

Safety and Compliance

Talk Pad

For devices:

TP10E
TP10H
TP10E-CASE
TP10H-CASE

TP08E
TP08E-CASE

TS10E
TS10H

TS08E

Smartbox

Communication is life

This device is manufactured by Smartbox Assistive Technology Ltd.

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1. Cleaning, decontaminating, and storing your device

Cleaning and decontaminating your device

- Before cleaning shut down your device and unplug the charger.
- Remove any cables that are connected to the device.
- Using a damp cloth or alcohol wipe, clean all the external surfaces.
- Allow the device to dry.
- Repeat the process for any accessories you may use with the device.
- Once dry, the screen can also be cleaned using a microfibre cloth.
- Tough dirt and residue can be removed using a toothbrush or similar.

Do not use spray cleaning fluid, gel, or polish directly onto your device, or immerse the device in water.

Storing your device

When not in use, your device should be stored safely. Do not rest or press hard objects against the screen. Disconnect any devices plugged into the ports of the device, including USB ports, switch ports and the power lead.

2. Device specification

This device is a communication aid designed for people with disabilities who cannot speak or have complex access needs.

Model

Standard

Device	Talk Pad 8	Talk Pad 10	Talk Pad 10
Model	TP08E	TP10E	TP10H

Slim

Device	Talk Pad 8	Talk Pad 10	Talk Pad 10
Model	TS08E	TS10E	TS10H

Case

Device	Talk Pad 8 Case	Talk Pad 10 Case	Talk Pad 10 Case
Model	TP08E-CASE	TP10E-CASE	TP10H-CASE





















Operating environment

Temperature	0 - 35 °C
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Storage and transport environment

Temperature	-20 °C - 45 °C
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3. Symbol explanation

Symbol	Meaning
	Headphone port
	Charging port 1
	Charging port 2
	Connect button
S1	Switch port 1
S2	Switch port 2
	Conformity European symbol to declare conformity with EU legislation.
	Federal communications commission symbol to declare conformity with US legislation.
	Waste electrical and electronic equipment symbol to indicate you should dispose of this equipment in accordance with local regulations.
	Power button symbol
	Increase volume symbol
	Decrease volume symbol
	Read the manual symbol
IP22	Ingress protection rating 22
	UK Conformity Assessed symbol to declare conformity in the UK
	Unique device identifier
	Medical device
	EU Authorised Representative
	Swiss authorised representative
	Model number
	Serial number
	Min / Max storage and transport temperature
	Mix / Max storage and transport humidity

4. Safety notices

Talk Pad is a class 1 medical device. Specifications and standards have been listed in the Compliance section of this manual.

Please consider these safety warnings to ensure safe operation of your device.

Application

Intended Use

It is used to generate synthesized speech.

Intended User

It is designed for individuals with complex communication and/or access needs. Complex communication and/or access difficulties may arise as a result of a variety of conditions including but not limited to:

Developmental disorders, e.g. cerebral palsy, developmental verbal dyspraxia, autistic spectrum disorder (ASD), developmental language disorder (DLD), global delay. Acquired disorders, e.g. cardiovascular accident (CVA/ stroke), dementia, traumatic/acquired brain injury (TBI/ABI)

It may also be used by individuals with complex access requirements in the absence of communication difficulties for computer control, environmental control and non-face-to-face communication e.g. including but not limited to

individuals with:

- Spinal cord injury
- Degenerative neuromuscular disease (e.g. muscular dystrophy, spinal muscular atrophy)

Intended environment

It can be used in a variety of settings in which the individual is likely to wish to utilise it for the above intended use. These settings may include but are not limited to:

- private homes
- supported living homes
- nursing care facilities
- schools, colleges, universities
- in the community, e.g. shops, restaurants

Significant contra-indications, warnings and precautions

Although designed to assist with expressive communication, it should be used in combination with a range of augmentative and alternative communication (AAC) methods and therefore should not be relied on in isolation to enable an individual to communicate expressively.

Other methods of AAC may include the use of paper-based systems, sign language or the use of eye pointing frames. Despite this, it is recognised that individuals with signification communication and/or access difficulties will rely heavily on

a VOCA (Voice Output Communication Aid), in this instance Talk Pad, to communicate given the significant enhancement to expressive communication that a VOCA often brings.

Although designed and manufactured to be extremely robust and reliable, it is possible to lose function due to power loss or other technical issues. For this reason, it should not;

- be used as a life supporting device.
- be relied upon for well-being.
- be relied upon as the user's only way of making an emergency call or alarm.
- be used to administer medicine.
- be relied upon as the only method of interaction with EC devices.

It is also not intended to provide information which is used to take decisions with diagnosis or therapeutic purposes.

When the device is working with other equipment, there may be inference between device and connecting equipment. For this reason, This device should not be used:

- in an MRI environment.
- in an X-ray environment
- in a military environment.
- in a harsh RF environment.

Avoiding hearing damage

Using headphones and speakers at high volume can cause permanent hearing loss. Always keep the volume of your device at a safe level.

Durability

Your device is tough and rugged but must be handled with care when moving around. It has been drop tested to one metre. Please note this does not include accessories.

Water and liquids

Do not get water or liquids on the device, especially in the ports or vents.

Incidents

If a serious incident occurs in relation to the device, please report to Smartbox (repairs@thinksmartbox.com) and the competent authority of your member state.

Contact with user

Touching the surface of the device with broken skin may aggravate a wound.

Infants or high-risk groups should not touch the surface of the device if there is a chance of burning the skin.

Power supply and batteries

Your device contains a rechargeable lithium-ion battery. All rechargeable batteries degrade over time. The usage time for your device after a full charge can become shorter over time.

For optimal performance your device should not be charged at extreme temperatures of below 0°C or above 45°C. At these temperatures your battery will charge slowly or not at all.

Do not expose your device to fire or temperatures above 90°C as these conditions can cause the battery to malfunction, ignite or explode.

Only charge your device with the supplied power lead. Using unofficial power supplies may cause severe damage to your device and cause fire. If your device's power lead is lost or damaged, contact your supplier.

When your device's battery is depleted, and the device is not connected to a power source, the device will automatically shut down to avoid damaging the battery and hardware. The operating system will attempt to do this as safely as possible, however it is recommended to attach the power lead before your device shuts down.

The battery that powers your device is subject to shipping

regulations. Check with your postal service or courier before shipping to ensure safe delivery of your device.

Do not place your device in a place where the power adapter plug is difficult to disconnect from the socket.

Only our authorized personnel be allowed to replace the battery. Otherwise, personal injury or equipment damage could occur.

Do not service or perform maintenance on the device while the device is in operation. Make sure to shut the device down and unplug all cables before starting and service or maintenance work on the device.

Transporting your device

When in transit, ensure your device is sufficiently protected from knocks and bumps.

There are strict regulations for lithium-ion batteries on airplanes. Rules vary between airlines, so it is recommended to contact your airline before you travel.

Temperature

Ensure that you shut down your device before storing or placing into a bag.

If used in hot temperatures or direct sunlight, your device

may reach temperatures that can trigger an automatic shutdown. This is a safety feature to prevent lasting damage to the device. If this occurs, please wait until your device has cooled before restarting.

Mounting

When mounting your device, follow the instructions in both your device and your mounting system manufacturer's guide. While we have taken every precaution to make this an easy and safe process, it is up to you to ensure the device is mounted safely.

Please use a mounting solution designed for your Talk Pad (sold separately). Ensure the mounting system you select is correct for your needs and perform a risk analysis if required.

Ports & Connections

Accessories connected to ports for a SIGNAL INPUT/OUTPUT must be compliant to the IEC standard 60601-1 or 62368-1.

Damage to the device

If damaged, small parts may detach from your device. These can present a choking hazard. Young children and people with cognitive disabilities should be supervised when using the device. They should also be supervised when unpacking the device as packaging can present a choking hazard.

In extreme circumstances, damage to the front screen of the device can result in sharp edges. In these circumstances the device should not be used.

Not sterile

Your device is not sterile. Do not operate with open wounds, or whilst undergoing invasive medical treatments.

Epilepsy warning

Some people with photosensitive epilepsy are susceptible to seizures when exposed to certain lights or light patterns. If you feel odd or nauseous when in front of your device, move away from the device and consult a medical professional.

Warranty

Standard and Slim models:

Your device is covered under the standard 3 year warranty from the time of purchase.

Case:

Your device is covered under the standard 1 year warranty from the time of purchase.

Repairs and Maintenance

Your device is not a user serviceable device. If your device requires a repair, please contact your local dealer.

Medical Device Interference

The iPad contains magnets that may interfere with medical devices. Consult your doctor and medical device manufacturer for information specific to your medical device and whether you need to maintain a safe distance of separation between your medical device and this device or any of its accessories. If you suspect this device is interfering with your medical device, stop using your device.

Risk of Strangulation

Your device is supplied with a strap. If there is risk the user may be strangled by the strap, do not use the strap.

Your device is supplied with a power cable and can be used with cabled accessories. These can present a strangulation hazard.

Troubleshooting and Customer Support

Contact support at:

hub.thinksmartbox.com

Please have your serial number ready. This can be found under the stand on your device.

Refurbishment

If the device needs repairs before it is re-used, please contact your local dealer.

Before reuse of the device, ensure the cleaning and decontamination procedure has been carried out.

You may also need to remove any personal data from the device. For support and advice, please contact Smartbox.

Incidents

If a serious incident occurs in relation to the device, please report to Smartbox (repairs@thinksmartbox.com) and the competent authority of your member state.

Accessories

Device is compatible with a number of accessories that can be combined together to adjust its function as a VOCA. For information on compatible accessories that are currently available visit:

hub.thinksmartbox.com/talkpad-2nd-gen

Disposal

Please dispose of in line with your regions local electronic waste regulations.

Data security

The device incorporates electronic programmable systems and software.

For the best performance we recommend keeping the operating system and supplied software updated with the latest security fixes and features.

Ensure that passwords and pass codes are kept securely to prevent unauthorised access.

The device has features that require an internet connection. Access to these services can be restricted as part of the setup of the device or through network administration.

4. EU / CE statement

Hereby, Smartbox Assistive Technology Ltd. declares that this product complies with 2017/745 EU Regulation on Medical Devices, 2014/53/EU RED, 2011/65/EU RoHS and (EU) 2015/863.

The full text of the EU declaration of conformity is available here:

hub.thinksmartbox.com/talkpad-2nd-gen

Applicable standards

ISO 14971:2019 Application of risk management to medical devices has been applied to Talk Pad.



This product and - if applicable - the supplied accessories too are marked with "CE" and comply therefore with the applicable harmonized European standards listed under the EMC Directive 2014/30/EU, the LVD Directive 2014/35/EU, the RoHS Directive 2011/65/EU, Wi-Fi device: the RE Directive 2014/53/EU.



This product and - if applicable - the supplied accessories too are marked with "UKCA" and comply therefore with the following directives: Electromagnetic Compatibility Regulations 2016, Electrical Equipment (Safety) Regulations 2016, the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012, Wi-Fi device: Radio Equipment Regulations 2017.



Directive 2012/19/EU (WEEE Directive): Products marked with this symbol cannot be disposed of as unsorted municipal waste in the European Union. For proper recycling, return this product to your local supplier upon the purchase of equivalent new equipment, or dispose of it at designated collection points. For more information see: www.recyclethis.info.

According to the Waste Electrical and Electronic Equipment Regulations 2013: Products marked with this symbol cannot be disposed of as unsorted municipal waste in the United Kingdom. For proper recycling, return this product to your local supplier upon the purchase of equivalent new equipment, or dispose of it at designated collection points. For more information see: www.recyclethis.info.

The following standards have been applied to the Talk Pad range:

Component	Smartbox Case (BB9A)	8.3" iPad (Apple A2567)	10.2" iPad (Apple A2200, A2198, A2199)	10.9" iPad (Apple A2602)
Legislation	2014/53/EC RED 2011/65/EU RoHS 2012/19/EU WEEE	2014/53/EU RED 2011/65/EU RoHS as amended by 2015/863/EU 2009/125/EC ECO	2009/125/EC ECO 2014/53/EU RED 2011/65/EU RoHS	2014/53/EU RED 2011/65/EU RoHS as amended by 2015/863/ EU 2009/125/EC ECO
Safety Article	EN 62368-1:2014/ A11:2017	EN 50566:2017 IEC 62368-1: 2018 [2020+A11:2020] EN 50665:2017	EN 60950-1:2006+A1: 2010+A11:2009+A12:2 011+A2:2013 EN 50566:2017	EN 50566:2017 IEC 62368-1: 2018 [2020+A11:2020]
RF and EMC Standards	EN 55032:2015 EN 61000-3-2:2014 EN 61000-3-3:2013 EN 61000-4-2:2009 EN 61000-4-3:2006 A1:2008 A2:2010 EN 61000-4-4:2012 EN 61000-4-5:2014 A1:2017 EN 61000-4-6:2014 EN 61000-4-11:2004 IEC 61000-4-2:2008 IEC 61000-4-3:2006 A1:2007 A2:2010 IEC 61000-4-4:2012 IEC 61000-4-5:2005 IEC 61000-4-6:2008 IEC 61000-4-8:2009 IEC 61000-4-11:2004 ETSI EN 300 328 V2.2.2 EN IEC 62311:2020 EN 300 328 V2.1.1	EN 301 489-1 V2.2.3 EN 301 489-3 V2.1.2 [DRAFT] EN 301 489-17 V3.2.4 EN 55035:2017 EN 300 328 V2.2.2 EN 301 893 V2.1.1 EN 300 440 V2.1.1 EN 300 330 V2.1.1	EN 301 489-1 V2.2.0 EN 301 489-17 V3.2.0 EN 301 489-19 V2.1.1 EN 301 489-52 V1.1.0 EN 301 511 V12.5.1 EN 301 908-1 V11.1.1 EN 301 908-2 V11.1.2 EN 301 908-13 V13.1.1_11.1.9 EN 300 328 V2.1.1 / V2.2.1 EN 300 440 V2.1.1 / V2.2.1 EN 303 413 V1.1.1	EN 301 489-1 V2.2.3 EN 301 489-17 V3.2.4 EN 55035:2017 EN 300 328 V2.2.2 EN 301 893 V2.1.1 EN 300 440 V2.1.1
Other Standards	RoHS: EN IEC 63000:2018	RoHS: EN IEC 63000:2018 Energy: Regulation 1275/2008	RoHS EN 50581:2012	RoHS: EN IEC 63000:2018 Energy: Regulation 1275/2008

5. FCC and ISED Canada Compliance

FCC Statement

Contains: FCC ID: XCO-QCC3031

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference.
- (2) This device must accept any interference received, including interference that may cause undesired operation.

NOTE: 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

NOTE: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.

RF Exposure

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance of 0 cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

ISED Canada Compliance

For use in Canada

Contains: IC: 7756A-QCC3031

This device complies with CAN ICES-003 (B)/NMB-003(B). This device contains licence-exempt transmitter(s)/ receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

- (1) This device may not cause interference.
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil est conforme à la norme CAN ICES-003 (B)/NMB-003 (B).

Cet appareil contient des émetteurs / récepteurs exempt (s) de licence qui sont conformes aux RSS exemptes de licence d'Innovation, Sciences et Développement économique Canada. Son fonctionnement est soumis aux deux conditions suivantes:

- (1) Cet appareil ne doit pas provoquer d'interférences.
- (2) Cet appareil doit accepter toute interférence, y compris les interférences susceptibles de provoquer un fonctionnement indésirable de l'appareil.

RF Exposure

This equipment complies with IC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance of 0 cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Cet équipement est conforme aux limites d'exposition aux rayonnements de la IC établies pour un environnement non contrôlé. Cet équipement doit être installé et fonctionner à au moins 0 cm de distance d'un radiateur ou de votre corps.

6. PSU

PD45W Wall Charger

Model No: S-TR-182D

Model: 34-0-000516S

Specifications

Input:

100V-240V, 50/60Hz, 1.2A Max

Type-C1/Type-C2 Output:

5.0V 3A, 9.0V 3A, 12.0V 3A, 15.0V 3A, 20.0V 2.25A, 45W

Type-C1/Type-C2 Output:

25.0W+20.0W

Total output:

45.0W Max

Working temperature

Max: 35°C

Size: 80x43.85x31mm

Average active efficiency: 85.92%

No-load power consumption (W): 0.254W

Safety information

WARNING: Failure to follow these instructions could result in fire, electric shock, injury, or damage to the user, product, or other property.

1. Connect the product into a power outlet that is close by and is easy to disconnect from the source.
2. Use indoors and in a dry location; avoid charging near sources of heat and humidity.
3. Keep the product away from any liquids or moisture.
4. Unplug the product from the AC socket when not in use.
5. Do not store your device in very hot or very cold locations. It is recommended to use your device at room temperature.
6. Do not use if visible defects are observed on the product.
7. Do not disassemble or remodel the product in any way.
8. Be mindful of using the PSU in places where children are likely to be present.



Talk Pad - Safety - UK - B