

January 25th, 2011

Account Name

City, State

FIELD NOTIFICATION

Update of cardioPAT[®] Manual for Leak Detection

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

Your Haemonetics’ territory manager 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’ territory manager.

Please note that the relevant Competent Authorities have been notified of this field notification.

Thanks for your attention

Sincerely,


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 Territory Manager or fax to **781-356-9919**.



Manual Addendum

Air Leak Detection

Introduction	2
Inserting the addendum into the Operation Manual	2
Postoperative operation mode – air leak management	2
Troubleshooting messages	3



Introduction

The *Air Leak Detection Manual Addendum* modifies several sections of the Haemonetics cardioPAT Operation Manual to clarify the following:

- The function of the vacuum system and the air leak rate indicator on the device display
- The procedures for determining the presence and potential source of an air leak.

This addendum is effective until revision EA or higher of the Operation Manual is released.

Inserting the addendum into the Operation Manual

- *If the cardioPAT Operation Manual uses a binder*, please insert this addendum and the index into the binder behind the Operation Manual.
- *If the cardioPAT Operation Manual is wire-bound*, please attach this addendum and the index securely to the inside of the back cover.

Postoperative operation mode – air leak management

The following information should be added to the text in the “Postoperative operation mode” section of Chapter 4 of the Operation Manual:

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)

Troubleshooting messages

The following text replaces the “Check chest drain suction pathway” warning in Chapter 6 of the Operation Manual:

Message	Cause	Response
Check chest drain suction pathway	Patient pneumothorax.	Check patient for pneumothorax.
	Reservoir not seated properly.	Re-seat reservoir to ensure vacuum port is seated properly. Check to see if warning message has been cleared.
	Reservoir spare port(s) clamp open.	Ensure all spare port clamps are tightly closed. Check to see if warning message has been cleared.
	Leak in the chest drain tubing.	Tighten connectors in chest drain tubing. Check to see if warning message has been cleared.
	High vacuum relief valve failure.	Reseat positive pressure / high vacuum relief valve (PPHV). Check to see if warning message has been cleared. If condition continues, replace PPHV valve.
	Leak in the cardioPAT pneumatic system.	Contact Haemonetics technical service.
	Loose QuickConnect couplings connection	Ensure that the connection between the QuickConnect Reservoir and the QuickConnect Processing set is secure.