

Customer
Hospital
City
Postal code
Country
Attn.: XXX

Issue date: ddmmyyyy

**Field Safety Notice:
Fixation kit N20, used with TCM CombiM and Philips
TcG10**

Priority Level: Urgent

Dear Customer

Radiometer has recently become aware that when the operator detaches the fixation ring from the paper liner, in some cases fractions of the paper liner's surface coating sticks to the adhesive surface of the ring. This leads to a varying degree of adhesiveness of the ring on the skin.

Affected product:

Fixation kit N20, 905-873 of Lots:

407221, 407231, 407241, 407251, 408041, 408191, 408201, 408211, 408231,
408232, 408261, 408271, 409021, 409101, 409231, 409291, 410021, 410141,
410281, 411171, 411201, 411261, 412021, 412111, 412161, 412201, 501081,
501131, 501191, 501311, 502031, 502101, 502131, 502171, 502231, 502261,
503091, 503231, 503311, 504031, 504081, 504111, 504271, 505041, 505061,
505141, 505181.

Consequence:

- If the sensor falls off, the value displayed on the monitor will not be in range and the problem will thus be detected by the medical professional.
- If the sensor does not adhere correctly (only partially contacts the patient's skin), this could result in an incorrect measurement.

What you should do:

- Please check your inventory and remove any Fixation kit N20 of the lot numbers listed above.
- Please discard all Fixation kit N20 from the affected lots in your possession.
- Complete page 2 of this letter and return it to your Radiometer representative.

Radiometer will provide compensation for all from the affected lots discarded by your institution.

If you have any questions, please contact your Radiometer representative.
Radiometer sincerely apologizes for the inconvenience this situation may cause you.

Best regards,
<Radiometer distributor>

Recall Response Fax Form

Fax No.:

Concerning:

Fixation kit N20

- I have received the customer letter, and reviewed my current inventory of Fixation kit N20, 905-873.
All kits from the lots listed above have been removed and discarded.

I have discarded the following quantity: _____ kits

- I have none of the affected lots in stock.

| | |
|----------------|--|
| Hospital Name: | |
| Your Name: | |
| Date: | |
| Signature: | |
| Email Address: | |