

Spiegelberg, Tempowerkring 4, D-21079 Hamburg



**Spiegelberg:**

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Tempowerkring 4  
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15.12.2009 AS

**Urgent: Recall of a Medical Device**

**Please pass this report on to the Risk Management Officer or to the Manager of Purchasing.**

Gentlemen,

unfortunately we have to report, that for certain serial numbers of the products „Probe 3 PN“ and „Probe 3 PS“ we have initiated a recall.

**1. Affected products**

REF	SN
SND 13.1.53/FV534P	12835-13393
SND 13.1.63/FV535P	6937-7122

**2. Description of the problem**

Spiegelberg ICP-Probes transmit the pressure via an air-pouch and a tube to an ICP-Monitor.

In a number of the products, specified above, the air-pouch shrank during the sterilization process. This results in false high readings in the lower measuring range.

The deviation was observed to be up to 8 mmHg, particularly in the lower end of the measuring range (around 0 mmHg). Neither false high nor

Dresdner Bank  
Konto 1 966 133 00  
BLZ 200 800 00

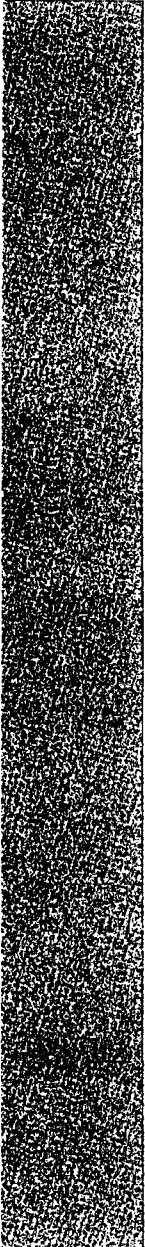
Vereins- und Westbank  
Konto 16 34310  
BLZ 207 300 00

Postgiro Hamburg  
Konto 3249-203  
BLZ 200 100 20

Volksbank Stade  
Konto 100 3300 900  
BLZ 241 910 15

Spiegelberg  
(GmbH & Co.) KG  
Registergericht  
Hamburg HRA 81393

Persönlich haftende  
Gesellschafterin:  
Spiegelberg  
Medizintechnik GmbH  
Hamburg  
Geschäftsführer:  
Dr. A. Spiegelberg  
Registergericht  
Hamburg HRB 46 157



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false low values were observed in the relevant range up from 20 mmHg.

The problem was observed to happen in the lower measuring range. False measurements at the usual threshold for treatment, which is between 20 and 25 mmHg, were not observed.

False high readings in the lower range can result in additional diagnostic measures, though.

After thoughtful consideration and deliberation we have decided to recall the affected products.

### **3. Measures on your side**

From our records we see that you have received affected products. Please check your stock for products affected. Please stop sales of the affected products and put them into quarantine. Please pass this recall on to all your customers who have received affected products from you. Please pass a copy of the attached form (Confirmation and Report) on to the respective customers. As a distributor you are obliged to report to us, that all customers who have received affected products, were notified.

Please fill in the attached form (Confirmation and Report) and send it to us by fax:

+49-40-790-178-10

Please send back all affected products with the original signed form (Confirmation and Report) to our address:

Spiegelberg (GmbH & Co.) KG  
Tempowerkring 4  
21079 Hamburg  
Germany



**3. Measures on our side**

We will send you replacement or a credit note as soon as possible. Please tick the respective box in the form.

Please pass this message on to all organizations and persons within your organization, who might have affected products under their control.

**4. Further information**

If you need further information in this matter, please get in touch with the person in charge:

Dr. Andreas Spiegelberg  
Tel.: +49-40-790-1780  
Fax: +49-40-790-17810  
Mobil: +49-1714340911  
E-Mail: [a.spiegelberg@spiegelberg.de](mailto:a.spiegelberg@spiegelberg.de)

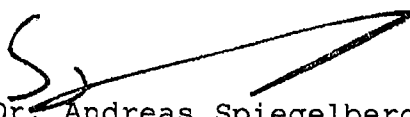
The Federal Institute for Drugs and Medical Devices in Germany was notified about this recall.

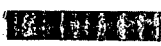
Please check, if for you there is an obligation to report this recall to your national authority and act accordingly.

We apologize for this unpleasant matter. At the same time we are very grateful for your co-operation.

Kind regards

Spiegelberg (GmbH & Co.) KG

  
Dr. Andreas Spiegelberg



Spiegelberg (GmbH & Co.) KG  
Tempowerkring 4  
21079 Hamburg

**Confirmation and Report**

Fax to: +49-40-790-178-10

Please fill in this form immediately  
and fax it back to the above mentioned number.

Re: Recall of the products

REF	SN
SND 13.1.53/FV534P	12835-13393
SND 13.1.63/FV535P	6937-7122

- There are no products in our stock that are affected by the recall.
- In our organization the following products are affected by the recall.  
We have stopped to use and to further distribute the products.  
All products were taken into quarantine and we will return the following products.
- We would like the products replaced.
- Wir would like to receive a credit note.

REF	SN

Name/Title	Date	Name of organization
<input type="text"/>	<input type="text"/>	<input type="text"/>
Signature		Street
<input type="text"/>		<input type="text"/>
		City, ZIP code
		<input type="text"/>