Operating Notes

Lumify Diagnostic Ultrasound System

July 15, 2020   4535 620 24941 Rev A

About These Operating Notes

Operating notes contain information that clarifies certain system responses that might be misunderstood or cause user difficulty. Review the operating notes and keep a copy with the system manuals. If appropriate, post the operating notes near the ultrasound system.

Labeling Information

For your records, retain the *Quick Guide* included in shipment; it contains the labeling information for the Lumify Diagnostic Ultrasound System.

CE Mark and EC Rep Address

Philips Ultrasound, Inc., is transitioning from the CE0086 Notified Body (UK) CE Mark to a new CE2797 Notified Body (EU-27) CE Mark, effective March 1, 2019. Additionally, our European Union Authorized Representative (EC Rep) has a new street address:

> Philips Medical Systems Nederland B.V.
> Veenpluis 6
> 5684 PC Best
> The Netherlands

During the transition, you may see the previous CE Mark and address on Instructions for Use and on the ultrasound system and its accessories.

Using the System

- **Fast Flow** and **Slow Flow** controls might overlap slightly in Color mode. This most often appears on 5th generation iPad mobile devices in landscape orientation. This does not affect the functionality of the controls.

- (iOS devices only) When you manually correct the patient **Date of Birth** field on the **Patient Info** form, clearing and reentering all four digits of the year results in an error. For best results, reenter the entire date.

- (iOS devices only) The navigation bar, including the **Back** control, is missing from the **Contact Information** form (accessed from **Customer Information** in **Settings**). To leave the page, you must enter your customer information, and then touch **Continue**.

- (iOS devices only) Rapidly touching **Save** multiple times when you scan might cause the Lumify software to shut down unexpectedly.

- (iOS devices only) The Lumify Power Module (LPM) might enter sleep mode if you exit the Lumify application or allow the mobile device to enter sleep mode. If you try to resume the

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scan with the LPM in sleep mode, the **LPM Connection Error** message appears. To wake the LPM, press the button on the back of the LPM.

Review

- (iOS devices only) When you scroll to the bottom of a long list of saved exams, the last exam in the list might be cut off by the edge of the screen.
- (iOS devices only) When you export multiple exams to a local directory, you must confirm the export destination for each exam; you cannot use a single window to control the export of all of the exams.
- (iOS devices only) The sequence of selected images and loops that appears in an exam is different from the sequence that appears on Android devices.
- (iOS devices only) During exam export, the **Export Queue** shows the export status as **Aborted**. The export status should appear as **In Progress**.
- (iOS devices only) When you view a list of exams in the **Saved Exams** window and then touch **Select**, the list scrolls away from your intended selection.

User Information Changes

The following information replaces or adds to the information included on your *User Information* USB media.

Recycling, Reuse, and Disposal

The following information adds to information in the *User Manual*.

Perchlorate Material

In this system, perchlorate material is present in lithium coin cells or batteries. Special handling may apply to those items. For more information, see this website:

www.dtsc.ca.gov/hazardouswaste/perchlorate

Safety

The following information adds to or replaces information in the *User Manual*.

Symbols

Symbol	Standards and Reference	Reference Description	Additional Information
	--	Product contains hazardous material. Dispose of properly. (Required by WEEE Directive; see EN 50419.)	--
	ISO 7000-3725	Importer	--

Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.4.3 ISO 7000-1641	Consult instructions for use.	--
	ISO 15223-1, Symbol 5.1.3 ISO 7000-2497	Date of Manufacture.	--
	ISO 15223-1, Symbol 5.1.1 ISO 7000-3082	Manufacturer.	--
	IEC 60417	Country of Manufacture.	--
	ISO 15223-1, Symbol 5.1.4 ISO 7000-2607	Use-by date.	--
	IEC 60878, Symbol 1135 ISO 7000-1135	General symbol for recovery/recyclable.	Do not throw away. Dispose of in accordance with local, state, or federal laws.
SN	ISO 15223-1, Symbol 5.1.7 ISO 7000-2498	Serial Number.	--
LOT	ISO 15223-1, Symbol 5.1.5 ISO 7000-2492	Batch code.	--
REF	ISO 15223-1, Symbol 5.1.6 ISO 7000-2493	Catalog Number.	--
STERILE EO	ISO 15223-1, Symbol 5.2.3 ISO 7000-2501	Sterilized using ethylene oxide.	--
CE	European Commission Medical Device Directive 93/42/EEC 2007/47/EC EU MDR 2017/745, Article 20, Annex 5	CE Mark of Conformity.	--
CE 0086	European Commission Medical Device Directive 93/42/EEC 2007/47/EC EU MDR 2017/745, Article 20, Annex 5	CE0086 - CE Mark of Conformity.	--

Symbol	Standards and Reference	Reference Description	Additional Information
CE 2797	European Commission Medical Device Directive 93/42/EEC 2007/47/EC EU MDR 2017/745, Article 20, Annex 5	CE2797 - CE Mark of Conformity.	--
	ISO 15223-1, Symbol 5.4.2 ISO 7000-1051	Do not reuse.	--
	ISO 15223-1, Symbol 5.4.4 ISO 7000-0434A	Caution (ISO 7000-0434).	--
	ISO 15223-1, Symbol 5.3.2 ISO 7000-0624	Keep away from sunlight.	--
	ISO 15223-1, Symbol 5.2.7 ISO 7000-2609	Non-sterile.	--
	ISO 15223-1, Symbol 5.2.8 ISO 7000-2606	Do not use if package is damaged.	--
	ISO 15223-1, Symbol 5.3.7 ISO 7000-0632	Temperature limit.	Indicates the temperature range (noncondensing) for transport and storage. Does not apply to media.
	IEC 15223-1, Symbol 5.3.8 ISO 7000-2620	Humidity limitation.	The relative humidity range (noncondensing) for transport and storage.
	IEC 15223-1, Symbol 5.3.9 ISO 7000-2621	Atmospheric pressure limitation.	Atmospheric pressure range for transport and storage.
	ISO 15223-1, Symbol 5.3.4 ISO 7000-0626	Keep dry.	--
	ISO 15223-1, Symbol 5.3.1 ISO 7000-0621	Fragile, handle with care.	--

Symbol	Standards and Reference	Reference Description	Additional Information
	IEC 60878, Symbol 2794 ISO 7000-2794	Packaging unit.	--
	ISO 7000-3724	Distributor	--

Specifications

The following information adds to information in the *User Manual*.

Service Life

The Lumify system is designed to have a minimum of 3 years of service life. The service life of the Lumify system will vary depending on the usage and environmental conditions.