MyoVista® DG-200 Wavelet ECG (*wav*ECG™)

Urgent Field Safety Notice

Line Filter Application to Glasgow Program Analysis

August 18, 2022

FSN Ref: CAPA-00022-COMP-00066

To: HeartSciences' MyoVista Distribution Partners

This Urgent Field Safety Notice is communicating an issue relating to the MyoVista DG-200 Electrocardiograph Device Software. It is important that MyoVista distribution partners be made aware of the potential impact of this issue.

HeartSciences has become aware that when the Frequency Interface filter is active, the filter is not being applied to the Glasgow Program Analysis. This could result in greater than expected variance in test measurements when line-related environmental noise is high and a patient's lead amplitude is low - i.e., **Low Signal-to-Noise ratio (Low SNR)**. The test measures that could be impacted in this circumstance are measurements from the Glasgow Program Analysis and the overall wavECG Classification. Whilst most output values remain within tolerance in the presence of Low SNR, the following outputs have been determined to be more sensitive to this condition and may result in larger than expected variance from the actual value.

The outputs in question and the potential impact level in a **Low SNR** environment are as follows:

Parameter	Sensitivity Level
QRS Duration	Low
P-Axis	High
QRS-Axis	Moderate
T-Axis	High
Glasgow Program Classifications (Including those for ST Segment Elevation and Complete Heart Block)	Low
MyoVista wavECG Classification	Moderate

The following parameters **are NOT significantly impacted** by this filtering issue:

- The Glasgow Program Rhythm Description
- The conventional ECG Traces or wavECG Colormaps
- The MyoVista wavECG Indices and Indices Statements
- Heart Rate / R-R Interval
- PR Interval
- QTc Interval
- QT Interval

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Based on the observed prevalence of **Low SNR** conditions (which may result in an inaccurate device output), and the estimated low prevalence of life-threatening conditions in the intended use population (related to measures sensitive to errors), **the estimated probability of patient harm can be classified as Rare, i.e., probability less than 0.001%.**

If you have customers currently using the MyoVista wavECG in a clinical or research setting, please advise them to adhere to the MyoVista User Manual, employ the MyoVista wavECG test results in conjunction with available health related information when determining the appropriate patient care and perform an overread of the ECG trace. Please also refer them to the sections in the User Manual on minimizing/reducing environmental noise**,** and if conducting a clinical research project have them contact HeartSciences for assistance with data extraction prior to analysis to ensure the accuracy of results.

As the probability of harm is **Rare**, any devices currently in situ with customers **do not** need to be recalled at this time. However, to prevent any additional possibility of patient harm please discontinue sales evaluations and further device distribution until a software modification is implemented.

We will work with you in the coming days to send a customer facing field notification to end users who utilise devices as part of their daily clinical pathway. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Transmission of this Notice:
This notice needs to be passed on all those who need to be aware within 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.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

A software repair has been identified and initiated; further communication from HeartSciences will be sent regarding availability of a software solution. When local regulatory approval is granted for the upgrade to take place, we will request your team to undertake the task in a timely manner and provide HeartSciences with traceability for all devices in your region running the patched version of software v2.0.

Kindly complete and return the enclosed Distributor/Importer reply form as acceptance of your reading and understanding of this Urgent Field Safety notice.

Please accept our apologies for any inconvenience this poses to your business and do not hesitate to contact either myself or Andy Webber should you have any questions relating to this information.

Best Regards,

Carol Krieger
VP, Clinical & Regulatory Affairs
Email: carol.krieger@heartsciences.com

Andy Webber
Director of Business Development - EMEA
Email: andy.webber@heartsciences.com

Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	CAPA-00022-COMP-00066
FSN Date	18 August 2022
Product/ Device name*	MyoVista® DG-200 wavECG™ Device
Product Code(s)	1 MV-SYS-1-EA-IEC 2 MV-SYS-1-EA-AHA 3 DO-MEC-04002

2. Distributor/Importer Details	
Company Name	
Address	
Country	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Return acknowledgement to Sender	
Email	andy.webber@heartsciences.com
Distributor/Importer Helpline	+44 7493 40 6596
Postal Address	550 Reserve Street, Suite 360, Southlake, TX 76092, USA
Web Portal	www.heartsciences.com
Deadline for returning the Distributor/Importer reply form	30 September 2022

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	I have checked my stock and quarantined inventory	Quantity: Date:
☐	I have identified customers that received or may have received this device	
☐	I have informed the identified customers of this FSN	I have informed the identified customers of this FSN
☐	I have received confirmation of reply from all identified customers	Date of communication:
☐	I have compiled a list of customers who have been contacted and/or replied	
Print Name		
Signature		
Date		