# URGENT FIELD SAFETY NOTICE

## MEDICAL DEVICE RECALL

### Power Knee™ Battery - Connection Issues

Reference – FA231001

2023-11-30

#### ATTENTION

Dear Össur customer,

Össur is committed to providing safe, high-quality medical devices to its customers. We have identified a recent issue related to Power Knee Battery connection. As such, Össur is implementing an Urgent Field Safety Notice for a Medical Device Recall of Power Knee Batteries shipped with new Power Knee units and additional batteries between the dates of January 24, 2023 and August 30, 2023.

The battery connection has been found to vary in some instances and may lead to unexpected shutdown. Unexpected shutdown is a momentary loss of power to the knee where the user may experience loss of support that can lead to a fall and potential injury.

As user safety is our highest priority, risk of falling with potential for injury as a result of this issue is regarded as unacceptable. Therefore, we are initiating a recall of the affected batteries.

A solution is in place to address this issue. Össur instituted inspection measures to ensure all new Power Knee Batteries as of August 30, 2023 are conforming.

#### AFFECTED DEVICES

Affected devices include all batteries shipped with new Power Knee (PKA) units and additional batteries shipped from January 24th through August 30th, 2023.

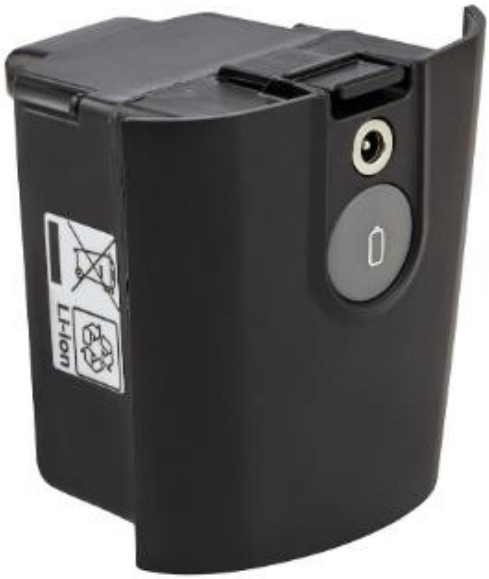
| Commercial Name | Product number |
|---|---|
| Power Knee™ Battery | PKA10002 |

The following are the serial number device identifiers for your specific Power Knee and battery (where x represents a number 0-9). Please refer to your personal customized letter for actual serial number information.

| Power Knee Serial Number | Affected Battery Serial Number(s) | Replacement Battery Serial Number(s) |
|---|---|---|
| HF51xxxx | HF55xxxx | HF55xxxx |
| | HF55xxxx | HF55xxxx |

## DESCRIPTION AND PICTURES OF THE AFFECTED DEVICES

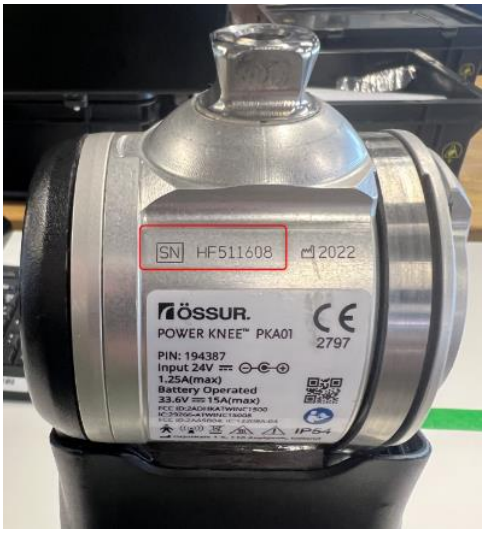
**Power Knee**



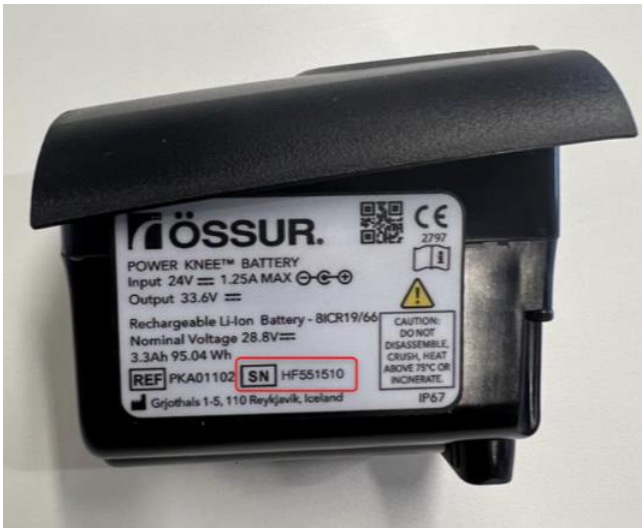

**Power Knee Battery**

### How to find the affected batteries

Match the Power Knee serial number in this letter with your records. Retrieve the knee and ensure the serial number of the knee matches. Remove the battery and match serial number found on the side of the battery with the affected battery serial number in this letter.




**Power Knee Serial Number (RED)**




**Battery Serial Number (RED)**

## DEVICE ISSUE

The fault presents as either a failure to turn on the device or an unexpected shutdown. Failure to turn on the device is easily identified as the knee will not turn on with battery engaged and pressing the power button. Unexpected shutdown is a momentary loss of power to the knee where the user may experience loss of support that can lead to a fall and potential injury. Unexpected shutdown may be caused by impact to the heel or toe of the prosthesis which can disrupt connection of the battery to the knee.

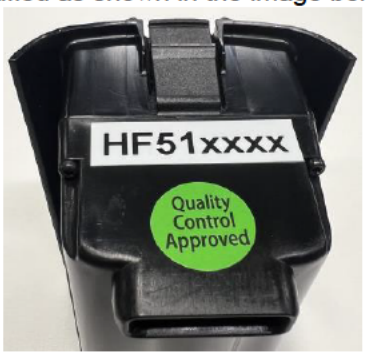
## THE SOLUTION

Össur has instituted inspection measures to ensure all new Power Knee Batteries as of August 30, 2023 are conforming.

## REQUIRED ACTIONS TO BE TAKEN

### REQUIRED ACTIONS

1. **REPLACE THE AFFECTED BATTERIES**
   a. Check the serial number of the Power Knee Batteries to confirm the affected units.
   b. Replace the affected batteries with the new batteries supplied along with this letter. (New batteries can be visually identified as shown in the image below).




   c. To ensure future traceability, please fit each new battery into the designated knee according to the Power Knee Serial Number indicated on the sticker on the back of the battery.
   d. If any issue with the new battery is observed, please contact Össur.

2. **PLEASE PASS THIS NOTICE** to those who need to be aware within your organization. If you have further distributed this product, please identify your customers, and notify them at once of this product alert. We recommend that you include a copy of this notice.
3. **PLEASE MAINTAIN AWARENESS** of this notice and required actions for an appropriate period to ensure effectiveness of the corrective action.
4. **SIGN THE ACKNOWLEDGEMENT FORM(S).**
5. **RETURN TO ÖSSUR ALL AFFECTED BATTERIES AND ACKNOWLEDGEMENT FORMS** in the pre-paid return packaging provided.

## ADDITIONAL COMMENT

Please report all device-related incidents to the manufacturer and the national Competent Authority, as this provides important feedback.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

We apologize for any inconvenience this causes you and your patients. If you have questions or concerns about this notification, please contact customer service.

This notice is also available at safetyalerts.ossur.com.