

January 25, 2011

Account Name
City, State

FIELD NOTIFICATION


URGENT - FIELD CORRECTION UPDATE of cardioPAT® MANUAL FOR LEAK DETECTION

Haemonetics has received a complaint where the user mis-interpreted the air-leak rate displayed by the cardioPAT device. In both cases, the information from the air-leak rate indicator was improperly utilized to make a determination about chest-drain removal and resulted in the patient experiencing a pneumothorax.

The cardioPAT cardiovascular perioperative autotransfusion system is designed to salvage RBCs from blood lost intraoperatively and/or postoperatively during cardiovascular surgical procedures. It contains a suction source to provide post-operative suction for chest drainage. The operator can set the post-op suction from -10 to -40 cmH₂O. The cardioPAT system sounds an alarm and displays the message “check chest drain suction pathway” when the system is not maintaining the vacuum in the reservoir at or near the pre-set level. The “Air Leak Rate” numerical display shows the deficit in the vacuum level; the higher the number, the greater the deficit. Haemonetics has updated its manual to provide that clarification on the air leak rate detector.

It is important that the following items be added to your existing cardioPAT system Operator’s Manual and machine:

1. Operator’s Manual Addendum: Air Leak Detection addendum and index which reads:
 - a) **The cardioPAT system is equipped with an electronic mechanism that evacuates air from the system in order to maintain the vacuum level in the reservoir and post-op line at the level set by the operator. In the event of an air leak, the vacuum level may be reduced if the cardioPAT system cannot compensate for the leak.**

 Warning: The cardioPAT system sounds an alarm and displays the message “Check chest drain suction pathway” when the system is not maintaining the vacuum in the reservoir at or near the pre-set level. The “Air Leak Rate” numerical display shows the deficit in the vacuum level; the higher the number, the greater the deficit

IMPORTANT: An air leak rate reading of “0” on the device display indicates that the system is maintaining suction at or near the pre-set vacuum level. It does not indicate the absence of an air leak. A reading of “0” may indicate the presence of an air leak that the cardioPAT system is compensating for on a continuous basis. The operator should always

follow standard clinical practice for detecting the presence of a pneumothorax (example: chest x-ray).

Air leaks may originate from:

- **The site of the surgical wound**
- **Elsewhere inside the patient's body**
- **The system itself (due to a loose clamp or improper seating of the reservoir)**

Your Haemonetics Sales Consultant will train you on the content of these items and insert them into your Operator Manuals. Please sign the attached acknowledgment indicating that you have received the manual addendum and that they have been inserted into the appropriate document, applied to all cardioPAT[®] devices on site. The serial number for each cardioPAT device on site should be recorded on the attached acknowledgement and the completed acknowledgement should be returned to your Haemonetics Sales Consultant.

Please note that the FDA has been notified of this field notification.

Thank you for your attention.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Gonsalves', with a long horizontal flourish extending to the right.

Bob Gonsalves
Haemonetics Corporation
Director, Autotransfusion Products

CUSTOMER ACKNOWLEDGMENT

Update of cardioPAT® Manual for Leak Detection

Account Name _____

City, State _____

By signing the document below, you are indicating that you have received the following items and that they have been inserted into the appropriate documents and applied to all cardioPAT devices on site.

- 1. Operator's Manual Addendum: Air Leak Detection addendum and index

Please list the Serial #s of all cardioPAT devices on site:

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Customer Signature

Date

Print Name

Please return this acknowledgment to your Haemonetics Sales Consultant or fax to 781-356-9910.