Rev 1: July 2020
FSN Ref: 2020-001 FSCA Ref: 2020-001

Date: 08-07-2020

Urgent Field Safety Notice
Epi-Care mobile

For Attention of*: Please see list of distributors attached

Contact details of local representative (name, e-mail, telephone, address etc.)*
Please see list of distributor contact persons in above mentioned attachment

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Danish Care

Urgent Field Safety Notice (FSN)
Epi-Care mobile
Product function affected by update of Android OS

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Epi-Care mobile, item number 1010070
1.	2. Commercial name(s)
	Epi-Care mobile
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	Epilepsy alarm for alerting caretakers of user's Generalised Tonic Clonic seizures.
1.	5. Device Model/Catalogue/part number(s)*
	Epi-Care mobile, item no 1010070, including a mobile phone. In actual case Moto G7 Play manufactured by Motorola Inc.
1.	6. Software version
	Current Epi-Care mobile app version 2.2.0
1.	7. Affected serial or lot number range
	From S/N 70101765 to 70102281.
1.	8. Associated devices
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	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	As of July 2020, Motorola released a major upgrade to the Android OS, against the information provided by our supplier. The upgrade to Android 10, impairs some of the key functionality of the Epi-Care mobile app. The phone would not always as intended deliver a voicecall to the alarm recipient, but always deliver a message as a SMS, using the current app version (2.2.0).
2.	2. Hazard giving rise to the FSCA*
	If the user updates the phone to Android 10 and the phone is idle for an extended period of time, a sensor alarm is only redirected to the caretaker in form of SMS. The app might not alert the caretaker via a phone call.
2.	3. Probability of problem arising
	The German and Danish market is informed during sales, that Android upgrades could potentially affect the intended purpose of use. Still the Norwegian and Swedish markets have not necessarily informed the users not to upgrade the phone.
2.	4. Predicted risk to patient/users
	There is no direct risk for the user, however we see a higher probability, that the careperson do not notice an alarm signal.
2.	5. Further information to help characterise the problem
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2.	6. Background on Issue
	7. Other information relevant to FSCA

2.	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User*** ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None **Customers are advised to** update App and phone to latest versions (Android 10 and ECM version 2.2.1)
3.	2. By when should the action be completed? — Specify where critical to patient/end user safety: Not applicable
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? N/A Provide further details of patient-level follow-up if required or a justification why none is required
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) — No
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.
3	6. By when should the action be completed? — Already done
3.	7. Is the FSN required to be communicated to the patient /lay user? — No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? No

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	2020-001
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Danish Care Technology ApS**
	b. Address	**Energivej 3 – DK-4180 Sorø**
	c. Website address	**www.danishcare.dk**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * YES	
4.	9. List of attachments/appendices:	**Guide to update Epi-Care mobile app, list of distributors**
4.	10. Name/Signature	**Jens Jørgen Eriksen - CEO**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.