Technical Service Bulletin

EENT Products

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Subject: TSB-Welch Allyn iExaminer Troubleshooting Guide

Distribution Scope: WA Internal
WA Technical Support, Product Service, & International Service Centers

Product(s) Referenced: Welch Allyn iExaminer (REF 11840)

Summary: This TSB provides a troubleshooting guide to assist in support of the
iExaminer, identifies the differences between the Welch Allyn iExaminer and
Intuitive Medical Technologies (IMT) iExaminer hardware and application,
and provides inspection guidelines for products returned to Service Centers.

Reference to Standards:
• 21 CFR Part 820, ISO 13485, MPD SOP-0002

Troubleshooting Guide:
The troubleshooting guide in Appendix A of this document is intended to
assist Welch Allyn representatives in remote troubleshooting and resolution
of common iExaminer hardware and application questions.

Where possible, the troubleshooting guide references customer-facing
documentation available on the iExaminer microsite (www.welchallyn.com/iexaminer), including the assembly guide, quick
reference guide, instructional video, frequently asked questions (FAQ), and
links to Apple support.

The troubleshooting guide is sorted into general categories containing
specific issues the customer may experience. The guide is presented in a
linear question and suggestion format, where the WA rep may walk through
each question for a specific issue and offer the related suggestions based
on the customer's response.
WA vs. IMT iExaminer:

Hardware:
The WA iExaminer hardware can be identified by color, WA branding, and the shape of the arm and arm insert, as shown in the pictures below:

![WA hardware](image1)
![IMT hardware](image2)

Application:
The WA iExaminer application can be determined by the branding on the app home screen, as shown below. Differences in the app include:

- The IMT app included a Visual Acuity Test under the “Full Exam” menu (including eye charts). This function will not be supported by WA.

- Standard / Hi-res selection was located on the IMT app Image Selection screen. This option is now in the Settings (⚙️) menu.
**IMT Installation:**

*The following steps are not required for customers using the WA iExaminer:*

Customers using the IMT hardware need to remove the c-clip and base collar ring from the PanOptic. After installing the IMT hardware, the base collar ring is used to secure the IMT arm assembly to the PanOptic:

![C-clip & base collar ring](image1)

![IMT arm installed with collar](image2)

**Product Service Inspection:**

Upon receipt of alleged failed WA hardware in a Product Service Center, the returned hardware may be compared to a known good iExaminer assembly to evaluate for physical damage or molding deficiencies. As necessary, assemble the returned iExaminer assembly to a PanOptic per the instructions in DIR 80017721 to evaluate assembly allegations.

If IMT hardware (as identified above) is received in a Product Service Center, IMT should be noted as the manufacturer of the returned part in the complaint investigation record.

**Quality Documents:**

- **All service centers using SAP to record service transactions:** For each monitor serviced, record the service activity in SAP.

- **All other service centers and Field Service:** For each monitor serviced, complete and file a service report and attach to the service DHR.

**Notes:**

1. Contact the Welch Allyn Complaints Department to initiate or process a medical device complaint resulting from this or other issues.
2. Drawings, illustrations, and part numbers in this document are for reference purposes only and subject to change.

**End of Bulletin**

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**Revision History**

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D* - Refer to SAP DIR digital signature log for approval details.

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Appendix A: Troubleshooting Guide

Assembly:

**Issue:** Customer is unable to assemble iExaminer.

**Q:** Do you have a copy of the assembly sheet?
  ➢ If the customer answers no, refer them to the Assembly Instructions available on the [microsite](#).

**Q:** Have you viewed the instructional video?
  ➢ If not, suggest the customer may want to watch this [instructional video](#).

**Q:** Do you have the materials shown on the assembly sheet (iExaminer hardware, PanOptic ophthalmoscope, handle) and an iPhone 4 or 4S?
  ➢ If customer does not have the iExaminer hardware kit or PanOptic, inform them of these requirements for use and begin the order process.
  ➢ Refer to [FAQ – iPhone Compatibility](#) for assistance determining iPhone model.
  ➢ The iExaminer is not validated for use with either the iPod or iPad. If the customer is attempting to use an iPod or iPad, inform them that the iExaminer requires an iPhone 4 or 4S for proper use.

**Q:** Are both of the iExaminer hardware components (plastic adaptor & arm) present and in good condition?
  ➢ If parts are missing or broken, evaluate warranty status and provide a replacement as applicable.

**Q:** Can the iExaminer hardware be mounted to the PanOptic per the assembly sheet?
  ➢ Verify the physician eye bumper and chrome ring have been removed from the PanOptic prior to installation, per assembly instructions. The c-clip near the physician eye piece and the base collar (near the handle) should not be removed from the PanOptic for the Welch Allyn iExaminer hardware. These two items are only removed when installing the IMT iExaminer hardware.
  ➢ Verify that the iExaminer hardware is firmly pressed into the Practitioner’s side of the PanOptic. This will help to ensure good optical alignment and proper fit.
  ➢ If assembly cannot be completed, the adaptor may be faulty. If so, evaluate warranty status and provide a replacement as applicable.

**Q:** Can the iPhone be inserted into the iExaminer adaptor?
  ➢ If not, verify there is no case or screen protector installed on the phone. These items will prevent proper fit of the phone into the adaptor. Refer to [FAQ – Assembly Questions](#) for additional detail.
  ➢ If iPhone does not fit, the adaptor may be faulty. Evaluate warranty status and provide a replacement as applicable.

**Q:** Is the iPhone securely seated within the iExaminer adaptor?
  ➢ If the iPhone is loose within the adaptor, the adaptor may be faulty. Evaluate warranty status and provide a replacement as applicable.
General App Questions:

**Issue:** Customer has questions about general use of the app.

Q: Do you have a copy of the Quick Reference Guide?
   - If the customer answers no, provide a link to the Quick Reference Guide available on the [microsite](#).

Q: Have you watched the instructional use video @ WA.com?
   - If not, suggest the customer may wish to watch this [instructional video](#).

As applicable, use the HTML app simulator to answer any remaining general use questions about the app.

Unable to Download and Install Application:

**Issue:** Customer is unable to download or install the iExaminer app.

Q: What version iOS is installed on your iPhone?
   - iOS 5.0 or higher is required for the iExaminer application. See [FAQ – iPhone Compatibility](#) for instructions on determining the iOS version.
   - Refer customer to [FAQ – iPhone Compatibility](#) for information on updating their iOS, as necessary.

Upgrading to iExaminer Pro:

**Issue:** Customer is unable to upgrade to iExaminer Pro.

From the Home screen of the iExaminer app, ask the customer to touch “Learn about iExaminer Pro,” then touch “Upgrade to iExaminer Pro.” A pop-up will appear to confirm the In-App purchase. Ask the customer to touch, “Buy.” Next, a prompt will appear for the customer to enter their Apple ID password (iTunes account password). After entering, the app should update to the Pro version.

- If the iPhone displays, “Error code=4” or “In-App purchases are not allowed,” In-App purchases may be disabled on the iPhone. Refer the customer to the [FAQ – Upgrading to iExaminer Pro](#) for instructions on enabling In-App purchases.
- All questions regarding billing or the customer’s iTunes account should be referred to Apple support. See the [FAQ – iPhone & App Store Questions](#) for links.
Taking a Photo:

**Issue:** Unable to take a picture with iExaminer / No image on iPhone display

Q: Is the iExaminer Application installed on the iPhone?
  - If not, instruct the user to download and install the iExaminer application. Refer customer to FAQ – General Product Questions for information on downloading and installing the app.

Q: Open the application. On the Home screen, touch “Retinal Image.” Does the iPhone display a live camera feed?
  - If an image is displayed, proceed to the next question.
  - If no image is displayed, a misalignment of the iExaminer hardware may be blocking the camera on the iPhone. Ask the customer to remove the phone from the iExaminer adaptor and see if a live camera feed is displayed.
  - If the camera feed is displayed on the phone when the iPhone is removed from the adaptor, verify the iExaminer hardware is assembled correctly per the Assembly troubleshooting section above. Verify the PanOptic is functional per standard PanOptic troubleshooting processes (PanOptic on The Pulse).
  - If the camera feed is not displayed on the phone when the iPhone is removed from the adaptor, this may indicate a problem with the app or the iPhone’s camera. Ask the customer to remove and reinstall the app. Ask the customer to ensure their iPhone camera is functional.

Q: From the Retinal Image screen, touch the camera icon at the bottom of the screen. Does the iPhone display an increasing image count, then advance to the Picture Selection screen?
  - If the application displays “Please wait...” with a spinning progress indicator but never advances to the Picture Selection screen, the iPhone may not have enough available memory to temporarily store the captured images. Recommend that the customer reduce the Recording Time and Resolution selection in the Settings menu prior to capture. If this corrects the issue, recommend that the customer free up available space on the phone, per the iPhone User Guide.

At this point, the iExaminer should have successfully captured a picture. See issues with picture quality or saving a picture or patient record for additional troubleshooting.

**Issue:** Picture quality is lower than expected

Q: Is the viewable image within the app obscured or obstructed?
  - If the hardware is not installed or installed incorrectly, the camera may be misaligned with the PanOptic. This may cause a loss of viewable area within the picture or a loss of picture quality. Verify the iExaminer hardware is assembled correctly per the Assembly troubleshooting section above.

Q: How are you holding the iExaminer / PanOptic?
  - For optimal picture quality, the iExaminer should be held differently than the traditional PanOptic ophthalmoscope. Refer customer this instructional video for additional information.

Q: Is the PanOptic turned on, focused and functioning?
  - Follow standard PanOptic troubleshooting processes to verify PanOptic is providing a good image.
Q: Is the color of the captured image too white or washed-out?
   ➢ Verify the customer is using the halogen model 03800 lamp with the PanOptic, per the Quick Reference Guide available on the microsite. Use of an LED lamp may result in a washed out image.

Saving a Photo or Patient Record:

**Issue:** Photos and/or patient records are not being saved

Have the customer capture an image through the iExaminer app per the “Unable to take a picture with iExaminer” issue above.

Q: Are you attempting to save a picture to the camera roll or to a patient file?
   ➢ Any pictures not saved to the Camera Roll or saved to a patient file will be deleted when navigating back to the Home screen, the Retinal Image screen, or exiting the app.
   ➢ If attempting to save to the camera roll, ask the customer to select the appropriate picture using the slider bar, then touch the icon, then touch “Save to camera roll.” At this point, the picture should be saved to the camera roll. Refer the customer to the iPhone User Guide for instructions on accessing and managing the camera roll. Note: pictures saved to the camera roll will not retain any patient information.
   ➢ If attempting to save to a patient file, ask the customer to select the appropriate picture using the slider bar, then touch the icon, then touch “Add to patient file.” The picture will be imported into the active patient file. If the application states, “You have already selected three pictures for the right (or left) eye,” one of the pictures for the selected eye will need to be removed prior to adding additional pictures to that eye.

Q: Have you saved the patient file?
   ➢ Pictures assigned to a patient file will only be saved if the patient file is saved within the iExaminer App. On the Patient File screen, ask the customer to touch the icon, then touch “Save patient file.”
   ➢ If the application displays “Please wait...” with a spinning progress indicator but never advances, the iPhone may not have enough available memory to save the patient file. Recommend that the customer free up available space on the phone, per the iPhone User Guide.
   ➢ If the customer has not created a Saved Exams password, they will be prompted to create a password at this time.

**Issue:** I’ve forgotten my password. How can I recover my patient files?

   ➢ It is not possible to recover patient files without the original password. Resetting the password will delete all patient files. WA cannot retrieve or recover the customer’s password.
Exporting a Photo or Patient Record:

**Issue:** Customer wants to export electronic patient records from iExaminer

**Q:** Do you have the Pro version of the iExaminer app?

- The preferred method for export of patient files is via email, which requires iExaminer Pro. If the customer will be exporting data via email, proceed to the next question. Recommend that customers wanting to export electronic patient files upgrade to the Pro version.
- If the customer does not have iExaminer Pro, the patient files can be exported manually as pictures. Ask the customer to navigate to the patient file, then take a screenshot by simultaneously pressing the iPhone power/standby button and the home button. This will save an image of the patient file to the Camera Roll. Refer the customer to the [FAQ – Exporting a Patient File](#) for instructions on taking a screenshot and Apple Support for transferring the image to a computer via iTunes sync or via manual file transfer.

**Q:** Do you have an email account setup on your phone?

- If not, refer the customer to the [FAQ – Exporting a Patient File](#) for a link to Apple’s email setup support.
- If an email account is setup, ask the customer to navigate to the patient file they want to export, touch the icon, then touch “Email.” The app will launch the iPhone’s email client with the patient file information imported into a new email. Instruct the customer to send the email to an appropriate email account for their access. Refer the customer to the [iPhone User Guide](#) for instructions on emailing.

**Issue:** Customer wants to export printed patient records from iExaminer

**Q:** Do you have the Pro version of the iExaminer app?

- The Pro version of the iExaminer app can print patient files.

**Q:** Do you have an AirPrint printer setup?

- Printing from the iPhone requires an AirPrint printer and iPhone configuration. Refer the customer to the [FAQ – Exporting a Patient File](#) for links to Apple’s printer setup support.
- If an AirPrint printer is setup, ask the customer to navigate to the patient file they want to export, touch the icon, then touch “Print.” The app will launch the iPhone’s print client. Refer the customer to the [iPhone User Guide](#) for instructions on printing.
Other Issues (responsiveness, crashes, iPhone operation):

**Issue:** App is frequently freezing or crashing.

Refer customer to FAQ - Troubleshooting and Application Assistant for additional information while walking through the troubleshooting steps below.

1. **Verify iOS requirement**
   - iOS 5.0 or higher is required for the iExaminer application. Instructions to identify the installed iOS are included on the Application Assistant page.

2. **Verify App is up to date**
   - Ask the customer to check for app updates on their iPhone.

3. **Ask the customer to restart the iPhone**

4. **Ask the customer to remove and reinstall the App**
   - Purchased Pro features can be reactivated free-of-charge via the In-App purchase, if using the same AppleID (iTunes) account originally used to purchase the upgrade.

5. **If none of the above steps resolve the issue, ask the customer to enable crash reports on their iPhone. Crash reports will be sent to Apple and forwarded to Welch Allyn for investigation.**
   - On the iPhone, select Settings, then touch General > About > Diagnostics & Usage > Automatically Send.

6. **Lastly, attempt to gather the following information for Engineering analysis:**
   - iOS version – See FAQ – iPhone Compatibility for instructions
   - App version – See FAQ – iPhone Compatibility for instructions
   - iPhone model – See FAQ – iPhone Compatibility for instructions
   - Where does the app crash?
   - Does it happen every time?
   - What steps do you take to make this crash occur?

**Issue:** Customer wants to transfer the app and patient files to a new phone.

- Refer to FAQ – Transferring App for information and links to Apple support for this process.

**Issue:** iPhone is frozen or unresponsive

- Refer to FAQ – iPhone & App Store Questions for information and links to Apple support for troubleshooting this issue.

**Issue:** Customer has questions on their iTunes account or billing.

- Refer to FAQ – iPhone & App Store Questions for information and links to Apple support for this iTunes account questions.