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Customer Service Center

ISO9001(2008)
ISO13485(2003)

Subject: **FIELD SAFETY NOTICE**
Field Safety Corrective Action for Diaphragm Chambers

To all Users of Metran R100/Vision α High Frequency Ventilators:

There was an incident reported by a hospital informing that after about 16 hours of being oscillating a patient an alarm was actuated and sizzling noises were hearable. HFOV had to be stopped. Patient was switched to conventional ventilator. Patient's situation was always stable, not critical. It was found that the reason was a failure in the bonding of the diaphragm chamber producing leakage.

The diaphragm chamber with the bonding failure was returned to Metran for investigation. Metran concluded that the pressure test before shipment could be weak, or mishandling of the product like dropping of the chambers could produce the bonding failure.

Based on those two points, Metran modified the procedure for the final testing and inspection of the diaphragm chambers by increasing the pressure for the stress test (from 1.0 to 1.1 kg/cm^2). Also for avoiding mishandling a new label indicating “Warning: Do not drop!” was added to each diaphragm chamber box.

These new tighter testing and packaging procedure is intended to produce safer chambers, avoiding recurrence of this problem.

Metran has sent new tested and labeled diaphragm chambers to the distributors.
Please make sure to use diaphragm chambers which passed the new testing and packaging procedure already. You can identify the improved diaphragm chambers by the label “Warning: Do not drop!” on the box easily. Also, users are requested to implement pre-use test as explained in the ventilator IFU.

Please contact our European Representative in case you have any question to this Field Safety Notice or the Field Safety Corrective Action.

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