Urgent Field Safety Notice

BABYSENSE Operation in the Hospital Environment

Date of issue: 09.10.2018

Type of action: safety information

FSCA Identifier: **SM047-2018**

To the attention of: distributor and users of-Hisense BABYSENSE monitors in hospitals and medical institutions

List of affected products: ***BABYSENSE 1 or BABYSENSE II***

List of affected Lot Numbers: all production series with a date code sign of 06/2016 or earlier

Note: Date code sign – 06/2016 – means production of June 2016.

Dear customer,

In the interest of the safety of our customers, we would like to bring to your attention the following communication concerning some BABYSENSE distributed in your country.

Details on affected devices

BABYSENSE 1 or BABYSENSE II produced up to June 30th 2016 **and used in hospital and medical institutions**. Estimated total number of units is about 2700. Please refer to our web site for further and detailed information (www.hisense.co.il/fsn)

Description of the problem and background of the corrective action:

Electromagnetic interference and wireless communications **in the hospital environment in Japan** were found to affect the proper operation of the BABYSENSE from the above production series including alarm activation.

Although no similar events were reported in Europe, Hisense Ltd. decided to re-emphasize the instructions for use of the affected series of BABYSENSE still operating in hospital environment, by issuing a communication to users.

Transmission of this Field Safety Notice

This notice is passed to all Hisense Ltd.'s distributors in the European countries in which the said BABYSENSE is also used in hospitals and medical institutions to be relayed to their customers.

Action to be taken by the distributor:

Please sign this notice Customer Acknowledgement of Receipt and return it to the contact point mentioned below.

Identify and issue a list of the hospitals and medical institutions using the affected BABYSENSE in your territory and send them this Field Safety Notice.

Collect the Customer Acknowledgement of Receipt signed and dated from the user and return them to the below contact point.

Hisense Ltd.
23 Becker St.
Rishon Le Zion, 7535929 Israel
www.hisense.co.il
Tel : 972-3-9566604
Fax : 972-3-9566607
Email : Office@hisense.co.il

Update the list of all the hospitals and medical institutions approached by this notice accordingly.

Actions to be taken by the user:

Dear BABYSENSE (hospital) customer,

With the proliferation of electromagnetic interference and wireless communications in the hospital environment, we would like to emphasize to customers using BABYSENSE in Hospitals and Medical Institutions, the importance of not operating the product in the presence of electromagnetic interference, whether caused by portable and mobile RF communications equipment or any other source. As indicated already in the instruction for use *(for BABYSENSE II: V.BS2.14.EN.8.17, "Warning" section page 2, "Environmentally caused malfunction" page 3; for BABYSENSE 1: V.BS1_HC.3.EN.8.17, "Warning" section page 1, "Environmentally caused malfunction" page 2)*, electromagnetic interference may affect the proper operation of the device, preventing or delaying its alarm activation. It should be stressed that these instructions must be strictly followed and if the BABYSENSE is concurrently used with other devices, it is required to conduct the daily performance test in an environment identical to the actual situation and while all concurrently used devices are "ON". Under such conditions, it is required to verify that the acoustic and visual alarms of BABYSENSE are activated during the daily test.

Please distribute this notice to any potential user at your facility or to any organization to which the products were supplied.

Please make sure that all the final users are made aware of this notice by signing the Customer Acknowledgement of Receipt in annex.

If you have any questions relating to this bulletin, or should you require any additional information, please contact your local BABYSENSE distributor or Hisense Ltd. via the contact details below.

Contact details for the return of forms and follow up of the FSCA:

Hisense Ltd.
23 Becker St.
Rishon Le Zion - 7535929 –
Israel
Eldad NAKAR
eldad@hisense.co.il

The undersigned confirms that the relevant Competent Authorities have been notified of this action.

Sincerely,

Eldad Nakar

Eldad NAKAR

QA Manager

Urgent Field Safety Notice

Product Range: BABYSENSE

Customer Acknowledgement of Receipt

Please complete this form and email it back to the sender

Customer information: (fill or stamp)

Name of customer:_____

Address:_____

_____

Tick as appropriate

☐ Distributor

☐ Medical institution

Product information:

All BABYSENSE 1 and BABYSENSE II with **a date code sign of 06/2016 or earlier**

Receipt acknowledgement of this notice:

By signing, you confirm that you have received the Field Safety Notice, dated October 9th 2018 concerning Hisense BABYSENSE monitors and have taken note on the information contained within

☐ I confirm that this facility has received the above notice, have read the content and will pass it to any customer/user of the device

Tick as appropriate

☐ I confirm that we have no remaining concerned device at our facility

Name of representative: _____

Signature: _____ Date: _____

Hisense Ltd.
23 Becker St.
Rishon Le Zion, 7535929 Israel
www.hisense.co.il
Tel : 972-3-9566604
Fax : 972-3-9566607
Email : Office@hisense.co.il