

Important Security Notice

Field Safety Corrective Action (FSCA) on a Medical Device, reference number 6.6.2-2018-35328

Product Item Number:

USA/CANADA: T10 Part Number 750394 and T15 Part Number 750423,

EUROW:

T10(FCA ref=113400 Dynavox T10)= 12003885

T15(FCA ref=113401 Dynavox T15)= 12003886

Batch Series Number Affected: **T10:** TS1308-TS1411xx &, **T15:** TL1405-TL1407xx

Dear Customers,

Tobii Dynavox issues a security message (reference number 6.6.2-2018-35328) regarding the T10 and T15 products.

The Field Security Communication's intention is to inform you of the following:

- what problem it is about
- the actions to be taken by the customer / user

This document contains important information about continued security and proper use of your product.

Review the following information with all employees who need to be aware of the content of this communication. It is important to understand the consequences of this communication.

Description of the problem:

We have detected a problem in some Tobii Dynavox T10 and T15, which are not used or not recharged as recommended regularly (i.e., do not charge over several months), over time, the battery may lose capacity and become discharged. This may cause the battery to start swelling more than normal for a battery. This was caused by faults in the safety circuit, where leakage currents have occurred as the drainage battery is lower than the set minimum level. If you have the problem on your devices where you see a swelling, it is necessary to replace the battery where this problem is fixed.

Measures to be taken by the customer / user:

- (1) Check if your product line number is affected by this problem.
- (2) Contact Tobii Dynavox to get an RMA number when your Serial Number is within range. See below for contact info.
- (3) Although it is not swollen but has serial numbers in the area specified, contact Tobii Dynavox to get an RMA number to get the device ready for action. Although it does not have any problems that are visible, we would like to replace the battery and get rid of the risk.

MEASURES PLANNED BY TOBII DYNAVOX

Tobii Dynavox will contact all end customers or distributors who have affected units to ensure that they can be brought in for repair. The units that have passed through distributors where end users are not known by Tobii Dynavox, then the notice of this will be shared by the distributors. Tobii Dynavox will collaborate with distributors to bring in all affected entities for action.

As part of this process, we also want to know if the products are not in use and a confirmation that they are out of order or scrapped to keep track of their status in our systems.

Tobii Dynavox is pleased to offer top quality products and services. It is very important to us that you are satisfied with the Tobii Dynavox products and our response to this issue. If you have any questions about this, contact your local Tobii Dynavox Support or Customer Service.

Customer Service:

Email: support.eu@tobiidynavox.com

Phone: +46 8 522 950 20 (press 1 för support)

Other good information:

As with any lithium ion battery, you should never try to puncture or ventilate a battery. You should not attempt to replace the battery yourself or remove the battery from the device. This should only be done by a trained service technician. Products with battery should not be stored under extremely hot conditions, according to the product spec.

Sincerely

Ali Demirel

Director of Global Quality & Industrialization Tobii Dynavox

Säkerhetsmeddelande Formulär

Vänligen faxa eller e-posta nedanstående information till oss så snart som möjligt.
Vi tackar för ert samarbete:

Namn: < _____ >
Adress/Land < _____ >
Email address: < _____ >

Meddelandereferens: < Recall T10/ T15 battery >
Produktreferens: < Serial No >

- Jag bekräftar att jag har mottagit och förstått det bifogade meddelandet.
- Enheten är inte i bruk, skrotat och kastat.
- Enheten har överförts till en annan, Namn och adress för den som fått

_____.

Skicka det ifyllda formuläret till e-post: customer.eu@tobiidynavox.com och uppge referenskode
ovan på ämnesraden.

För att skicka in enheten för åtgärd, nedan är Web formulär för att få ett RMA nummer:

<https://www.tobiidynavox.com/sv/support-utbildning/forms/device-return-request/>