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Urgent Medical Device Notice

HeartWare Ventricular Assist Device (HVAD™)

Instructions for Use, Emergency Responder Guide, and Patient Manual Updates

30 March 2022

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear VAD Coordinators,

Medtronic is writing to provide information correcting errors and inconsistencies that were identified in the Instruction for Use (IFU), Emergency Responder Guide (ERG), and Patient Manual (PM) for the HeartWare™ Ventricular Assist Device (HVAD™) system. The errors and inconsistencies consist of incorrect figures and inconsistent translations. These corrections are detailed in full in attachment A, and will be incorporated in the IFU, ERG, and PM as part of an upcoming update.

Through 14 March 2022, Medtronic has received two (2) complaints regarding inconsistencies in the product literature resulting in no patient harm. Potential harms from these inconsistencies can result in confusion and annoyance.

Customer Instructions:

Medtronic records indicate that your site has patients that may still be on active support; we request that you do the following:

- Please ensure your patients on support are aware of the changes to the PM.
- Please share this notice with everyone in your organization who needs to be aware.
- Continue to monitor patients per your practice's standard follow-up procedures.

- Please complete the enclosed Customer Confirmation Form and email or hand back to your local Medtronic field representative

Adverse reactions or quality problems experienced with this product should be reported to your local Medtronic field representative.

Medtronic will notify all applicable regulatory agencies of this matter. This letter serves as a notification for your records regarding the upcoming updates to the HVAD™ System's IFU, ERG, and PM; the content within this letter is intended to bridge the time until the updated IFU, ERG, and PM are available.

If you have questions regarding this material, please contact your local Medtronic field representative.

Sincerely,



Diana Teo
Medtronic QRA Lead
Singapore and Malaysia




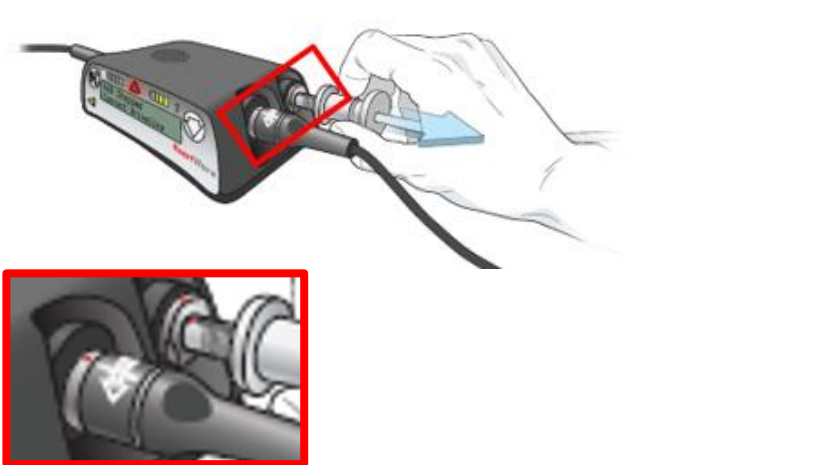
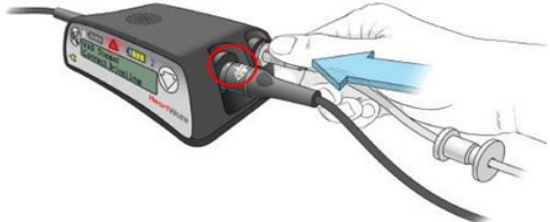
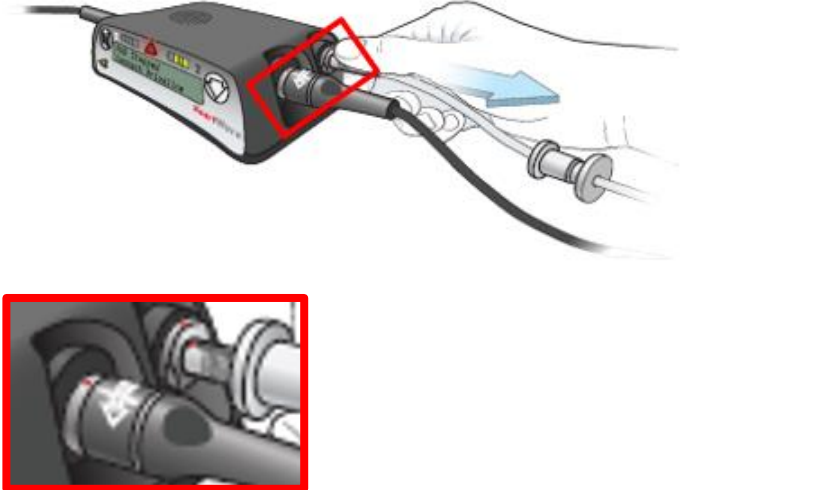
Chloe Tan
Medtronic QRA Lead
Indochina and Frontier Market Plus

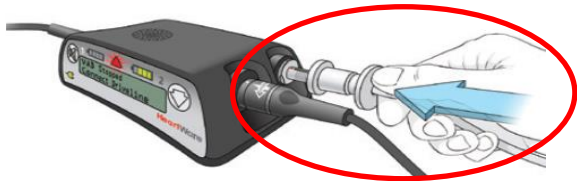


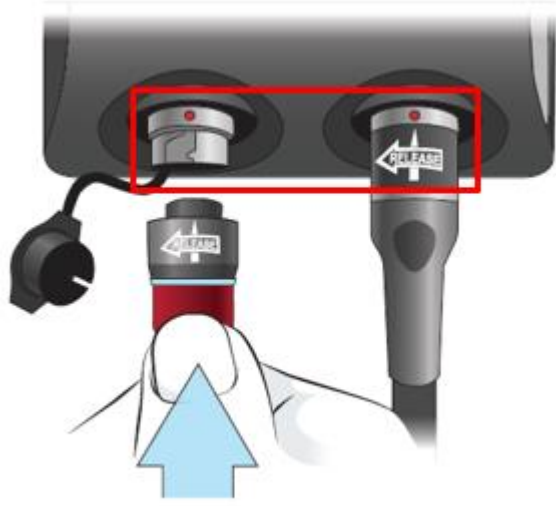


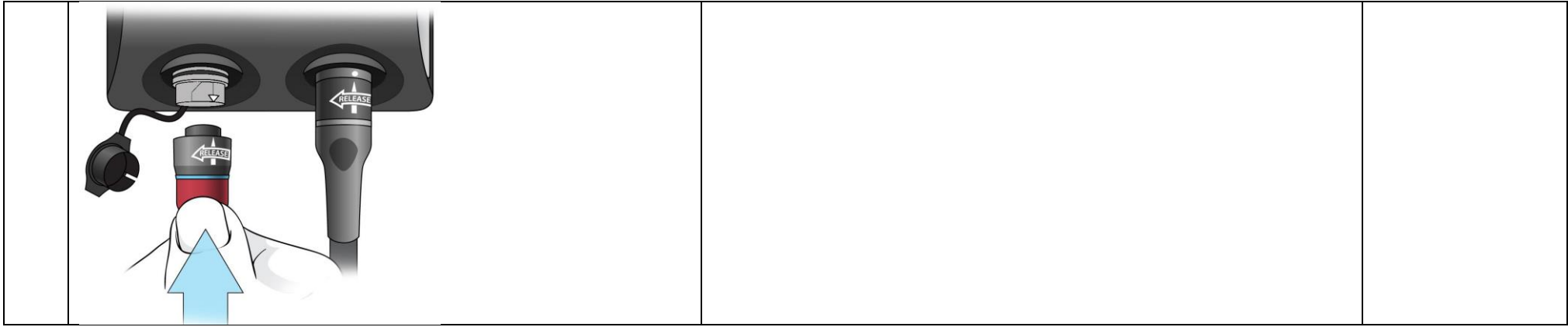
Parichart Bunjobchokchai
Medtronic QRA Lead
Thailand









Attachment A

No.	Issue	Correction	Impacted Languages
1	<p>Figures throughout the IFU and Patient Manual show HVAD Controller 1.0 instead of HVAD Controller 2.0 (which replaced Controller 1.0 in 2018.) Controller 1.0 and Controller 2.0 have differences in the color of the data port connector and the color of the alignment indicator on the data port connector. The impacted images are shown below in 1.1–1.4.</p>		<p>English (US), English (OUS), German, Arabic, Bulgarian, Traditional Chinese, Croatian, Czech, Danish, Dutch, Estonian, Finnish, French, Greek, Hungarian, Italian, Korean, Latvian, Lithuanian, Malay, Norwegian, Polish, Romanian, Russian, Serbian, Slovak, Slovenian</p>
1.1	<p>Section 4.1 "HVAD™ Controller Connections" of the IFU and Section 3.2.1 "Driveline Connection" of the PM Power connector visible portion (fore) is not shown as metallic (not light grey) and shows the incorrect color for the alignment indicator (white versus red).</p>	<p>The corrected image shows the alignment indicator mark as red. See highlighted area.</p>	<p>English US, English (OUS), German</p>

			
<p>1.2</p>	<p>Section 4.1 "HVAD™ Controller Connections" of the IFU and Section 3.2.1 "Driveline Connection" of the PM</p> <p>Power connector (fore) is not shown as metallic (grey) and does not show a red alignment indicator at the top of the connector base. These are inconsistent with Pioneer 2 Controller features. The blue directional arrow is also pointing in the wrong direction for the step to disconnect the driveline.</p> 	<p>The corrected image shows the alignment indicator mark as red. See highlighted area.</p> 	<p>English US, English (OUS), German</p>

<p>1.3</p>	<p>Section 4.1 "HVAD™ Controller Connections" of the IFU and Section 3.2.1 "Driveline Connection" of the PM</p> <p>Power connector (fore) is not shown as metallic (grey) and does not show a red alignment indicator at the top of the connector base. These are inconsistent with Pioneer 2 Controller features.</p> 	<p>The corrected image shows the alignment indicator mark as red. See highlighted area.</p>  	<p>English (US), English (OUS), German</p>
<p>1.4</p>	<p>Section 8.7 "How to Change the Controller" of the IFU and Section 4.9 "Changing Controller to Back-Up Controller" of the PM and Step 4 of the Emergency Responder Guide.</p> <p>The right-side Power Connector color is not gray (metallic), alignment indicators are not top-center, and color of alignment indicators is not red. These are inconsistent with Pioneer 2 Controller features.</p>	<p>The corrected image shows the alignment indicator mark as red. See highlighted area.</p> 	<p>English (US), English (OUS), German, Arabic, Bulgarian, Traditional Chinese, Croatian, Czech, Danish, Dutch, Estonian, Finnish, French, Greek, Hungarian, Italian, Korean, Latvian, Lithuanian, Malay, Norwegian, Polish, Romanian, Russian, Serbian, Slovak, Slovenian</p>



2	<p>Section 3.2.2 "Power Source Connections" of the Patient Manual</p> <p>There is a missing warning and caution from section 3.2.2 of the English Patient Manual.</p> <p>3.2 Making Connections (continued)</p> <p>3.2.2 Power Source Connections</p> <p>To Connect a Power Source:</p> <ol style="list-style-type: none"> To connect all power supplies (battery, AC adapter or DC adapter) grasp the power cable near its connector. Leave the connector free to rotate.  Figure 23 Line up the solid white arrow on the cable connector with the dot on the controller (figure 24).  Figure 24 Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally lock in place. A good connection will turn on the battery or AC/DC indicator on the controller, as well as beep. If an alarm is active or muted, the beep will not be heard.  Figure 25 <p>NOTE: When pushing the connector into the controller the white arrow will shift slightly into the correct locking position.</p> <ol style="list-style-type: none"> Confirm that the power cable is properly locked to the controller by gently pulling on the cable near the connector. Repeat steps above for second power source. 	<p>Warning and caution call out boxes are represented below:</p> <p>3.2 Making Connections (continued)</p> <p>3.2.2 Power Source Connections</p> <p>To Connect a Power Source:</p> <ol style="list-style-type: none"> To connect all power supplies (battery, AC adapter or DC adapter) grasp the power cable near its connector. Leave the connector free to rotate.  Figure 23 Line up the solid white arrow on the cable connector with the dot on the controller (Figure 24).  Figure 24 Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally lock in place. A good connection will turn on the battery or AC/DC indicator on the controller, as well as beep. If an alarm is active or muted, the beep will not be heard.  Figure 25 <p>NOTE: When pushing the connector into the controller the white arrow will shift slightly into the correct locking position.</p> <ol style="list-style-type: none"> Confirm that the power cable is properly locked to the controller by gently pulling on the cable near the connector. Repeat steps above for second power source. <div data-bbox="951 776 1556 1040" style="border: 2px solid red; padding: 5px;"> <p> WARNING! Never disconnect both power sources (batteries, AC adapter, DC adapter) at the same time since this will stop the pump and activate the [No Power] alarm. At least one power source must be connected at all times.</p> <p> CAUTION: ALWAYS confirm that the power cables are properly locked to the controller by gently pulling the cable near the connector.</p> <p>CAUTION: DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.</p> <p>CAUTION: ALWAYS keep all connectors free of liquid, dust and dirt, or the HeartWare™ HVAD™ System may not function as intended.</p> </div>	English (US only)
3	<p>Section 6.6 "Traveling and Transport" of the Patient Manual</p> <p>There is missing a bullet in the Travel and Transport section. The bullet should say "Controller DC adapter" and should be</p>	Corrected image is represented below:	English (US Only)

listed after the "Controller AC adapter"

6.0 Living with the HeartWare™ HVAD® System

6.6 Traveling and Transport

As you resume activities of daily living, you may wish to travel away from home. Prior to making travel plans, talk with your clinician to make sure it is safe for you to travel. Once you are approved for travel, your clinician will work with you to ensure you are prepared for traveling safely. Always remember to take all prescribed medication with you and to make sure you have emergency contact information.

When you travel, please make sure you have the following:

- Back-up controller
- Fully charged, spare batteries
- Battery charger
- Controller AC adapter
- Emergency Responder Guide

Equipment should be kept with you at all times for safety and security. If traveling by air, carry equipment with you on board the aircraft. During the flight, you should power the controller with two batteries or with one battery and an AC adapter.

6.6 Traveling and Transport

As you resume activities of daily living, you may wish to travel away from home. Prior to making travel plans, talk with your clinician to make sure it is safe for you to travel. Once you are approved for travel, your clinician will work with you to ensure you are prepared for traveling safely. Always remember to take all prescribed medication with you and to make sure you have emergency contact information.

When you travel, please make sure you have the following:

- Back-up controller
- Fully charged, spare batteries
- Battery charger
- Controller AC adapter
- Controller DC adapter
- Emergency Responder Guide

Equipment should be kept with you at all times for safety and security. If traveling by air, carry equipment with you on board the aircraft. During the flight, you should power the controller with two batteries or with one battery and an AC adapter.

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Customer Confirmation Form

Urgent Medical Device Notice

Medtronic HeartWare™ Ventricular Assist Device (HVAD) System

For completion by Medtronic Customers Only - Please complete all fields below and return immediately

Customer Contact Details	Medtronic Contact Details
Distributor/HCP:	Name:
	Contact:
Address:	Email:
Phone no:	
E-mail:	

Medtronic is asking that you sign and date this form to acknowledge receipt of the enclosed letter.

Note: The addressee may continue to receive reminders of this notice until a response is received.

By signing this form, I confirm that I have read the Urgent Medical Device Notice Notification Letter, dated 30 March 2022 , from Medtronic regarding the HeartWare™ Ventricular Assist Device (HVAD) system listed above and will take appropriate action.

Name (print): _____ Signature: _____ Stamp: _____ Date: _____

For questions, contact your local Medtronic Field Representative.