

PRINTED MATERIAL SPECIFICATION

Spec. No. 903588 Rev A

Issue Date 9/8/03

Supersedes NA

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Product Description: MPS CONSOLE

Code No. 5001000

A. Dimensions: 8 1/2" W x 11" (approx)

B. Description: Special Instruction For Use, CANADA E7.1

1. Stock and color: 70 lb. White, Three hole Cougar Opaque
2. Style: See following pages
3. Printing: Black, front and back
4. Manufacturer's Joint: none
5. Copy Requirements: See following pages
6. Other: Refer to Quest Inspection Procedure 900-01
7. Filename: K:QSHARE:DOCUMENT:

Label Spec No. 903588

REVISION HISTORY

REV	DESCRIPTION OF CHANGE	BY	DATE	ECO
A	New Document	Unk	Unk	Unk

SPECIAL INSTRUCTIONS FOR USE FOR CANADA [SOFTWARE REV E7.1]

This Special Instructions For Use is for users at Toronto General Hospital (TGH) using modified MPS units to meet the special clinical needs of TGH cardiac surgery team for myocardial protection. There are also new message screens included in this software upgrade Rev E7.1 that we want all to notice. Over the past several weeks, you have made us aware of the need for new capabilities of the MPS to be fully supportive of all clinical scenarios you engage on a daily basis. These included increased flow rates, increased pressure capabilities for the additive/arrest pumps to allow easy use of the MPS with more viscous additive solutions at higher additive and system pump pressures, increased upper system pressure limits to accommodate higher flows, and also the ability of the MPS to accommodate higher system pressures in AUTO MODE. This document is to expedite the awareness of these new features contained in this version of software to all users of the MPS at TGH, and to easily explain how these features are incorporated.

FEATURES

Several new features are now available to the users of the Myocardial Protection System®.

1. Increase the maximum flow rate from **500 ml/min to 650 ml/min**.
2. Raise the alarm limit for occlusion of the Additive and/or Arrest delivery from 1000mmHg to 1300mmHg. The message for Additive and Arrest occlusion has been changed. [See Fig.1 and Fig.2]
3. Extend the upper System Pressure limit during Antegrade delivery from **400mmHg to 500mmHg**. If the user chooses to override the upper pressure limit by pressing the “Override” key, the MPS will allow **system pressure up to 600mmHg**. [See Fig.3]
4. Allow “AUTO” mode to be selected at System pressures up to 500 mmHg. The upper flow limit in “AUTO” mode will now be 650 ml/min for flow rates of 325 ml/min and above. Upper flow limits in “AUTO” mode can now be set up to 650 ml/min when “AUTO” mode is selected during lower flow rates. [see Fig. 4 and Fig.5]

The message for Additive and Arrest occlusion.

The MPS will display the following screens.

Fig. 1

```
WARNING
Arr line occluded
Conc will be zeroed
CONFIRM
```

Fig. 2

```
WARNING
Add line occluded
Conc will be zeroed
CONFIRM
```

System Pressure limits

The upper system pressure limits can be set up to 500 mmHg.

Fig.3

```
<< SET
antegrade System
upper
pressure limit
```

Flow rate limits in “Auto” mode

Upper flow rate limit in “AUTO” mode will now be 650 ml/min when selected during flow rates of 325 ml/min and above. Upper flow limits in “AUTO” mode can now be set up to 650 ml/min when “AUTO” mode is selected during lower flow rates.

Fig.4

```
<< SET
Upper flow rate
limit
(antegrade delivery)
```

Fig. 5

```
<< SET
Upper flow rate
limit
(retrograde delivery)
```