

# BREAS

## SAFETY INFORMATION

VIVO K EP

Information communicated via the Safety Information is of high priority. All actions stipulated in the Safety Information should be implemented and communicated further to any customer affected by the information.

## Limited mandatory field action PV 403 PEEP

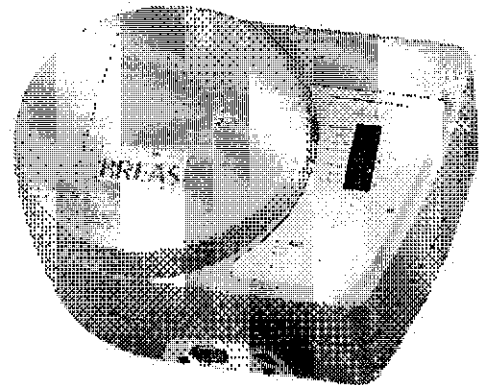
We have received few reports where PV 403 PEEP does not operate from mains supply. Based on an investigation, the conclusion is that a limited amount of components from a batch of the resistor **R2**, mounted on the CPU, have a higher incidence of failure and should be replaced.

**The R2 resistor only affects the *start-up* on mains. Accordingly, it does not affect the operation or alarms during treatment.**

If R2 fails during operation, the PV 403 PEEP will continue to operate from mains and the internal battery and the alarm battery are being charged as normally.

If R2 has failed, the following occurs:

1. If PV 403 PEEP is turned off and disconnected from mains, it will not start-up from mains when mains is reconnected, although it will start-up from internal or external battery. It will not, however, charge the internal battery or the alarm battery.
2. If PV 403 PEEP is turned off but *not* disconnected from mains, it will still operate normally, even from mains.



CPU boards equipped with components from this batch were produced during 2006.

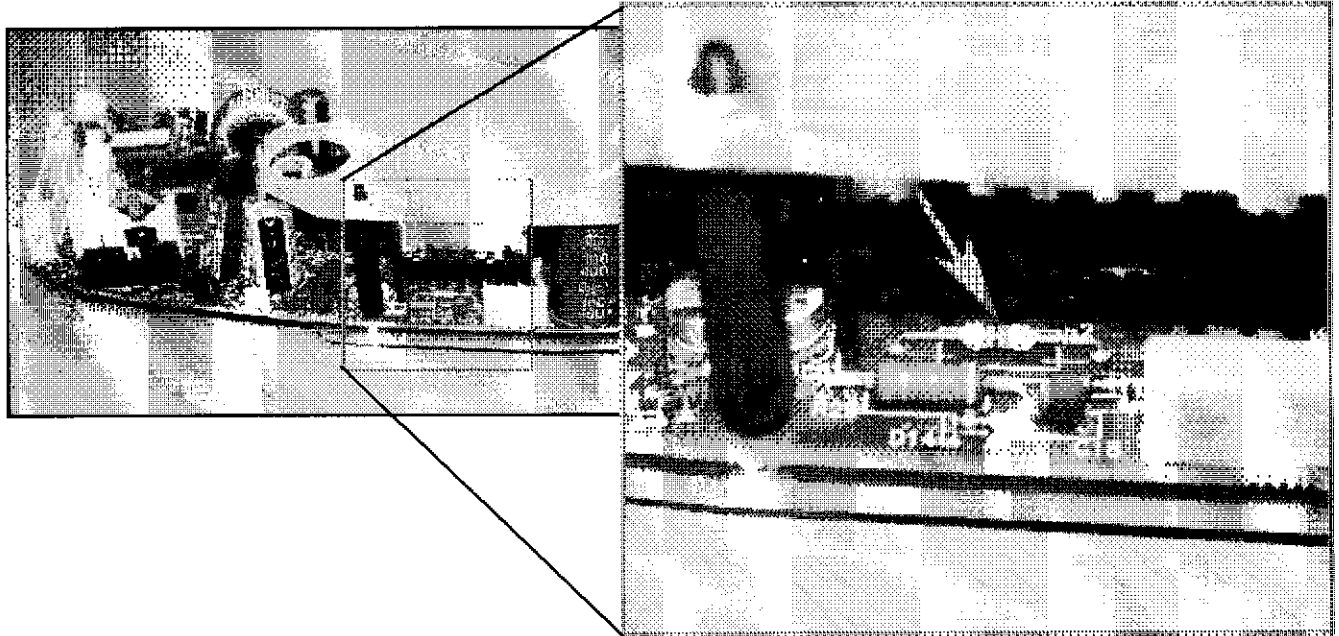
How to determine if the PV 403 PEEP CPU board needs to be replaced:

- Open the PV 403 PEEP
- Visually inspect the component **R2** on the CPU board (see pictures)
- If the **R2** component is in a light blue colour, it needs to be replaced

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12/07



**Action alternatives:**

- Replace the CPU board (part number 003229)
- Send the PV 403 PEEP to Breas Medical, Sweden, for upgrade

Please send an e-mail to [tech.support@breas.com](mailto:tech.support@breas.com) with the preferred action alternative and if you require loaner units during the process.

This is considered to be a limited mandatory field action and must be performed at the next possible service opportunity, meaning before April 30, 2008.

Please send your progress, according to this bulletin, by the end of each month to [tech.support@breas.com](mailto:tech.support@breas.com).

This limited mandatory field action will be reported to the appropriate government authorities in Europe and elsewhere as required.

Attached to this bulletin, you will find a list of the PV 403 PEEP units on your market affected by this limited mandatory field action. Please use this list when reporting your progress.

For further information, please contact us at [breas@breas.com](mailto:breas@breas.com)

*Breas Global Sales & Marketing Team*