

Wednesday, 15th of August 2018

Urgent Field Safety Notice

Reference number: CAPA-18-009

Affected Products:

fabian Therapy evolution (REF 121001)

Reason for this Urgent Field Safety Notice:

Update of the original warning in Chapter 2.1 (*fabian Therapy evolution* – Instructions for Use) from:

" *Warning: only use this ventilator in combination with a CO₂ measuring device.*"

to:

" *Warning: only use this ventilator in combination with an external monitoring (e.g. SpO₂) device.*"

Description of the Problem:

Without an independent external monitoring system there is a risk that, should the device's internal monitoring system fail (e.g. loudspeaker defect), the user would have no notification of an alarm-triggering event which may require user intervention.

Previously, the warning "*only use this ventilator in combination with a CO₂ measuring device*" was included in Chapter 2.1 of the IFU from the *fabian Therapy evolution*. After receiving feedback from customers, Acutronic have been made aware it is common to use other external monitoring systems rather than CO₂.

Acutronic have decided to update this warning to clarify that other external monitoring systems (e.g. SpO₂) can be used in lieu of CO₂ monitoring.

Therefore, the IFUs will be updated until end of October 2018.

Manufacturer's Actions:

- ACUTRONIC, as the legal manufacturer of the *fabian Therapy evolution* device, will inform their distributors and provide the updated IFU for the *fabian Therapy evolution*
- The IFU's has to be provided to the distributors before end of October 2018

Distributor's Actions:

- Please read this FSN carefully and acknowledge the receipt to ACUTRONIC
- The distributor has to inform the end-users about this FSN
- The distributor has to provide the IFU to the end-users before end of November 2018

End-Users Actions:

- Please read this FSN carefully and acknowledge the receipt to the distributor
- Notify all care environments in which the *fabian Therapy evolution* is used and ensure all relevant staff are aware of this FSN
- Ensure the updated IFU for this device is received before the date specified above
- Retraining of the relevant staff who is working with the *fabian Therapy evolution* for the changed warning:
"Warning: only use this ventilator in combination with an external monitoring (e.g SpO₂) device."
- Please contact your local distributor with any queries you may have



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