

Urgent Medical Device Notice
Medtronic Heartware™ HVAD™ System
Instructions for Use and Patient Manual Updates

February 2021

Dear Healthcare Professional,

Medtronic is writing to inform you of upcoming updates to the HVAD™ System Instructions for Use (IFU) and Patient Manual (PM). These updates will (1) provide new information relating to the useful life of the HVAD™ System carrying cases (Waist Pack, Shoulder Pack, and Convertible Patient Pack), (2) clarify the HVAD™ Controller connections, power-up sequence, and notifications, and (3) clarify expected duration of HVAD™ System alarms. The following updates are being made to the PM only: (1) provide additional information relating to the care and use instructions for the HVAD™ System carrying cases and (2) provide additional information relating to the HVAD™ Controller driveline cover. The full updates to the IFU and PM are attached in Appendix A.2.

HVAD™ System Carrying Cases Care and Useful Life. The PM is being updated to clarify use of the support strap and wear instructions in addition to cleaning instructions of the carrying cases. The IFU and PM are being updated to add a useful life for the carrying cases. Between 01 January 2009 and 14 January 2021, Medtronic has received 59 complaints relating to carrying case care. Of the 59 complaints, one (1) event resulted in a cardiac arrest after driveline disconnection due to the carrying case being dropped, 36 events resulted in no patient harm, and 22 events resulted in negligible to major patient harm associated with driveline exit injury due to the carrying case being dropped. No complaints have been received regarding the useful life of the carrying cases.

HVAD™ Controller Power Up Sequence. The IFU and PM are being updated to clarify the power-up sequence that causes the alarm indicator LEDs and both sets of battery LEDs to turn red for 2.5 seconds while the LCD displays the power-on message. Between 01 January 2009 and 19 January 2021, Medtronic has received 16 complaints regarding potential confusion about the power-up sequence of the controller/batteries being misconstrued as a "red alarm." In two (2) of those events, minor harms (such as dizziness or palpitations) associated with controller loss of power and subsequent hypoperfusion were observed. No major patient harm was observed in any of these events.

Expected Alarm Duration. The IFU and PM is being updated to clarify the expected duration of HVAD™ System alarms, and to instruct patients to contact their clinicians if they cannot identify an alarm before it is cleared. No complaints have been received relating to this issue.

HVAD™ Controller Connections. The IFU and PM are being updated to clarify that the Controller will not make an audible sound if an active alarm is muted and a power source is connected. Between 01 January 2009 and 25 January 2021, Medtronic has received nine (9) complaints associated with the inability to hear the 'audible click' upon making a connection to the controller. Of the nine (9) complaints, one (1) resulted in hospitalization for a driveline repair unrelated to this issue, and the remaining eight (8) events resulted in no patient harm.

Driveline Cover. Consistent with recent IFU updates, the PM is being updated to inform users to keep the driveline cover on when disconnecting and reconnecting the driveline. Between 01 January 2009 and 02 February 2021, there have been 24 complaints related to this issue. Of the 24 complaints, in one (1) event where the driveline cover was improperly oriented, it may have resulted in intermittent driveline disconnection(s) from the Controller and an adverse event. In the remaining 23 events, no major patient harm was observed including in 18 events where a temporary pump stop occurred while correcting the driveline cover orientation.

YOUR ACTIONS:

Medtronic records indicate that your facility and patients are impacted by these IFU and PM changes. As a result, Medtronic requests that you take the following actions:

- Please review the updated IFU and PM steps as included in Appendix A.2 and share with patients as needed
- This notice must be shared with all those who need to be aware within your organization or to any organization where potentially affected patients have been transferred
- Please complete the enclosed Customer Confirmation Form and email to RS.CFQFCA@medtronic.com.

<Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This letter serves as a notification for your records regarding the updates to the HVAD™ System Instructions for Use and Patient Manual; no further actions are needed.

If you have questions regarding this material, please contact your Medtronic Field Representative.






Sincerely,



A handwritten signature in cursive script, appearing to read "Gail Schroeder".

Gail Schroeder
Senior Director, Quality
Medtronic Mechanical Circulatory Support

Appendix A.2 Instructions for Use

Change From	Change To
N/A	The expected Useful Life of the HeartWare™ Shoulder Pack, Waist Pack, and Convertible Patient Pack is 12 months. Carry cases should always be inspected prior to use. DO NOT use a carry case if it shows signs of damage. Contact HeartWare for a replacement.
<p>3. Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally lock in place. A good connection will result in an audible click.</p> <p>NOTE: When pushing the connector into the controller the white arrow will shift slightly into the correct locking position.</p>	<p>3. Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally lock in place. A good connection will result in an audible click. 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.</p> <p>NOTE: When pushing the connector into the controller the white arrow will shift slightly into the correct locking position.</p>
N/A	<p>Controller Power-up Sequence</p> <p>When first adding power to the controller the battery and alarm indicator lights will go on and then off. Both the green and red lights will be turned on and then off. Although the red alarm indicator will turn on for 2.5 seconds, this is normal and does not mean there is a problem with the system. The power-up sequence is complete when the controller screen shows the pump information.</p>
N/A	Some alarms may be triggered and then resolve after a very short period making them difficult to read and identify. If this happens, it may mean there is an intermittent problem. The cause of the alarm can be evaluated by obtaining a controller log file analysis.

Change From	Change To
<p>3. Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally lock in place. A good connection will result in an audible click.</p> <p>NOTE: When pushing the connector into the controller the white arrow will shift slightly into the correct locking position.</p>	<p>3. Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally lock in place.</p> <p>A good connection will result in audible click 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.</p> <p>NOTE: When pushing the connector into the controller the white arrow will shift slightly into the correct locking position.</p>
<p>3.8 How Long HeartWare™ HVAD™ System Equipment Should Last</p> <p>The HeartWare™ HVAD™ System components were designed and tested to function for the following periods:</p> <ul style="list-style-type: none"> • HVAD® Pump for two years. • The controller for two years. • Each fully charged battery provides... • Similar to the battery in a... • During your clinic visit... • If you rotate the use of your batteries, you should get 1 year of battery service. 	<p>The HeartWare™ HVAD™ System components were designed and tested to function for the following periods:</p> <ul style="list-style-type: none"> • HVAD® Pump for two years. • The controller for two years. • Each fully charged battery provides... • Similar to the battery in a... • During your clinic visit... • If you rotate the use of your batteries, you should get 1 year of battery service. • Carry cases for 12 months of use. Many factors may affect the useful life of carry cases. Always inspect your carry case prior to use and DO NOT use the case if it shows signs of damage. Contact your clinician for a replacement case.
<p>N/A</p>	<p> WARNING! DO NOT detach the driveline cover from the driveline.</p>
<p>3. Pull back on the ringed area to release the locking mechanism.</p>  <p>Figure 19</p>	<p>3. Pull back on the ringed area to release the locking mechanism. DO NOT remove the driveline cover from the driveline.</p>  <p>Figure 19</p> <p> WARNING! DO NOT detach the driveline cover from the driveline.</p>
<p>N/A</p>	<p> CAUTION: Always use the support strap when putting on or taking off the Convertible Patient Pack. After the waist belt is secured, the support</p>

	<p>strap may be removed to wear the Convertible patient pack around the waist.</p>
<p>N/A</p>	<p>7. Lift the support strap over your head to hold the HeartWare™ Convertible Patient Pack up, then buckle the belt around your waist and adjust it to fit. If necessary, use the belt extender to make the belt bigger.</p> <p>Check the driveline and battery cables to make sure that they are not twisted or kinked. Adjust the pack as necessary to remove kinks in the driveline or cables.</p>  <p>Figure xx</p> <p>8. Adjust the belt so that the Controller Display is visible at all times. When the HeartWare™ Convertible Patient Pack is comfortably fastened around the waist, the support strap can be removed.</p> <p> CAUTION: Always use the support strap when putting on or taking off the Pack. After the waist belt is secured, the support strap may be removed to wear the convertible patient pack around the waist.</p> <p>To Remove the Waist Belt from Your HeartWare™ Convertible Patient Pack:</p> <ol style="list-style-type: none"> 1. Place the pack with the belt side up on a table or other flat surface, with the clear window facing away from you.

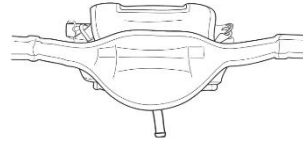


Figure xx

2. Unclip the two side clasp hooks.



Figure xx

3. Detach the bottom buckle.

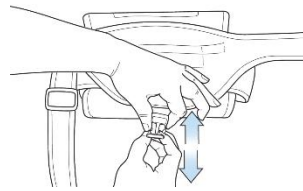


Figure xx

4. Peel the waist belt away from the pack.

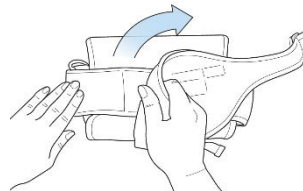


Figure xx

To attach the Waist Belt to Your Convertible Patient Pack:

1. Place the convertible patient pack on a table or other flat surface with the flap side facing down.

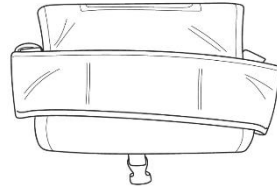


Figure xx

2. Align the belt and bag Velcro strips, then press firmly.

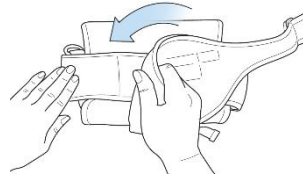


Figure xx

3. Attach the clasp hooks on the ends of the waist belt to the metal rings on each side of the bag.



Figure xx

4. Attach the buckle on the bottom side of the bag. Adjust the strap as needed.

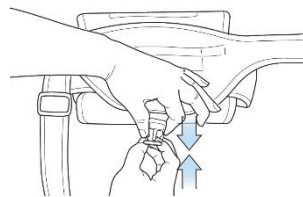


Figure xx

The HeartWare® Shoulder Pack and Waist Pack can be washed by hand using a mild detergent and cold water, or machine washed using the delicate cycle. Do not use bleach. Allow the pack to air dry. Do not use a clothes dryer to dry the pack. Make sure that pack is completely dry

The HeartWare™ Shoulder Pack, ~~and~~ Waist Pack, and Convertible Patient Pack can be washed by hand using a mild detergent and cold water, or machine washed using the delicate cycle. Do not use bleach. Allow the pack to air dry. Do not use a clothes dryer to dry the pack. Make sure that pack is completely dry before using, and inspect it for damage or wear before each use.

<p>before using, and inspect it for damage or wear before each use.</p>	
<p>N/A</p>	<p>NOTE: If an alarm appears on the controller screen and then goes away before you can read the cause of the alarm, contact your clinician as it might mean there is an intermittent problem.</p>
<p>N/A</p>	<p>Controller Power-up Sequence When first adding power to the controller the battery and alarm indicator lights will go on and then off. Both the green and red lights will be turned on and then off. Although the red alarm indicator will turn on for 2.5 seconds, this is normal and does not mean there is a problem with the system. The power-up sequence is complete when the controller screen shows the pump information.</p>