

FIELD SAFETY NOTICE

Device commercial name:

TD Navio Midi (1000798)

TD Navio Maxi (1000799)

FSN reference: FSN-2026-00001

FSCA reference: FSCA-2026-00001

Date: 2026-07-10

Attention: Users, Distributors, Governmental Healthcare Organizations, and Procurement Bodies

Dear Customer,

Tobii Dynavox issuing this Field Safety Notice (FSN) regarding a Field Safety Corrective Action (FSCA-2026-00001) for certain TD Navio Midi and TD Navio Maxi devices.

This notice informs you about the issue, associated risks, and required actions. Please review it carefully and share it with all relevant users to ensure safe and proper use of the device.

1. Description of the Issue

Through post-market surveillance and investigation of returned devices, a mechanical robustness issue has been identified in the internal battery structure.

If the device is exposed to significant drop, repeated impacts, or mechanical stress, internal battery mounting components may become damaged. This can allow the battery to move within the device. In limited cases, this movement may damage the battery insulation and lead to an internal short circuit, potentially resulting in localized heating and gas venting within the device enclosure.

2. Risk Involved

Based on available data:

No incidents have been reported. The likelihood of occurrence is low, as it requires a specific sequence of mechanical stress events. Overall risk is considered low and acceptable with corrective action; without action, a low residual risk of internal battery damage remains.

3. Affected Products and Identification

Device Type: Medical Device, Augmentative and Alternative Communication (AAC) device

Intended Use: Devices intended to provide communication support for individuals with speech and language impairments via touch or eye-tracking.

Affected Serial Number Ranges:

- TD Navio Midi: TDNM1-240628000004 - TDNM1-260617070001
- TD Navio Maxi: TDNL1-240904000016 - TDNL1-260617070001

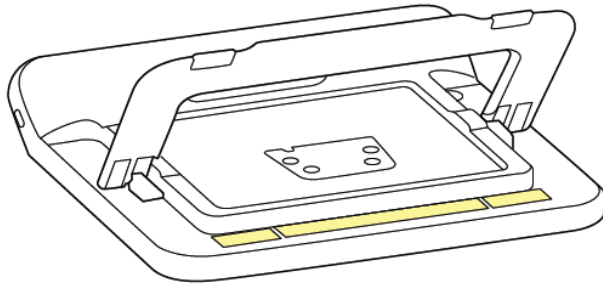
Contact Details Manufacturer:

Dynavox Group AB

Löjtnantsgatan 25 115 50 Stockholm, Sweden

SRN: SE-MF-000008884

How to Locate the Serial Number



The serial number is located on the barcode label on the back of the device. To find it, lift the kickstand and look for the number marked with "SN". If the label is missing or unreadable, please contact support. We can help identify your device using other information.

4. Actions to Be Taken

4.1 Actions for Direct Customers / End Users

Affected TD Navio Midi and TD Navio Maxi devices should be sent in for repairs to ensure they continue to perform as intended.

It is safe to continue using your device as normal while waiting for repair. However, if you are experiencing or begin to experience any of the following circumstances with your device, please proceed straight to contacting our support team:

- unusual movement or noise inside the device
- device shutting down unexpectedly
- visible damage to the device housing

When it is time to send in your device, you can begin the repair process by contacting us in one of several ways:

- Online: www.tobiidynavox.com/pages/td-navio-recall
- By phone or email
 - North America:
 - Email: support.na@tobiidynavox.com
 - Phone: +1-800-344-1778
 - Europe and all other countries:
 - Email: support.eu@tobiidynavox.com
 - Phone:
 - UK: +44 114 481 0011
 - Ireland: +353 (0)21 2428566
 - Germany: +49 6990 7200 500
 - Norway: +47 55 55 10 60
 - Denmark: +45 35 15 13 42
 - Sweden and all other countries: +46 8 522 950 20

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We will provide your repair authorization and shipping instructions, and we will support you throughout the process. Out of respect for the needs of those who use our devices, our goal is always to keep users communicating and minimizing any time without the device as much as possible.

If you do not already have a communication tool in addition to your TD Navio Midi or Maxi, we have prepared resources to support you in utilizing your communication software on another device or print-based options: www.tobiidynavox.com/pages/td-navio-recall.

As with any lithium-ion battery device, you should not attempt to open the device, remove the battery, or perform repairs yourself. This should only be done by trained service personnel.

Please use any of the methods above to tell us if your device is no longer in service. We are committed to reaching and supporting all affected customers, and our support team is here to help at every step.

Deadline: Please arrange action within 60 days of receiving this notice.

4.2 Actions for Distributors and Importers, Governmental Healthcare Organizations and Centralized Hubs

Your support is requested to help ensure timely communication, identification of affected devices, and coordination of corrective actions. We kindly ask you to:

- forward the attached Field Safety Notice (FSN) to all customers, users, facilities, and relevant organizations within your network who have affected TD Navio Midi or TD Navio Maxi devices.
- identify affected devices by using the partner portal (<https://partner.tobiidynavox.com/s/support>) for access to serial numbers of your assets, however we ask that you also check your own records for any additional devices not identified in that list.
- support the coordination and scheduling of corrective actions and repairs through our recall webpage (www.tobiidynavox.com/pages/td-navio-recall). To begin the process, please complete the repair authorization request form available on the recall page. Once submitted, you will receive the necessary shipping instructions. Additional contact options are also available on the recall page and listed below. Our team will support you throughout the entire process to ensure a smooth and timely resolution.
- maintain traceability and records of communications with all customers and completed actions.

Affected devices will receive a retrofit repair performed by Tobii Dynavox or authorized service partners, free of charge. You can continue to use these devices while waiting for the repair unless otherwise advised by Tobii Dynavox.

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To reduce the time that people are without their AAC device, we recommend that either they or you ship the device directly to Tobii Dynavox, and we will return it to an address of your choice. Further details, including affected serial number ranges, repair instructions, and support resources, are available at:

www.tobiidynavox.com/pages/td-navio-recall] and <https://partner.tobiidynavox.com/s/support>

To support customers while their device is being repaired, we are offering a variety of resources. This includes information about using a free software version or companion license, printable communication boards, and guidance for printing custom page sets: www.tobiidynavox.com/pages/td-navio-recall.

For support with device identification, coordination, or scheduling, please contact:

- Email: support.eu@tobiidynavox.com
- Phone:
 - UK: +44 (0)114 481 00 11
 - Ireland: +353 21 242 8566
 - Germany: +49 6990 72 00 50 0
 - Norway: +47 55 55 10 60
 - Denmark: +45 35 15 13 42
 - Sweden and all other countries: +46 (0)8 522 950 20

5. Corrective Action

A design improvement has been developed to reinforce the battery mounting structure and prevent the identified failure mode. This will be implemented through a field modification in our repair centers involving installation of reinforcement inserts. The corrective action will be performed free of charge.

6. Contact Information Mon–Fri, 9:00–17:00 (CET)

- Email: support.eu@tobiidynavox.com
- Phone:
 - UK: +44 114 481 0011
 - Ireland: +353 21 242 8566
 - Germany: +49 6990 7200 500
 - Norway: +47 55 55 10 60
 - Denmark: +45 35 15 13 42
 - Sweden and all other countries: +46 8 522 950 20

7. Regulatory Information

This Field Safety Corrective Action has been reported to the appropriate Competent Authorities.

8. Transmission of This Field Safety Notice

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This notice must be forwarded to all individuals and organizations who need to be aware, including where devices have been transferred.

Please:

- Share this notice with all relevant stakeholders
- Maintain awareness of this notice and resulting actions
- Report any device-related incidents to the manufacturer or Competent Authority

Thank you for your cooperation in ensuring continued safety.

Sincerely,

Atoosa Bayat
Global Head of Quality and Regulatory
Tobii Dynavox AB

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