SCHULTE-ELEKTRONIK GmbH
medical technology

Important safety information

Supplementary information of the manufacturer for the safe use of the following devices:

SISS BABYCONTROL	**Respiration monitors**
SISS BABYCONTROL plus	**Respiration and heart rate monitors**
SISS BABYCONTROL BCE	**Respiration and heart rate monitors**
SISS BABYCONTROL BCS	**Respiration, heart rate and SpO2 monitors**
SISS BABYCONTROL DE	**Respiration and heart rate monitors**
SISS BABYCONTROL DS	**Respiration, heart rate and SpO2 monitors**
SISS BABYCONTROL H	**Respiration and heart rate monitors**
SISS BABYCONTROL M	**Respiration, heart rate and SpO2 monitors**

SCHULTE-ELEKTRONIK reference : BC_2018_12_14 **date: 14.12.2018**

Dear user, operator or distributor of the medical devices mentioned above,

this document contains important information that will enable you to continue the proper and safe use of the above listed devices.

Taking into account feedback from users of the SISS BABYCONTROL respiration monitor, we see the necessity to provide you with the following supplemental safety information on the use of said devices in the monitoring of respiration.

Description of the problem:

In certain application situations, due to the sensitivity of the respiratory sensor, it is also possible that signals are triggered which in fact do not originate from the respiratory movement of the patient. The monitor processes the sensor signals. In doing so, the signals that do not belong to the respiratory movement can be misinterpreted, with the result that a possible alarm for a lack of respiratory movement is not released, erroneously. It has been reported by some users that, for example, the patient's own heartbeat or vibration in the immediate environment of the patient were interpreted as a breathing movement, mistakenly.

As part of our investigation of these reports, we discovered that the affected devices have been used in a clinical environment and under special circumstances, which are not covered by the intended purpose of our devices. Our devices are designed as babymonitors helping to prevent possible endangered babies and infants for Sudden Infant Death Syndrome or for babies and infants which are suspicious after a polysomnographic examination as well as according to a physicians diagnose.

Within said intended purpose, the devices can be used both in the home environment, as well as in the hospital sector. However, the monitoring of intensive care patients is not covered by the intended purpose of our devices. Therefore, we would like to provide you with additional safety information and warnings (hereinafter and in the appendix) which are not yet included in the instructions for use in so many words.

Possible risks:

When the breathing monitoring function of the devices is used an alarm is set off, if no respiratory movement is detected in a defined period. In certain situations, this alarm may not be set off since the device interprets external movements erroneously as breathing movements of the patient.

Recommended action:

Please respect the additional instructions we have added as following:

WARNINGS

The device is not suitable for:

- Monitoring premature babies with a current weight of less than 1,500 grams
- Monitoring of babies and infants who do not (yet) have independent breathing
- Monitoring of intubated babies and infants
- Postoperative monitoring of babies and infants
- Monitoring premature babies or babies in incubators when the electrical components of the incubator interfere with the functioning of the device

The respiratory sensor must be placed in the abdominal area of the patient in accordance with the instructions for use. It must be ensured that the detected signal is a respiratory signal. The basic requirement for this is that the sensor is fixed firmly on the skin by use of tape. Sensitive and inflamed areas of the skin should be avoided. Therefore, the use of the device may be limited for patients with sensitive skin. An effective strain relief of the sensor cable is to be made by use of tape.

Safety note:

The proper functioning of the device and in particular the sensitivity of the respiration detection can only be determined with the appropriate test devices of the manufacturer. Other means of testing may lead to misinterpretations

Measures to be taken by the recipients:

Please keep a copy of this letter and the appendix **"Supplement to the instructions for use - New safety instructions and warnings"** and add them to the instructions for use.

Passing on of information:

For specialist distributors:

You are required to forward a copy of this letter as well as the appendix "Supplement to the instructions for use - New safety instructions and warnings" to all customers and to document the successful transfer. Alternatively, you can provide us with the relevant customer information so that we can arrange the forwarding of the information mentioned.

For users and operators:

Make sure that all users of the above-mentioned devices and other persons who may be concerned are informed of this urgent safety information and the appendix "Supplement to the Instructions for use - New safety instructions and warnings". In case you handed over the devices to third parties, please forward a copy of this information together with the attachment to the third parties or inform our contact person listed below.

Please enclose a copy of our letter and the appendix "Supplement to the instructions for use - New safety instructions and warnings" in the instructions for use.

Additional information:

The competent authority received a copy of this urgent safety information.

This urgent safety information, including the appendix "Supplement to the instructions for use - New safety instructions and warnings", will be sent by registered mail. The confirmation of the post about the delivery serves as a receipt confirmation for our documentation.

We regret any inconvenience, which may arise for you or your customers by these facts.

In case any query should arise by this information, please contact us directly as the legal manufacturer:

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Schörenbergstrasse 20
59939 Olsberg
Germany
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fax: 0049 2962 9707 15
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Yours sincerely
SCHULTE-ELEKTRONIK GmbH

Attachment:
Appendix "Supplement to the instructions for use - New safety instructions and warnings"