Operating Notes

Lumify Diagnostic Ultrasound System

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

- (Android devices only) In PW Doppler mode, quickly freezing and unfreezing the exam might cause the audio to stop working. Exiting and reentering PW Doppler mode sometimes fixes the issue.
- (Android devices only) Rotating the device while changing from 2D mode to PW Doppler mode might cause the software to stop working.
- (Android devices only) A frozen trace might not scale properly when you change the sweep speed setting.
- (Android devices only) When you are viewing PW Doppler mode in full-screen landscape orientation, the image for the exiting full-screen view ⊞ control covers the image for the inverting the trace 🔁 control, but the activation area for the inverting the trace control remains on top. When you touch the control to exit full-screen view, the trace may invert instead.
- (Android devices only) In PW Doppler mode, the 2D image can become distorted if, after switching to the spectral trace, you adjust the **Depth** ↕ dial and switch back to the 2D image.

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- **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 scan with the LPM in sleep mode, you receive a connection error message. To wake the LPM, press the button on the back of the LPM.

Using Reacts (Android Devices Only)

Answering a Reacts call from another Lumify device might cause the Lumify software to shut down unexpectedly. To reduce the occurrence of this problem, grant camera and microphone access to the Lumify app on the receiving device in advance of receiving a Reacts call.

Review

- Playing exported loops in Windows Media Player on a Windows PC might cause gaps in the playback. Use a different media player to avoid this issue.
- (Android devices only) Rotating the device might cause annotations to disappear.
- (Android devices only) In M-mode or PW Doppler mode, switching to full-screen view might cause annotations to change position.
- (Android devices only) Annotations made in M-mode or PW Doppler mode might change position in 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.

System Maintenance

(iOS devices only) The iPad mini 5 mobile device might not be able to charge when it is connected to the Lumify Power Module (LPM). To make sure that the LPM and the iPad mini 5 mobile device are fully charged, charge them separately.

User Information Changes

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

Safety

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

Symbols

Symbol	Standards and Reference	Reference Description	Additional Information
IP67	IEC 60529	Degrees of protection provided by enclosures.	Indicates that the equipment inside the enclosure is protected against ingress of dust and effects of immersion for up to 30 minutes at 1 m of submersion.

Using the System

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

Connecting Transducers

⚠ **WARNING**
Always connect the transducer cable directly to your mobile device. Philips does not recommend using adapters. For approved cable options, contact your Philips representative.

Using Reacts (Android Devices Only)

The following information replaces information in the *User Manual*.

Reacts Access Codes

Reacts access codes can be redeemed or shared to provide limited, trial access to the Standard Plan of Reacts. For more information about your Reacts access codes, review the Terms and Conditions of your sale. If you select **Remember Me** when you log in to Reacts, Lumify preserves redeemed Reacts access codes with other Lumify user settings during Lumify app upgrades or Android operating system upgrades.

If you prefer, you can redeem or share your access codes through the Reacts website:

https://reacts.com/philips/redeem

Performing an Exam

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

Using PW Doppler (Android Devices Only)

Sweep Speeds

Speed	Cardiac	Noncardiac
Fast	2 seconds	3 seconds
Medium	3 seconds	5 seconds
Slow	5 seconds	8 seconds

Performing PW Doppler Measurements (Android Devices Only)

PW Doppler measurements on the Lumify system fall into three major categories: **Velocity**, **Distance**, and **Trace** measurements. The measurement data that appears after completing each measurement varies based on the exam preset, as shown in the following table:

PW Doppler Measurements Available for Each Exam Preset

Exam Preset	Velocity Measurements	Distance Measurements	Trace Measurements
Cardiac	Velocity, PG	Time, Slope, P1/2t	Vmax, MaxPG, MeanPG, VTI
OB/Gyn	Velocity	PSV, EDV, S/D, RI	PSV, EDV, MDV, S/D, RI
Vascular	Velocity	PSV, EDV, RI	PSV, EDV, MDV, RI, VTI
FAST	Velocity	PSV, EDV, RI	PSV, EDV, MDV, RI
Abdomen	Velocity	PSV, EDV, RI	PSV, EDV, MDV, RI
Lung	Velocity	PSV, EDV, RI	PSV, EDV, MDV, RI
MSK	Velocity	PSV, EDV, RI	PSV, EDV, MDV, RI
Soft Tissue	Velocity	PSV, EDV, RI	PSV, EDV, MDV, RI
Superficial	Velocity	PSV, EDV, RI	PSV, EDV, MDV, RI

Key to Measurement Abbreviations and Acronyms			
EDV = end-diastolic velocity	MeanPG = mean pressure gradient	PSV = peak systolic velocity	Vmax = maximum velocity
MaxPG = maximum pressure gradient	P1/2t = pressure half-time	RI = resistivity index	VTI = velocity time integral
MDV = minimum diastolic velocity	PG = peak pressure gradient	S/D = systolic to diastolic ratio	

Performing Velocity Measurements

1. Obtain the Doppler trace image that you want to measure.
2. Touch **Measure**.
3. Touch **Velocity**, and then drag the caliper to the peak of the velocity you want to measure.
4. Repeat step 3 for up to four separate velocity measurements.
5. To save an image with the displayed measurements, touch **Save Image**.

Performing Distance Measurements

1. Obtain the Doppler trace image that you want to measure.
2. Touch **Measure**.
3. Touch **Distance**, and then drag the first caliper to the peak systolic velocity (PSV).
4. Drag the second caliper to the end-diastolic velocity (EDV).
5. To save an image with the displayed measurements, touch **Save Image**.

Performing Trace Measurements

1. Obtain the Doppler trace image that you want to measure.
2. Touch **Measure**.
3. Touch **Trace**, and then drag the first caliper to the start of the waveform you want to measure.
4. Touch the start of the waveform again to create a second caliper, and then drag the new caliper over the shape of a single cycle.
5. To save an image with the displayed measurements, touch **Save Image**.

References

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

Adult Echocardiography References

Baumgartner, Helmut, et al. "Echocardiographic Assessment of Valve Stenosis: EAE/ASE Recommendations for Clinical Practice." *European Journal of Echocardiography*, 10: 1-25, 2009.

Calafiore, P., Stewart, W.J. "Doppler Echocardiographic Quantitation of Volumetric Flow Rate," *Cardiology Clinics*, Vol. 8, No. 2: 191-202, May 1990.

Rudski, Lawrence, et al. "Guidelines for the Echocardiographic Assessment of the Right Heart in Adult: A Report from the American Society of Echocardiography." *Journal of the American Society of Echocardiography*, Vol. 23, No. 7: 685-713, 2010.

Zoghbi, William, et al. "Recommendations for Evaluation of Prosthetic Valves with Echocardiography and Doppler Ultrasound." *Journal of the American Society of Echocardiography*, Vol. 22. No. 9: 975-1014, 2009.

Maximum Pressure Gradient (Simplified Bernoulli)

Silverman, N. H., Schmidt, K. G. "The Current Role of Doppler Echocardiography in the Diagnosis of Heart Disease in Children." *Cardiology Clinics*, Vol. 7, No. 2: 265-96, May 1989.

Reynolds, T. *The Echocardiographer's Pocket Reference*, *Second Edition*. Arizona Heart Institute Foundation, Phoenix, AZ, 2000, p. 382.

Maximum Pressure Gradient (Full Bernoulli)

Silverman, N. H., Schmidt, K. G. "The Current Role of Doppler Echocardiography in the Diagnosis of Heart Disease in Children." *Cardiology Clinics*, Vol. 7, No. 2: 265-96, May 1989.

Mean Pressure Gradient

Reynolds, T. *The Echocardiographer's Pocket Reference*, *Second Edition*. Arizona Heart Institute Foundation, Phoenix, AZ, 2000, p. 382.

Pressure Half-Time

Hatle, L., Angelsen, B., Tromsal, A. "Noninvasive Assessment of Atrioventricular pressure half-time by Doppler Ultrasound" *Circulation*, Vol. 60, No. 5: 1096-104, November, 1979.

Velocity Time Integral (VTI)

Silverman, N. H., Schmidt, K. G. "The Current Role of Doppler Echocardiography in the Diagnosis of Heart Disease in Children." *Cardiology Clinics*, Vol. 7, No. 2: 265-96, May 1989.

Vascular References

Doppler Velocity (VEL)

Krebs, C. A., Giyanani, V. L., Eisenberg, R. L. *Ultrasound Atlas of Vascular Diseases*, Appleton & Lange, Stamford, CT, 1999.

End-Diastolic Velocity (EDV)

Strandness, D. E., Jr. *Duplex Scanning in Vascular Disorders*. Lippincott, Williams & Wilkins, Philadelphia, PA, 2002.

Minimum Diastolic Velocity (MDV)

Evans, D. H., McDicken, W. N. *Doppler Ultrasound Physics, Instrumentation, and Signal Processing, Second Edition*. John Wiley & Sons, Ltd., 2000.

Peak Pressure Gradient (PG)

Powls, R., Schwartz, R. *Practical Doppler Ultrasound for the Clinician*. Williams & Wilkins, Baltimore, Maryland, 1991.

Peak Systolic Velocity (PSV)

Krebs, C. A., Giyanani, V. L., Eisenberg, R. L. *Ultrasound Atlas of Vascular Diseases*, Appleton & Lange, Stamford, CT, 1999.

Resistivity Index (RI)

Zwiebel, W. J., ed. *Introduction to Vascular Ultrasonography, Third Edition*. W. B. Saunders Company, Philadelphia, PA 1992.

Systolic to Diastolic Ratio (S/D)

Zwiebel, W. J., ed. *Introduction to Vascular Ultrasonography, Third Edition*. W. B. Saunders Company, Philadelphia, PA 1992.

Velocity Time Integral (VTI)

Reynolds, T. *The Echocardiographer's Pocket Reference*, *Second Edition*. Arizona Heart Institute Foundation, Phoenix, AZ, 2000, p. 383.