Tobii Dynavox Speech Case Mini User's Manual



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User's manual Tobii Dynavox Speech Case Mini

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Speech Case Mini Mini Device Identifier: 7340074601738

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1 Introduction

Thank you for purchasing a Speech Case Mini from Tobii Dynavox!

To ensure the optimal performance of this product, please take the time to read this manual carefully.

The Speech Case Mini is a Tobii Dynavox speech accessory intended for use with a 8.3" iPad Mini[®] as an augmentative communication aid and for computer access for those with speech, language, physical, and cognitive disabilities.

1.1 Explanation of Admonitions

In this manual we use five (5) levels of admonitions as follows:



The Note symbol is used for notifying the user of something important or of something that needs special attention.



The Caution symbol is used to inform of something that could cause harm to, or malfunction of, the equipment.



The Warning symbol is used to inform of something in which there is a conceivable risk of harm to the user if the Warning is ignored.



The High Volume symbol is used to inform of something that can cause damage to hearing.

The High Temperature symbol is used to inform of surface temperature conditions that may cause injury or discomfort.

1.2 Symbols and Markings

This section provides information about the symbols that are used on the Speech Case Mini, its accessories, or packaging.

Symbol or Markings	Description
	Safety Class II double insulated equipment.
	Dispose of in accordance with your country's requirements.
CE	CE is the abbreviation of the European Communities and this mark tells customs officials in the European Union that the product complies with one or more of the EC Directives.
FC	This mark is a certification mark employed on electronic products manufactured or sold in the United States which certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.
	Refer to instruction manual/booklet.
	Australian Electrical Equipment Safety System Regulatory Compliance Mark.

Symbol or Markings	Description
RoHS	Reduction of Hazardous Substances directive compliant.
+	Volume up.
-	Volume down.
	Manufacturer.
REF	Reference number.
SN	Serial Number.
MD	Indicates the item is a medical device.
SGS	SGS is the world's leading inspection, verification, testing and certification company.
UK CA	The UKCA (UK Conformity Assessed) marking is a UK product marking that is used for goods being placed on the market in Great Britain (England, Wales and Scotland). It covers most goods which previously required the CE marking.
VI	Mark indicating a power supply meets the level VI requirements at both 115 V/60 Hz and 230 V/50 Hz, if designed to operate at multiple input voltages. Products with a nameplate marked for only one voltage and frequency should also use this mark assuming the product meets the performance requirements; in other words, manufacturers do not have to indicate the voltage with the mark.
c FL [®] us	Recognized component mark for Canada and the United States.
Roms	Dispose of in accordance with your country's requirements.

1.2.1 Product Label

The product label for the Speech Case Mini is located on the inside of back piece of the device, see Figure 1.1 Location of product label, page 7.



Figure 1.1 Location of product label

Posi- tion	Description
1	Product Label

For information on how to disassemble the Speech Case Mini, see 5.6 Removing the iPad from the Speech Case Mini, page 19.

1.3 Intended Use

When used with an appropriately configured iPad Mini, the Tobii Dynavox Speech Case Mini is a speech generating device (SGD) for people who have challenges in their ability to speak due to injury, disability or illness. The Tobii Dynavox Speech Case Mini pairs with the iPad Mini through Bluetooth® to work as an audio output device.



Contraindication: The Speech Case Mini device should never be, for the user, the only means of communicating important information.

In case of failure of the Speech Case Mini device, the user cannot communicate using it.



Intended use is primarily an indoor environment.

Package Contents 1.4



It is recommended to keep the original packaging materials for the Speech Case Mini.

If the device needs to be returned to Tobii Dynavox for Warranty-related issues or repair, it is beneficial that the original packaging or equivalent is used for shipping. Most shipping carriers require at least 2 inches of packing material around the device.

Note: Due to Joint Commission regulations, any shipping materials (including boxes) sent to Tobii Dynavox must be discarded.

The items below are included in the Speech Case Mini package:

- 1 Speech Case Mini
- 1 Screwdriver
- 1 Carrying strap
- 1 Dual-port USB charger
- AC Cable

- 1 USB-C to-USB-A Cable •
- 1 Getting Started Guide •
- 1 Safety and compliance 1 Warranty Document •
- •

2 Safety

The Speech Case Mini device has been tested and approved as compliant to all the Specifications and Standards listed in *Appendix B Compliance Information, page 24* of this manual and in the *Appendix D Technical Specifications, page 29*. Nevertheless, in order to ensure safe operation of your Speech Case Mini, there are a few safety warnings to bear in mind:



No modification of this equipment is allowed.



Repairs to a Tobii Dynavox device must only be performed by Tobii Dynavox or a Tobii Dynavox authorized and approved repair center.



Contraindication: The Speech Case Mini device should never be, for the user, the only means of communicating important information.

In case of failure of the Speech Case Mini device, the user cannot communicate using it.



The Speech Case Mini is not waterproof or water resistant. The device should not be kept in excessively humid, damp or otherwise wet conditions. Do not submerge the device in water or in any other liquid. Be careful not to allow liquids to be spilled upon the device, especially in the connector areas.



The user may never attempt to change the battery. Altering of the battery may cause risk of explosion.



The Speech Case Mini is not to be used as a life supporting device, and it shall not be relied on in case of loss of function due to power loss or other causes.



There could be a choking hazard risk if small parts detach from the Speech Case Mini device.



The strap and charging cable could present strangulation hazards to young children. Never leave small children unattended with the strap or charging cable.



The Speech Case Mini device shall not be exposed to or used in rain or weather conditions outside the Technical Specification of the Speech Case Mini device.



Young children or people with cognitive disabilities should not have access to, or use, the Speech Case Mini device without parental or guardian supervision.



The Speech Case Mini device shall be used with care when moving around.

2.1 Avoiding Hearing Damage

Permanent hearing loss may occur if earphones, headphones or speakers are used at high volume. To prevent this, the volume should be set to a safe level. You can become desensitized over time to high sound levels which may then sound acceptable yet still could be damaging your hearing. If you experience symptoms such as ringing in your ears, please lower the volume or stop using the earphones/headphones. The louder the volume, the less time is required before your hearing could be affected.

Hearing experts suggest the following measures to protect your hearing:

- Limit the amount of time you use earphones or headphones at high volume.
- Avoid turning up the volume to block out noisy surroundings.
- Turn the volume down if you cannot hear people speaking near you.

To establish a safe volume level:

- Set your volume control at a low setting.
- Slowly increase the sound until you can hear it comfortably and clearly, without distortion.

2.2 Power Supply and Batteries



The power source shall conform to the requirement of the Safety Extra Low Voltage (SELV) standard, and supply power with rated voltage which conforms to Limited power Source requirement according to IEC60950-1.

The Speech Case Mini device contains a rechargeable battery. All rechargeable batteries degrade over time. Thus the possible usage times for the Speech Case Mini after a full charge can become shorter over time than when the device was new.



The Speech Case Mini device uses a Li-ion Polymer battery.

If you are in a hot environment, be aware that it can affect the ability to charge the battery. The internal temperature has to be between 0 °C/32 °F and 45 °C/113 °F for the battery to charge. If the internal battery temperature raises above 45 °C/113 °F, the battery will not charge at all.

Move the Speech Case Mini device to a cooler environment to let the battery charge properly.



Avoid exposing the Speech Case Mini device to fire or to temperatures above 60 $^{\circ}$ C/140 $^{\circ}$ F. These conditions may cause the battery to malfunction, generate heat, ignite or explode. Be aware that it is possible, in a worst case scenario, for temperatures to reach greater than those stated above in, for example, the trunk of a car on a hot day. So, storing the Speech Case Mini device, in a hot car trunk could conceivably lead to a malfunction.



Only charge the Speech Case Mini battery in an ambient temperature of 0 °C/32 °F to 45 °C/113 °F.



Use only the supplied power adapter to charge the Speech Case Mini device. Using unauthorized power adapters may severely damage the Speech Case Mini device.



For safe operation of the Speech Case Mini device, use only the charger and accessories approved by Tobii Dynavox.

Do not open, or modify, the casing of the Speech Case Mini device or of the power supply, since you may be exposed to potentially hazardous electrical voltage. The device contains no serviceable parts. If the Speech Case Mini device or its accessories are mechanically damaged, **do not use them**.



If the battery is not charged or the Speech Case Mini is not connected to the power supply, the Speech Case Mini device will shut down.



If the Power Supply Cord is damaged, it needs to be replaced by Service Personnel only. Do not use the Power Supply Cord until replaced.



Disconnect the AC power plug of the Power adapter from the wall socket when not charging the device and disconnect the power cable from the device.



Special regulations apply to shipping devices containing Li-ion Polymer batteries. If dropped, crushed, or shortcircuited, these batteries can release dangerous amounts of heat, may ignite, and may be dangerous in fires.





The Power adapter shall not be used without an adult or caregiver supervision.

2.3 Temperature



Due to use in direct sunshine or in any other hot environment, the Speech Case Mini device may have hot surfaces.

2.4 Emergency



<u>/!</u>\

Do not rely on the Speech Case Mini device for emergency calls. We recommend having multiple ways to communicate in emergency situations.

2.5 Electricity

Do not open the casing of the Speech Case Mini device, since you may be exposed to potentially hazardous electrical voltage. The device contains no user serviceable parts.

2.6 Child Safety

The Speech Case Mini is an advanced computer systems and electronic device. As such, they are composed of numerous separate, assembled parts. In the hands of a child certain of these parts have the possibility of being separated from the device, possibly constituting a choking hazard or another danger to the child.

Young children should not have access to, or the use of, the device without parental or guardian supervision.

2.7 Magnetic Field

If you suspect that the Speech Case Mini device is interfering with your pacemaker or any other medical device, stop using the Speech Case Mini device and consult your physician for specific information about that affected medical device.

2.8 Third Party

Any use of the Speech Case Mini outside the intended use and together with any third party software or hardware that changes the intended use is a risk and nothing that Tobii Dynavox can take any responsibility for.

3 Overview of the Speech Case Mini

3.1 Key Features

The Speech Case Mini has several built-in features.

- 2 × Internal speakers
- 1 × On/Off Selector
- 1 × Bluetooth® radio
- 1 × Charging port

3.2 Product Layout





Figure 3.1 Front and Top View

Position	Description
1	Volume rocker switch
2	Speakers
3	Foldable Leg
4	Lanyard Connection



Figure 3.2 Side Views

Position	Description	
5	Charging port	
6	Charging indicator light (Power LED)	
7	On/Off selector	
8	8 iPad Mini Charging port	
9	iPad Mini Power button	

(!)

Never force a connector into a port. If the connector and port do not join with reasonable ease, they probably do not match. Make sure that the connector matches the port and that you have positioned the connector correctly in relation to the port.

3.3 Pre-installed Firmware

The Speech Case Mini is delivered with all required firmware installed and ready to use.

4 Batteries in the Speech Case Mini

4.1 Batteries

The Speech Case Mini has one built-in battery. If the Speech Case Mini battery is not charged sufficiently, the Speech Case Mini will shut down automatically.



When the Speech Case Mini shuts down due to loss of battery charge, the Bluetooth[®] pairing is lost. When the Speech Case Mini is powered on again, re-establish Bluetooth[®] pairing as described in section *5.2 Install the iPad Mini and Pair through Bluetooth*[®].

4.2 Charging the Speech Case Mini

- 1. Connect the Power cable to the charging port on the Speech Case Mini and to the Power adapter.
 - Use the USB-A to USB-C charging cable to charge the Speech Case Mini. Position 4 in Figure 3.2 Side Views.
 - Use the USB-C to USB-C charging cable to charge the iPad Mini. Position 8 in Figure 3.2 Side Views.



Charge the Speech Case Mini and the iPad Mini through two (2) separate ports.

- 2. Connect the Power adapter to an electrical outlet.
- 3. Charge the Speech Case Mini until the battery is fully charged.
- 4. After the Speech Case Mini is fully charged, disconnect the charger from both the device and the electrical outlet.

You can't overcharge the battery. It is fine to charge the battery overnight.

You can use the Speech Case Mini while the battery is charging.



1

Because of internal chemical reactions, battery performance may deteriorate over time. In addition, failure to keep the conditions of use (charge, discharge, ambient temperature, etc.) within specified ranges may shorten the battery life expectancy, or damage your Speech Case Mini device. If the battery cannot maintain a charge for long periods of time, even when it is charged correctly, it may need to be replaced.

The battery may need to be replaced every 12 to 18 months with typical use. Don't try to replace the battery yourself. The battery is internal and is not intended for service or replacement by the user or anyone other than a Tobii Dynavox technician.

For battery storage and charging temperatures, see 2.2 Power Supply and Batteries, page 10.

4.2.1 Charging Indicator Light (Power LED) Behavior

The Charging indicator light (Power LED) (Position 5 in *Figure 3.2 Side Views*) will shine when the power adapter is plugged in and the battery is charging:

- Steady blue light on Charging in progress
- Blinking blue light Charging fault, can occur if battery has failed, or if attempting to charge.
- Light off Unit is fully charged

5 Using the Speech Case Mini

The Speech Case Mini has three modes:

- Touch mode Navigate apps using touch.
- Shipping mode turns off the Bluetooth® radio.
- Firmware upgrade mode use only if the user is directed to update the Speech Case Mini firmware.

5.1 Starting the Device

To start the Speech Case Mini in Touch mode



If you have paired this Speech Case with this iPad Mini previously, see 5.3 Unpair the Bluetooth® Connection, page 16.

When the On/Off Selector is moved from 0 (Off) to Touch (1), the unit will say "Power On" and after a few seconds, one (1) click will be heard.

- 1. Make sure the On/Off Selector is in position 1.
- 2. Follow the instructions in 5.2 Install the iPad Mini and Pair through Bluetooth®, page 16

To put the Speech Case Mini in Firmware Upgrade mode

- 1. Press and hold the Volume + button while moving the On/Off Selector from 0 to 1.
 - The Speech Case Mini is designed to remain powered on.

5.2 Install the iPad Mini and Pair through Bluetooth®

- 1. Follow the steps in the Tobii Dynavox Speech Case Mini Getting Started Guide to properly install the iPad Mini.
- On your iPad Mini device, go to Settings > Bluetooth and turn on Bluetooth[®]. Stay on this screen until you complete the remaining steps to pair your Speech Case Mini.
- 3. Make sure that the Speech Case Mini is in powered on as described in 5.1 Starting the Device.
- 4. Select the SC Mini in the My Devices or Other Devices list of the iPad Mini's Bluetooth[®] menu. The Speech Case Mini is now paired and ready to use.



The Speech Case Mini Bluetooth® ID ends with the same last 5 digits as the Speech Case Mini case serial number. The Speech Case serial number may be found on the label on the inside of the stand.

5.3 Unpair the Bluetooth® Connection

If you have paired this Speech Case Mini with this iPad Mini previously, you must first "forget" the Speech Case Mini in the Bluetooth® device list.

- 1. Go to Settings > Bluetooth.
- 2. Find the Speech Case Mini in the list.
- 3. Select the "i" icon next to it.
- 4. Select "Forget this Device."
- 5. Confirm by selecting "Forget Device."

5.4 Powering Down the Speech Case Mini

To put the Speech Case Mini in Shipping mode (Device will be turned OFF)

- 1. Hold down the iPad Mini Power button (pos. 7 in *Figure 3.2 Side Views, page 14*) and the Volume button (either one doesn't matter) (Pos 1 in *Figure 3.1 Front and Top View, page 13*) at the same time. The shutdown slider will appear on the iPad Mini screen.
- 2. Shut down the iPad Mini by using the shutdown slider.
- 3. Move the On/Off Selector to position 0.

5.5 Inserting the iPad to the Speech Case Mini

Do not over-tighten the screws.

- 1. Separate the Speech Case Mini front plate and body by pulling the two pieces apart.
- 2. Press the iPad Mini into the front plate, aligning the iPad Mini camera with the cutout in the plate.



3. Press the iPad/plate assembly into the Speech Case Mini body.



4. Squeeze around the edges to click it together.



- 5. Place the Speech Case Mini with the face down on a flat surface.
- 6. Tighten the top two Phillips screws.



7. Lift up the foldable leg and tighten two Phillips screws at the bottom.



5.6 Removing the iPad from the Speech Case Mini

- 1. Place the Speech Case Mini with the face down on a flat surface.
- 2. Lift up the foldable leg and loosen the two Phillips screws behind the leg



3. Loosen the two top Phillips screws.



4. Separate the Speech Case Mini front plate and body by pulling the two pieces apart.



5. Remove the iPad Mini.

5.7 Battery Status and Power Saving

The Speech Case Mini battery status is monitored through your paired iPad Mini . Follow the steps below to show the Batteries widget on your Today screen.

Add the Battery Status widget

- 1. On your iPad Mini, swipe right over the Home screen to get to the Today screen.
- 2. Scroll to the bottom and tap Edit.
- 3. Select the + (plus) sign in the upper left corner.
- 4. Locate Batteries in the list of widgets and tap + to add it to your Today screen.
- 5. Select Done.

You can now swipe right over the Home screen at any point to get to the Today screen and view the battery status of the Speech Case Mini (the Speech Case Mini must be paired).

The widget also shows the iPad Mini's charge.



The Speech Case Mini battery displays in 10% status increments. When the battery reaches 10%, the Speech Case Mini should be connected to a power source, otherwise it will power off soon.

The Power saving settings in the Speech Case Mini are preset to optimize the battery run-time. The Speech Case Mini is designed to remain powered on.

5.8 Adjusting the Volume

To adjust the volume, use the Volume Up and Down rocker (Position 1 in *Figure 3.1 Front and Top View*) on the top of the Speech Case Mini.



Volume adjustments can be done in TD Snap, TD Talk, or iPadOS software on the iPad Mini.

6 Product Care

6.1 Temperature & Humidity

6.1.1 General Use - Operating Temperature

The Speech Case Mini is best kept in dry conditions at room temperature. The recommended range for temperature and the humidity value for the device is as follows:

- Ambient temperature: 0°C to 35°C (32°F to 95°F)
- Relative humidity: 10% to 90% (no condensation on the device)

6.1.2 Transportation and Storage

For transportation and storage the recommended range for temperature and the humidity value for the device is as follows:

- Temperature: -30°C to 70°C (-22°F to 158°F)
- Humidity: 10% to 95% @40°C (104°F)(no condensation on the device)
- Atmospheric Pressure: 70 kPa to 106 kPa (375 mmHg to 795 mmHg)



The Speech Case Mini is not waterproof or water resistant. The device should not be kept in excessively humid, damp or otherwise wet conditions. Do not submerge the device in water or in any other liquid. Be careful not to allow liquids to be spilled upon the device, especially in the connector areas.

6.1.3 Charging

For charging, the recommended range for temperature and the humidity value for the device is as follows:

- Temperature: 10°C to 45°C (50°F to 113°F)
- Relative humidity: 5% to 90% (no condensation on the device)

6.2 Cleaning of the Speech Case Mini Device

- 1. Before cleaning, fully shut down your device.
- 2. Unplug your device.
- 3. Remove all cables.
- 4. Wipe over all external surfaces using 70 percent isopropyl alcohol wipe, 75 percent ethyl alcohol wipe, or Clorox Disinfecting Wipe for infection control.
- 5. Allow the device to dry naturally.
- 6. Any accessories included must also be disinfected in the same way.
- 7. If streaky residue remains from cleaning, buff screen with a soft dry cloth.
- 8. Dispose of used cleaning materials properly.



Do not use spray products directly on to the device as these may saturate the device and allow unwanted moisture into the unit.

6.3 Transporting the Speech Case Mini

Disconnect all the cables from the Speech Case Mini while carrying the device.



It is recommended to keep the original packaging materials for the Speech Case Mini.

If the device needs to be returned to Tobii Dynavox for Warranty-related issues or repair, it is beneficial that the original packaging or equivalent is used for shipping. Most shipping carriers require at least 2 inches of packing material around the device.

Note: Due to Joint Commission regulations, any shipping materials (including boxes) sent to Tobii Dynavox must be discarded.

6.4 Disposing of the Speech Case Mini Device

Do not dispose of the Speech Case Mini device in general household or office waste. Follow your local regulations for the disposal of electrical and electronic equipment.

6.5 Disposing of the Batteries

Do not dispose of the batteries in general household or office waste. Follow your local regulations for the disposal of batteries.

Appendix A Support, Warranty, Training Resources

A1 Customer Support

For support, please contact your local representative or Support at Tobii Dynavox. In order to receive assistance as quickly as possible, make sure you have access to your Speech Case Mini device and, if possible, an Internet connection. You should also be able to supply the serial number of the device, which you find on the back of the device.

For further product information and other support resources, please visit the Tobii Dynavox website <u>www.tobiidynavox.com</u>.

A2 Warranty

Please read the Manufacturer's Warranty paper included in the package.



Tobii Dynavox does not warrant that the Software on the Speech Case Mini will meet your requirements, that the operation of the software will be uninterrupted or error-free, or that all software errors will be corrected.



Tobii Dynavox does not warrant that the Speech Case Mini will meet Customer requirements, that the operation of the Speech Case Mini will be uninterrupted, or that the Speech Case Mini is free from bugs or other defects. Customer acknowledges that the Speech Case Mini will not function for all individuals and in all light conditions.

Please read this User's Manual carefully before using the device. The warranty is only valid if the device is used according to the User's Manual. Disassembling the Speech Case Mini device will void the warranty.



It is recommended to keep the original packaging materials for the Speech Case Mini.

If the device needs to be returned to Tobii Dynavox for Warranty-related issues or repair, it is beneficial that the original packaging or equivalent is used for shipping. Most shipping carriers require at least 2 inches of packing material around the device.

Note: Due to Joint Commission regulations, any shipping materials (including boxes) sent to Tobii Dynavox must be discarded.

A3 Training Resources

Tobii Dynavox offers a range of training resources for the Speech Case Mini products and related communication products. You can find them on <u>www.tobiidynavox.com</u> and <u>https://learn.tobiidynavox.com/</u>.

Appendix B Compliance Information



The Speech Case Mini is CE-marked, indicating compliance with the essential health and safety requirements set out in European Directives.

B1 FCC Statement

This device contains FCC ID: 2AAOV-SCTMI and complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.



Modifications not expressly approved by Tobii Dynavox could void the user's authority to operate the equipment under FCC rules.

B1.1 For Part 15B Equipment

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

B1.2 For Portable Devices

FCC RF Radiation Exposure Statement:

- 1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This
 device was tested for typical hand held operations with the device contacted directly to the human body to the sides
 of the device. To maintain compliance with FCC RF exposure compliance requirements, avoid direct contact to the
 transmitting antenna during transmitting.

B2 Industry Canada Statement

Caution

(i) The device for operation in the band 5150-5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems;

(ii) The maximum antenna gain permitted for devices in the bands 5250-5350 MHz and 5470-5725 MHz shall be such that the equipment still complies with the e.i.r.p. limit;

(iii) The maximum antenna gain permitted for devices in the band 5725-5850 MHz shall be such that the equipment still complies with the e.i.r.p. limits specified for point-to-point and non-point-to-point operation as appropriate; and
 (iv) Users should also be advised that high-power radars are allocated as primary users (i.e. priority users) of the bands 5250-5350 MHz and 5650-5850 MHz and that these radars could cause interference and/or damage to LE-LAN devices.

Avertissement

(i) les dispositifs fonctionnant dans la bande 5150-5250 MHz sont réservés uniquement pour une utilisation à l'intérieur afin de réduire les risques de brouillage préjudiciable aux systèmes de satellites mobiles utilisant les mêmes canaux;
(ii) le gain maximal d'antenne permis pour les dispositifs utilisant les bandes de 5250 à 5350 MHz et de 5470 à 5725 MHz doit être conforme à la limite de la p.i.r.e;

(iii) le gain maximal d'antenne permis (pour les dispositifs utilisant la bande de 5725 à 5850 MHz) doit être conforme à la limite de la p.i.r.e. spécifiée pour l'exploitation point à point et l'exploitation non point à point, selon le cas;
(iv) De plus, les utilisateurs devraient aussi être avisés que les utilisateurs de radars de haute puissance sont désignés utilisateurs principaux (c.-à-d., qu'ils ont la priorité) pour les bandes 5250-5350 MHz et 5650-5850 MHz et que ces radars pourraient causer du brouillage et/ou des dommages aux dispositifs LANEL.

This device contains IC ID: 5534A-SCTMI and has been tested to the safety requirements for exposure to radio waves (SAR) in RSS-102 to the General Public (Uncontrolled Environment) limits (1.6W/Kg).

This Class B digital apparatus complies with Canadian ICES-003.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

B3 CE Statement

This equipment complies with the requirements relating to electromagnetic compatibility, the essential protection requirement of Electromagnetic Compatibility (EMC) Directive 2014/30/EU on the approximation of the laws of the Member States relating to electromagnetic compatibility and Radio Equipment Directive (RED) 2014/53/EU to meet the regulation of the radio equipment and telecommunications terminal equipment.

B4 Directives and Standards

The Speech Case Mini complies with the following directives:

- Medical Device Regulation (MDR) 2017/745/EU
- Electromagnetic Compatibility (EMC) Directive 2014/30/EU
- Radio Equipment Directive (RED) 2014/53/EU
- RoHS2 Directive 2011/65/EU
- WEEE Directive 2012/19/EU
- Reach Directive 2006/121/EC, 1907/2006/EC Annex 17
- Batteries Directive 2013/56/EU
- IEC 62368-1
- ISO 60601-1

The device has been tested to comply with ISO 14971:2019 and other relevant standards for the intended markets.

Appendix C Guidance and Manufacturer's Declaration

C1 Electro Magnetic Compatibility (EMC) Information

This electrical medical equipment needs special precautions regarding EMC and must be put into service according to the EMC information provided in the user's manual. The equipment conforms to the IEC 60601-1-2:2014 standard for both immunity and emissions. Nevertheless, special precautions need to be observed.

The equipment with no ESSENTIAL PERFORMANCE/following ESSENTIAL PERFORMANCE is intended for use in a home healthcare environment.



Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this product, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



If the use location is near (e.g. less than 1.5 km from) AM, FM, or TV broadcast antennas, before using this equipment, it should be observed to verify that it is operating normally to assure that the equipment remains safe with regard to electromagnetic disturbances throughout the expected service life.

STATEMENT: For the purpose of its operation, the equipment has wireless communication function. It includes RF transmitter and receiver, 2.4GHz, pulse modulation.

Cable	Max. cable length	Shielded/unshielded	Number	Cable classification
AC Power cord	1m	unshielded	1 Set	AC Power
DC Power cord (USB Cable)	1m	shielded	1 Set	DC Power
DC Power cord (USB Cable)	1m	shielded	1 Set	DC Power

Table C.1 Cable information for EMC reference.

Table C.2 EMI Compliance Table - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11	Home healthcare environment
	Group 1, Class B	
Harmonic distortion	IEC 61000-3-2	Home healthcare environment
	Class A	
Voltage fluctuations	IEC 61000-3-3	Home healthcare environment
and flicker	Compliance	

Table C.3 EMS Compliance Table — Enclosure Port

Phenomenon	Basic EMC	Immunity test levels
	standard	Home healthcare environment
Electrostatic	IEC 61000-4-2	±8 kV contact
Discharge		±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	10V/m
		80MHz-2.7GHz
		80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to Table C.4 EMS Compliance Table — Proximity fields from RF wireless communications equipment
Rated power frequency	IEC 61000-4-8	30A/m
magnetic fields		50Hz or 60Hz

Table C.4 EMS Compliance Table — Proximity fields from RF wireless communications equipment

Test	Band	Immunity test levels
frequency	(MHz)	Home healthcare environment
(MHz)		
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Table C.5 EMS Compliance Table — Input AC Power Port

Phenomenon	Basic EMC standard	Immunity test levels Home healthcare environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100kHz repetition frequency
Surges	IEC 61000-4-5	±0.5 kV, ±1 kV
Line-to-line		

Phenomenon	Basic EMC standard	Immunity test levels
		Home healthcare environment
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands and amateur radio bands between 0.15MHz and 80MHz
		80%AM at 1kHz
Voltage dips	IEC 61000-4- 11	0% U _T ; 0.5 cycle
		At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U _T ; 1 cycle
		and
		70% U _T ; 25/30 cycles
		Single phase: at 0°
Voltage interruptions	IEC 61000-4- 11	0% U _{T;} 250/300 cycles

Table C.6 EMS Compliance Table — Signal input/output parts port

Phenomenon	Basic EMC standard	Immunity test levels
		Home healthcare environment
Conducted	IEC 61000-4-6	3V, 0.15MHz-80MHz
disturbances induced by RF fields		6V in ISM bands and amateur radio bands between 0.15MHz and 80MHz
		80%AM at 1kHz

Appendix D Technical Specifications

D1 Speech Case Mini

Standard	Speech Case Mini	
Туре	Speech accessory for 8.3" iPad Mini	
Model	Speech Case Mini	
Dimensions (WxHxD)	215 × 170 × 50 mm	
	8.5 × 6.7 × 2.0 inches	
Weight	624 g	
	1 lb 6 oz	
Speakers	2 × 31 mm × 9 mm, 4.0 ohms, 5 W	
Connectors	1 × USB-C	
Buttons	1 × Volume Up	
	1 × Volume Down	
	1 × 2 Position Selector	
Bluetooth®	Bluetooth® 3.0	
Battery Run Time	~ 8 hours normal usage	
Battery Technology	Li-ion Polymer rechargeable battery	
Battery Capacity	15.54 Wh	
Battery Charge Time	~ 4 hours	
Power Supply	5.0 VDC 4.8A AC adapter	
IP class	IP22	
	Valid only for the Speech Case Mini	

D2 Power Adapter

Item	Specification
Model	HM2072
Input voltage	100 to 240 VAC
Input current (max)	2.0 A
Input frequency	50 to 60 Hz
	USB-A: 5VDC, 2.4A, 12W
DC Output	USB-C: 5VDC, 3.0A, 15W or 9.0VDC, 3A, 27W or 12VDC, 3A, 36W or 15VDC, 3A, 45W or 20VDC, 3A, 60W

Appendix E Approved Accessories

For information about the latest approved accessories for the Speech Case Mini, please visit <u>www.TobiiDynavox.com</u> or contact your local Tobii Dynavox reseller.

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Contact Your Solution Consultant or Reseller For questions or problems with your product, contact your Tobii Dynavox solution consultant or authorized reseller for assistance. They are most familiar with your personal setup and can best help you with tips and product training. For contact details, visit <u>www.TobiiDynavox.com/contact</u>