# 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 wavECG Clinicians**

HeartSciences is communicating through this Urgent Field Safety Notice an issue relating to the MyoVista DG-200 wavECG Device Software. Whilst the risk of patient harm is classified as **Rare**, it is important that MyoVista users be made aware of the potential impact of this issue on patient ECG test results, and the interim recommendations as given below.

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 | Impact 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%.** This can be further reduced by following the interim recommendations given below.

**If you are currently using the MyoVista wavECG in a clinical setting:** Please adhere to the MyoVista User Manual and employ the MyoVista wavECG test results in conjunction with available health related information when determining the appropriate care and treatment pathway for each patient. As with all ECG automated/interpretive software, confirmation of a classification should be performed via overread of the ECG trace by a licensed healthcare practitioner to avoid the remote potential of risk to the patient. Please also refer to the sections in the User Manual on minimizing/reducing environmental noise.

**If you are using the MyoVista wavECG as part of a clinical research project:** Please contact HeartSciences for assistance with data extraction prior to analysis of your study data to ensure the device outputs contain the most accurate results.

This notice needs to be passed on all those who need to be aware within your organization.

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 initiated and you will receive further communication from HeartSciences regarding availability of this repair once it is released for use.

Kindly complete and return the enclosed customer reply form as confirmation of your reading and understanding of this Urgent Field Safety Notice.

Please accept our apologies for any inconvenience this poses to your clinical practice, and do not hesitate to contact either HeartSciences or your local MyoVista wavECG representative should you have any questions relating to this information.

Best Regards,

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..
VP, Clinical & Regulatory Affairs
Email: ..

..
Director of Business Development - EMEA
Email: …

## Customer 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<br>2 MV-SYS-1-EA-AHA<br>3 DO-MEC-04002 |

| **2. Customer Details** | |
|---|---|
| Account Number | |
| Healthcare Organization Name | |
| Organization Address | |
| Department/Unit | |
| Contact Name | |
| Title or Function | |
| Telephone number | |
| Email | |

| **3. Customer action undertaken on behalf of Healthcare Organization** | | |
|---|---|---|
| ☐ | I confirm receipt of the Field Safety Notice and that I read and understood its content. | |
| ☐ | I performed all actions requested by the FSN. | |
| ☐ | The information and required actions have been brought to the attention of all relevant users and executed. | |
| ☐ | Other Action (Define): | |
| ☐ | I have a query please contact me<br>(e.g., need for replacement of the product). | Customer to enter contact details if different from above and brief description of query |
| Print Name* | | Customer print name here |
| Signature* | | Customer sign here |
| Date* | | |

| **4. Return acknowledgement to sender** | |
|---|---|
| Email | andy.webber@heartsceinces.com |
| Customer 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 customer reply form | 30 September 2022 |