

URGENT-FIELD SAFETY NOTICE
2014-02-11

Please forward this information to all relevant users concerned in your facility

Subject: Introduction of a User's Manual for the Edi catheter included in the packaging

Products affected:

Article number	Description
6685775	Edi Catheter, 6Fr, 49 cm, PHT free 5 pcs/pkg
6685777	Edi Catheter, 6Fr, 50 cm, PHT free 5 pcs/pkg
6685780	Edi Catheter, 8Fr, 100 cm, PHT free 5 pcs/pkg
6685782	Edi Catheter, 8Fr, 125 cm, PHT free 5 pcs/pkg
6685787	Edi Catheter, 12Fr, 125 cm, PHT free 5 pcs/pkg
6685790	Edi Catheter, 16Fr, 125 cm, PHT free 5 pcs/pkg

Dear Customer,

We would like to inform all users of the NAVA and NIV NAVA ventilation modes available in the SERVO Ventilator Systems, that the accessory Edi catheter has received its own User's Manual included in the packaging. The instructions for use of the Edi Catheter have previously been available in the User's Manual for the SERVO Ventilators.

The Edi catheter is a single-use naso-gastric feeding tube with an electrode array of ten electrodes with three functionalities:

- Detecting diaphragmatic electrical activity (Edi signals) by which the two ventilator modes NAVA and NIV NAVA can be controlled.
- Detecting diaphragmatic electrical activity (Edi signals) by which the respiratory drive from the brain can be monitored.
- Administrating nutrition, fluids and medications by the naso-gastroenteric route.

Maquet Critical Care has received information/complaints where the users have indicated that they have not received all information about the usage of the Edi catheter.

Maquet Critical Care has therefore initiated a new multilingual User's Manual in the packaging for the Edi catheter so the information for proper use is available with the product.

For example these warnings are included:

- The Edi catheter and guide wire are for single use only.
- Reprocessing will degrade biocompatibility and/or cleanliness.
- Each Edi catheter may be used for up to 5 days.
- Never re-insert or manipulate the guide wire once the Edi catheter has entered the patient, otherwise the guide wire may penetrate a feeding hole.
- The Edi catheter must be removed from the patient before an MR examination.
Due to the metallic electrodes:
 - Strong magnetic and RF fields could generate heat in the electrodes.
 - Artifacts (distortions) may appear in the MR images.

For all information available for safe usage, please see the enclosed User's manual.

The usage of the catheter with the SERVO ventilators will still be described in the SERVO Ventilator systems User's Manuals.

Should you have questions or require additional information, please contact your local MAQUET representative.

Enclosure

- User's manual Edi catheter

Sincerely,



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