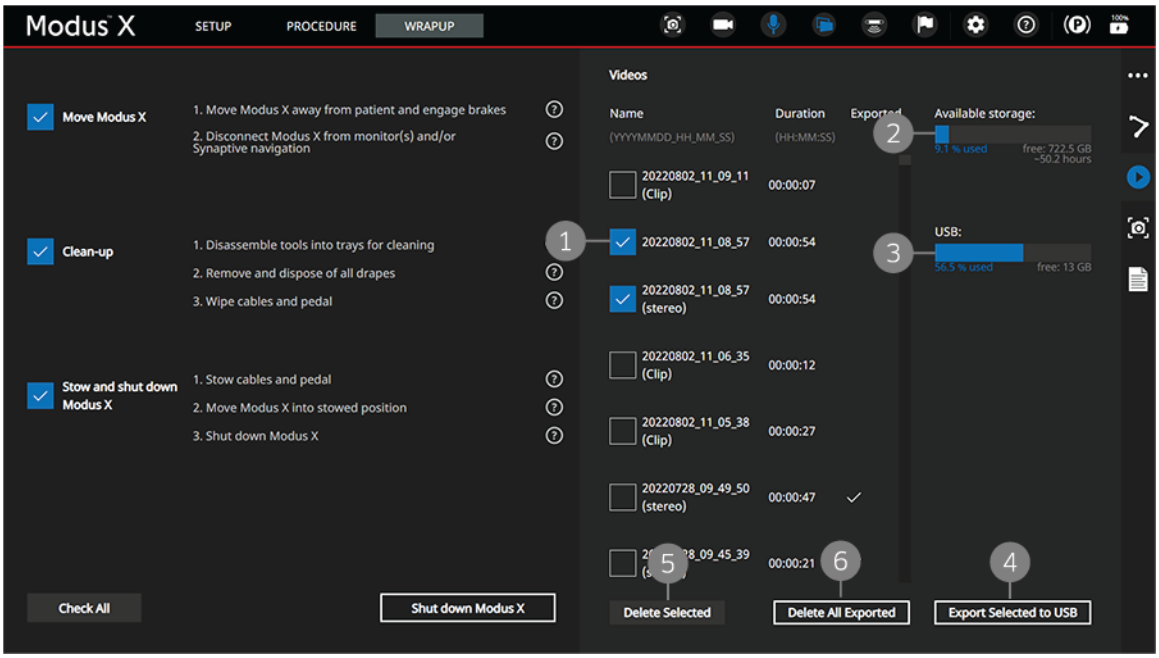

Figure 6 Videos screen

1 File list. Files are named by the date and time they were recorded. Clips have "(clip)" in the file name. Videos that were recorded in 3D have "(stereo)" appended to the file name.

   Tap the checkbox beside a file to select it for export or deletion. A check mark appears in the Exported column if the file has already been exported from the Synaptive surgical exoscope.

2 Synaptive surgical exoscope storage. The amount of storage space available on Synaptive surgical exoscope is displayed here.

3 USB storage available. When a USB drive is plugged in to the Synaptive surgical exoscope mobile base, the amount of storage space available on the drive is displayed here.

4 Export Selected to USB. Tap this button to export the selected files to a USB drive.

5 Delete Selected. Tap this button to delete the selected files from the Synaptive surgical exoscope.

6 Delete All Exported. Tap this button to delete all files that have been exported from the Synaptive surgical exoscope.

The Synaptive surgical exoscope saves clips with a file name based on the date and time the clip was recorded. Items are listed on the Videos screen in reverse chronological order.

To export a clip:

1. Connect a USB drive to the USB port on the Synaptive surgical exoscope mobile base.
2. On the Videos screen, tap the checkbox corresponding to the item you want to export.
3. Tap **Export Selected to USB**. Synaptive surgical exoscope displays a progress bar indicating the time remaining to copy the file to the USB drive.
4. When the export is complete, remove the USB drive from the Synaptive surgical exoscope mobile base.

NOTES:

- You cannot export while video is being recorded. Stop recording before exporting.
- If you connect a USB drive with multiple partitions, Modus IR always exports the video file to the first partition.

To delete a clip, tap the checkbox corresponding to the item you want to delete and tap **Delete Selected**.

To delete all items that have been exported, tap **Delete All Exported**.

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