



Accura Medizintechnik GmbH
Max-Planck-Straße 33
61194 Karben, Germany
Tel +49 6039 92010
Email: info@accuramed.de

Urgent Field Safety Notice

Recall

of

Infusion Controller STAT 2

6.7.2017

Customer

Distributor and User

Identification of the concerned Medical Product

Infusion Controller STAT 2

Description of problem and cause therefore

Accura has received information from the manufacturer of the control unit used in STAT 2 gravity flow controllers that there may be an incorrect flow rate in single cases. Therefore, the manufacturer has recalled all infusion controllers.

If the device is unable to regulate flow, as set and confirmed by the attending medical staff, and the delivery of essential medications or treatment is dependent on the device's function, this may result in possible injury to the patient. In no instance has it been reported to Accura Medizintechnik that inconsistent flow rate has resulted in illness or injury.

Based on this information, Accura Medizintechnik GmbH has decided to recall the above mentioned products.



Accura Medizintechnik GmbH
 Max-Planck-Straße 33
 61194 Karben, Germany
 Tel +49 6039 92010
 Email: info@accuramed.de

Please do not use any infusion controller STAT 2 which has been delivered between April 2012 to June 2017.

List of LOT No.

Nr.	Artikel Nr.	Artikel Beschreibung	Lot / Charge Nr.	Date
1	331	Infusionsregler Stat 2	17/0910	23.06.2017
2	331	Infusionsregler Stat 2	030716	20.04.2016
3	331	Infusionsregler Stat 2	031215	20.03.2015
4	331	Infusionsregler Stat 2	040913	07.05.2013
5	331	Infusionsregler Stat 2	051314	06.06.2014
6	331	Infusionsregler Stat 2	051315	09.06.2015
7	331	Infusionsregler Stat 2	010416	03.02.2016
8	331	Infusionsregler Stat 2	51315	02.07.2015
9	331	Infusionsregler Stat 2	062113	27.06.2013
10	331	Infusionsregler Stat 2	070215	04.08.2015
11	331	Infusionsregler Stat 2	070913	31.07.2013
12	331	Infusionsregler Stat 2	071116	11.08.2016
13	331	Infusionsregler Stat 2	010716	15.02.2016
14	331	Infusionsregler Stat 2	071312	16.08.2012
15	331	Infusionsregler Stat 2	081213	04.09.2013
16	331	Infusionsregler Stat 2	91615	08.12.2015
17	331	Infusionsregler Stat 2	091912	25.09.2012
18	331	Infusionsregler Stat 2	101314	17.11.2014
19	331	Infusionsregler Stat 2	101916	04.11.2016
20	331	Infusionsregler Stat 2	17/0910	19.06.2017
21	331	Infusionsregler Stat 2	17/0994	23.06.2017
22	331	Infusionsregler Stat 2	011915	09.02.2015
23	331	Infusionsregler Stat 2	031512	17.04.2012
24	331	Infusionsregler Stat 2	011314	16.01.2014



Accura Medizintechnik GmbH
Max-Planck-Straße 33
61194 Karben, Germany
Tel +49 6039 92010
Email: info@accuramed.de

Which actions have to be taken by the customer?

1. Please review your inventory for any of the devices of the above mentioned products.

We ask that you contact all of those departments within your facility and any other facility within your organisation that may have received affected products.

It is imperative that all end users of these devices receive this notice and respond immediately.

2. If you have inventory of any of the devices please return them to us.

You will of course receive free replacement for the returned products as soon as new infusion regulator sets are available.

In cases where you urgently need controllers, we leave you, to check the flow rate using the drop rates at the beginning of any infusion. Since a possible incorrect flow rate already exists at the beginning of the infusion, it can be determined immediately whether the infusion regulator is operating correctly. Incorrect operating controllers shall not be used at all.

Please do not return used devices.

3. If you do not have any affected devices to return, please complete the business reply form and send it back to us:

info@accura.info. In case of questions, please contact us:
phone: +49-6039 – 92010 oder FAX 06039 - 920122. (Herr Martin Bruch).

Please send the information back till 31.07.2017.

Best regards

ACCURA
Medizintechnik GmbH
Max-Planck-Straße 33
61184 Karben
Tel. 06039 / 92 01-0, Fax 92 01-22



Accura Medizintechnik GmbH
Max-Planck-Straße 33
61194 Karben, Germany
Tel +49 6039 92010
Email: info@accuramed.de

Attachment
Effectivness Check Field safety notice
Business Reply Form

Please check all that apply:

- ... We do not have any stock of the suspected items
- ... we have notified our accounts to return their affected inventory of the products to us
- ... We return the following products

STAT 2, Art. Nr. 331	Quantity.....	LOT No
		
		

Have you received any reports of illness or injury related to this product?

Yes No

If yes, please document specific information here:

Return to

- info@accura.info
- FAX: +49 6039 – 920122

Adress for return of controllers.

Accura Medizintechnik GmbH
Max-Planck Str. 33
D – 61184 Karben