



FSN Ref: FSN-0000196
FSCA Ref: CAPA-0000021

Date: 13 July 2023

Field Safety Notice Embrace2

For Attention of: Embrace2 users with devices from lots G11 and H11

Dear Madam or Sir,

With this letter, we would like to inform you about a safety notice concerning Embrace2 devices with lot numbers G11 and H11 due to a potential problem with the battery duration of these devices. If you are receiving this letter, it means you have bought an Embrace2 device from the affected lots. Empatica is asking you to consider this notice and follow the instructions presented below.

We remain at your disposal for any further information you might need.

Empatica Srl



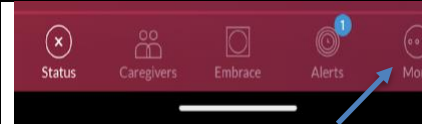
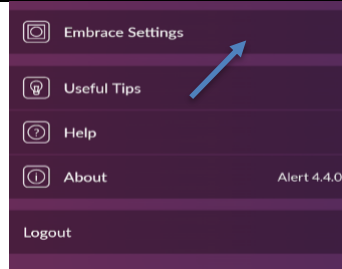
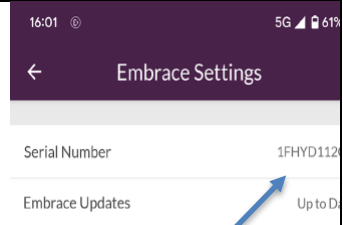
Field Safety Notice Embrace2 Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)* The Embrace is a wrist-worn wearable device that is intended to help identify potential generalized tonic-clonic seizures and provide alerts to designated caregivers.
1.	2. Commercial name(s) Embrace2
1.	3. Unique Device Identifier(s) (UDI-DI) 00853858006133, 00853858006140, 00853858006126, 00853858006119, 00853858006102
1.	4. Primary clinical purpose of device(s)* The Embrace is a wearable device, worn on the wrist of a child or adult, for use in home or in professional healthcare environments. Embrace senses electrodermal activity and motion data in order to detect patterns that may indicate a possible convulsive seizure in patients with epilepsy or at risk of having epilepsy. When a seizure event is detected, Embrace sends a command to a paired wireless device that is programmed to initiate an alert (or send an alarm) to a designated caregiver.
1.	5. Device Model/Catalogue/part number(s)* Flamingo Pink – EM2-FP-S Sky Blue – EM2-SB-2 Seoul Grey – EM2-SG-S Boston Blue – EM2-BB-S Milan Black – EM2-MB-S
1.	6. Software version Non relevant
1.	7. Affected serial or lot number range Lot numbers: G11 and H11
1.	8. Associated devices None

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* Once fully charged, the battery of the Embrace device is expected to last 48 hours, provided that the device is stored and charged as directed in the instructions for use. Empatica is issuing this Field Safety Notice to alert customers that Embrace devices from affected lots may have a battery life lasting less than the full 48 hours, requiring the device to be charged more frequently.
2.	2. Hazard giving rise to the FSCA* The hazard is a reduced battery duration over the lifetime of the device, which may require more frequent charging sessions.
2.	3. Probability of problem arising Users of devices from the affected lots might experience shorter battery duration. Based on the available data and internal analysis the reduced battery duration might start after some months of device usage.

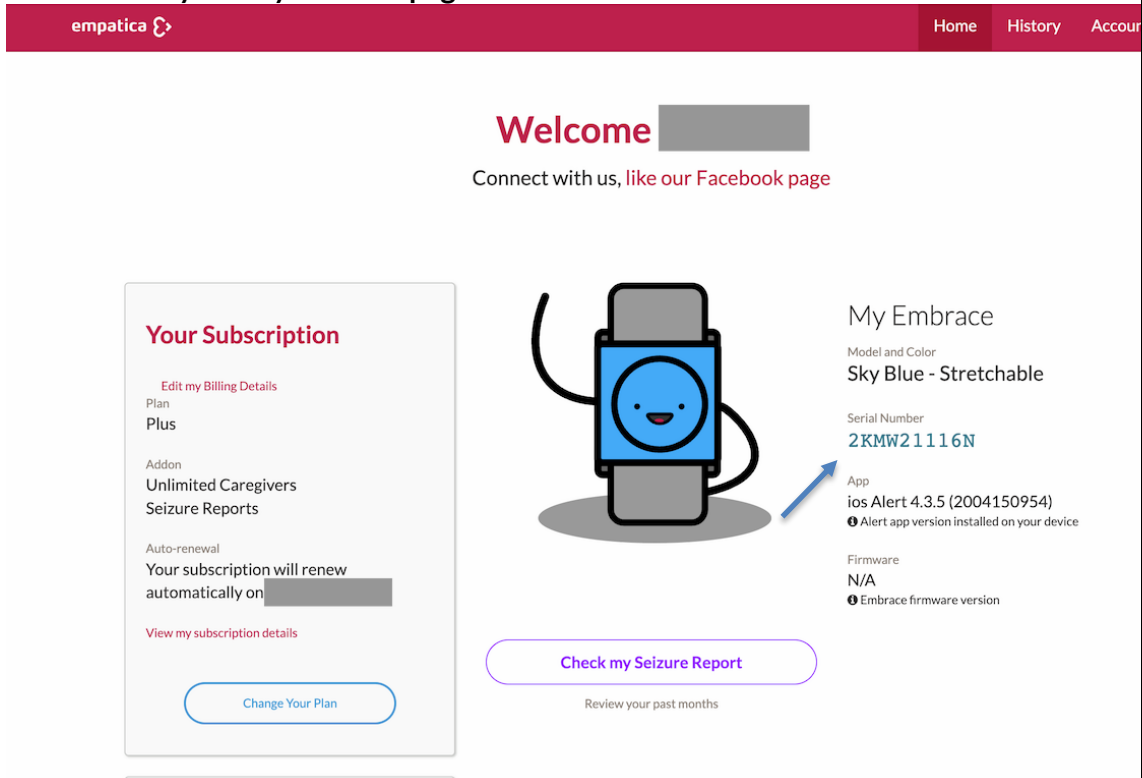


2.	<p>4. Predicted risk to patient/users</p> <p>A reduced battery life may require more frequent charging sessions, increasing the time during which the device is not worn and therefore cannot detect or issue alerts regarding potential tonic-clonic seizure activity. Battery life does not impact the accuracy or sensitivity of the Embrace seizure detection algorithm, nor the software functionality of sending caregiver alerts.</p>
2.	<p>5. Further information to help characterise the problem</p> <p>Accelerated battery depletion may occur due to issues arising during the manufacturing process, when the device is not routinely charged (at least every 30 days), or when the device is stored in an environment subject to extreme temperatures. The Embrace device has been designed to notify the user through haptic and visual alerts on the device and the paired mobile phone app when the device has 10% and 5% remaining battery percentage.</p>
2.	<p>6. Background on Issue</p> <p>After receiving an elevated rate of complaints related to accelerated battery depletion in Embrace devices, Empatica conducted an investigation and determined that the reduced battery duration was caused by a manufacturing issue confined to two specific lots of devices (G11 and H11). The battery duration of a limited number of these devices may decrease faster than expected throughout the device's lifetime.</p>
2.	<p>7. Other information relevant to FSCA</p> <p>Nothing relevant to add.</p>

3.	<p>3. Type of Action to mitigate the risk*</p>
3	<p>1. Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input checked="" type="checkbox"/> Other <input type="checkbox"/> None Check your device lot number. You can check your device lot number by: <ul style="list-style-type: none"> • From the Alert App </p> <div style="display: flex; justify-content: space-around;"> <div style="width: 30%;">  <p>From the main page of the alert app click on "More"</p> </div> <div style="width: 30%;">  <p>Click on "Embrace Settings"</p> </div> <div style="width: 30%;">  <p>Check the device "Serial Number" the lot number is represented by the 5th, 6th and 7th digit of the serial number. In the picture above the Lot number is "D11"</p> </div> </div>



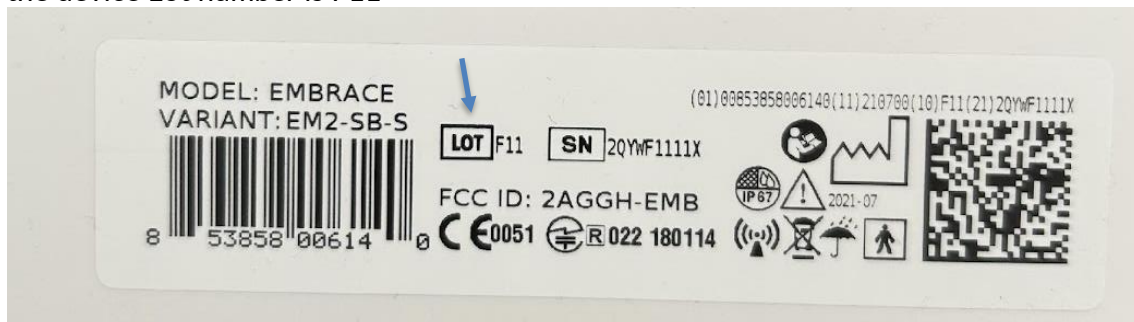
- **From your MyEmbrace page**



On the home page of your MyEmbrace account on the right hand side of the screen you will see your Embrace Serial Number. The lot number is represented by the 5th, 6th and 7th digit of the serial number.

- **On the packaging of your device**

On the box that contained your Embrace2 there is an identification label (See picture below). The device Lot number is identified with the LOT symbol. In the picture below the device Lot number is F11



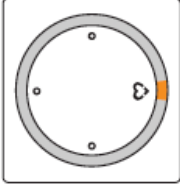
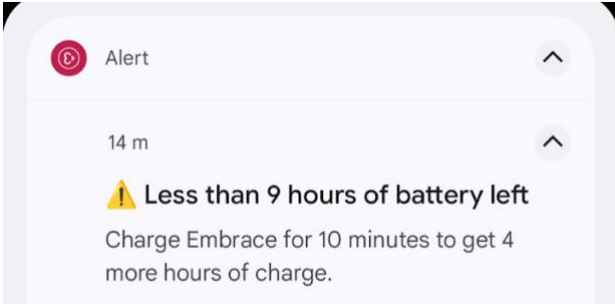
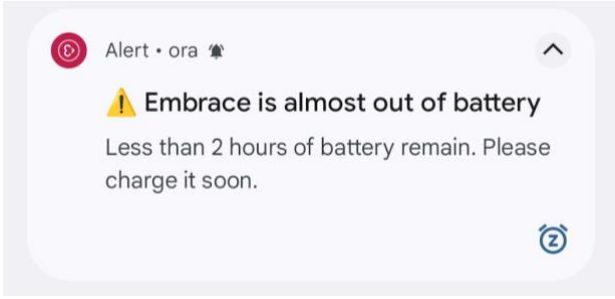
- **From your device**

On the back of your Embrace2 the device serial number is engraved. The lot number is represented by the 5th, 6th and 7th digit of the serial number.

Track battery level notifications.


Empatica recommends that you pay increased attention to the product battery level notifications intended to inform you about the remaining battery charge. As noted in the user manual, the Embrace device is not intended to be used as a stand-alone monitoring device. As the system is not meant to substitute for ongoing seizure monitoring practices, patients are strongly advised to ensure that alternative methods of obtaining medical assistance are available at all times, including during device charging sessions.



<p>Patients are also encouraged to contact Empatica customer support for any concern related to battery life impacting usability of the Embrace device. Embrace presents to you battery level notification in two different ways:</p> <ul style="list-style-type: none"> An orange light will start blinking on the Embrace device and will not stop until the device is placed in the charger. 		
		
<p>Embrace battery low Orange dot blinking</p>		
<ul style="list-style-type: none"> The Alert app will notify you on your mobile device when the Embrace battery reaches 10% with the below notification 		
		
<ul style="list-style-type: none"> The Alert app will also notify on your mobile device when the Embrace battery reaches 5% with the below notification 		
		
<p><u>The affected products will not be removed from the market, and you can continue using your Embrace2 following the actions listed above.</u></p>		
3	<p>2. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</p>	Yes
3	<p>3. Action Being Taken by the Manufacturer</p> <p> <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Empatica designed and implemented a program to actively monitor device battery duration and proactively reach out to customers when a device within warranty (2 years from production) shows a rate of battery duration degradation that is faster than expected. Customers contacted by the Empatica customer support team regarding battery duration are offered a free-of-charge replacement device.</p>	
3	<p>4. Is the FSN required to be communicated to the patient /lay user?</p>	N/A

	4. General Information*
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4.	1. FSN Type*	New
4.	2. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Empatica S.r.l
	b. Address	Via Stendhal, 36 - 20144 Milan (IT)
	c. Website address	www.empatica.com
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	4. Name/Signature	Alberto Poli Director, Quality and Regulatory Compliance
		
Transmission of this Field Safety Notice		
<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>		