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Urgent Field Safety Notice

VeinViewer 1.1 GS
FSCA-identifier (3008161930-02_9_2012-001-C)
Device Modification

April 12, 2012

Attention: Distributor/End User

Details on affected devices:
VeinViewer 1.1 GS (Model No: P00800-L)

We began shipping the VeinViewer 1.1 GS (Model No: P00800-L) on February 11, 2008.

Table 1: VeinViewer 1.1 GS Serial Numbers shipped to EU countries.				
Z1AAA024	Z1AAA236	Z1AAA336	Z1AAA497	Z1AAA584
Z1AAA119	Z1AAA237	Z1AAA337	Z1AAA498	Z1AAA585
Z1AAA121	Z1AAA238	Z1AAA445	Z1AAA502	Z1AAA589
Z1AAA144	Z1AAA239	Z1AAA448	Z1AAA503	Z1AAA590
Z1AAA147	Z1AAA247	Z1AAA449	Z1AAA504	Z1AAA591
Z1AAA148	Z1AAA248	Z1AAA460	Z1AAA505	Z1AAA723
Z1AAA149	Z1AAA249	Z1AAA462	Z1AAA547	Z1AAA724
Z1AAA151	Z1AAA250	Z1AAA463	Z1AAA548	
Z1AAA152	Z1AAA265	Z1AAA464	Z1AAA549	
Z1AAA153	Z1AAA266	Z1AAA465	Z1AAA550	
Z1AAA154	Z1AAA267	Z1AAA466	Z1AAA551	
Z1AAA155	Z1AAA268	Z1AAA467	Z1AAA576	
Z1AAA156	Z1AAA269	Z1AAA475	Z1AAA579	
Z1AAA157	Z1AAA272	Z1AAA494	Z1AAA580	
Z1AAA161	Z1AAA334	Z1AAA495	Z1AAA582	
Z1AAA235	Z1AAA335	Z1AAA496	Z1AAA583	

Description of the Problem:
If not moved properly the Luminetx VeinViewer 1.1 GS has the potential to tip over. Under normal operating conditions per the User Guide, the device is stable. The device is able to be used with the head and arm fully extended; however, the head unit product is not designed to be pulled on or tilted more than 5 degrees during normal use. Further, the device is not intended to be moved without the head unit secured in the designated travel position. The User Guide for VeinViewer 1.1 GS states the method of moving or transporting the device multiple times and warns of tilting the device more than 5 to 10 degrees. In addition, users are warned in the User Guide not to place, hang or otherwise apply weight to the unit arm.

An annual review of the complaints received for the VeinViewer 1.1 GS incited additional review of the medical device report (MDR0504540000-2011-8004) from the United States Food and Drug Administration. Review of the event and additional risk analysis determined that while the User Guide does provide warning and instruction, an improvement could be made by providing labeling on the product so that the user will be more likely to see the warning immediately.

Enclosure (4)

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No illness or injuries have occurred with proper use of the device. No injuries or illness have been reported to Christie Medical Holdings, Inc. or to the best of our knowledge, Luminetx, Inc.

Advise on action to be taken by the user:
Please see the enclosed product label "Correct Transport" (013-101825-01) and "Do Not Pull" (013-101994-01) and Service Bulletin (020-300122-01). Users are instructed to place the provided "Correct Transport" label (013-101825-01) on the column of the unit approximately 3.5 feet or 1 meter high and the provided "Do Not Pull" label on both sides of the head of the unit as shown in the attached Service Bulletin. These labels provide simple examples on "how-to" and "how-not-to" move or transport the units in order to prevent the potential of tipping. The Service Bulletin (020-300122-01) should be kept and placed with the User Guide for future reference.

It was recommend that users examine inventory, quarantine all product subject to correction, and apply the labels prior to use. Notified parties have been requested to perform the correction and complete and return a response form (enclosed) as soon as possible.

Transmission of this Field Safety Notice:
This notice needs to pass on all those who need to be aware with your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:
Dawn N. Norman
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Dawn.Norman@Christiedigital.com

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

Sincerely,
Dawn N. Norman
Manager Regulatory, Quality, and Clinical

Enclosure (4)