Grid Pad 13
Safety and Compliance

Document:	Grid Pad 13 - Safety - UK – A
Device:	GP13A
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Cleaning, storing and decontamination

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 Grid Pad, or immerse the device in water.

Storing your Grid Pad

When not in use, your Grid Pad should be stored safely.

Do not rest or press hard objects against the screen. Disconnect any devices plugged into the ports of the Grid Pad, including USB ports, switch ports and the power lead.

Storing the remote power button

When packing away your Grid Pad, we recommend removing the AAA batteries from the remote power button and disconnecting any switches.

Technical specification

Model number: GP13A

Operating environment

Temperature	0 – 35
Relative humidity	0 – 90%
Atmospheric pressure	70 kPa to 106 kPa

Storage and transport environment

Temperature	-20°C - 60°C
Relative humidity	0 – 90%
Atmospheric pressure	<50 kPa to 106 kPa>

Safety classification

Protection against electrical shock	Class II and internally powered
Mode of operation	Continuous

Symbol explanation

Model number: GP13A

Symbol	Meaning
TBC	Headphone port
TBC	Charging port and indicator
TBC	Switch port 1
TBC	Switch port 2
TBC	Switch port 3
TBC	Switch port 4
TBC	Conformity European symbol to declare conformity with EU legislation.
TBC	Federal communications commission symbol to declare conformity with US legislation.
TBC	Waste electrical and electronic equipment symbol to indicate you should dispose of this equipment in accordance with local regulations.
TBC	Power button symbol
TBC	Increase volume symbol
TBC	Decrease volume symbol
TBC	Read the manual symbol
TBC	Read the manual symbol
TBC	Ingress protection rating XX
TBC	UK Conformity Assessed symbol to declare conformity in the UK
TBC	Unique device identifier
TBC	Medical device
TBC	EU Authorised Representative
TBC	Swiss Authorised Representative
TBC	Model number
TBC	Serial number
TBC	Min / Max storage and transport temperature
TBC	Min / Max storage and transport humidity

Intended use, user and environment

Model number: GP13A

Grid Pad 13 has been tested as 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 Grid Pad.

Application

Intended Use

- It is used as a voice output communication aid (VOCA)
- It is used to control a Windows computer
- It is used to operate external devices via environmental control (EC)

Intended User

It is designed for individuals with complex communication and/ or access needs. Complex communication and/or access needs 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 needs 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:
• supported living homes
• nursing care facilities
• schools, colleges, universities
• in the community, e.g. shops, restaurants
• hospitals (acute, rehabilitation and community)

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 (in this instance Grid 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 interference. For this reason, Grid Pad should not be used:

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

Accessories

Grid Pad 13 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/gridpad10s>

Safety warnings

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 Grid Pad 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

Your device is protected from splashing water and light rain.

Do not submerge the device in water. When the port covers are removed, the USB ports are not protected.

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

Contact with user

Type of applied part	B
Applied part	Screen, enclosure

Conditions for Safe Contact – Time

Accessible part	Contact time limit
Metal accessible part	Less than 1 minute
Plastic accessible part	Less than 10 minutes
Screen	Less than 10 minutes

Conditions for Safe Contact – Temperature

Accessible part	Maximum Temperature while Device is in use (ambient temperature 35°C)
Metal accessible part	50.1
Plastic accessible part	46.1
Screen	44.9

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.

Do not leave the device on the users lap or body if they cannot remove it.

Power supply and batteries

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

For optimal performance your Grid Pad 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 Grid Pad to fire or temperatures above 90°C as these conditions can cause the battery to malfunction, ignite or explode.

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

When your Grid Pad’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 connect the power lead before your Grid Pad shuts down.

The battery that powers your Grid Pad 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.

To avoid personal injury or equipment damage, only our authorised personnel are permitted to replace a Grid Pad battery.

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 service or maintenance work on the device.

Transporting your Grid Pad

When in transit, ensure your Grid Pad 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 Grid Pad 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 Grid Pad, follow the instructions in both your Grid Pad 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 the dual Daessy and Rehadapt mounting solution provided. 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 609501/62368-1.

Choking hazard

If damaged, small parts may detach from your Grid Pad. 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.

Not sterile

Grid Pad is not sterile. Do not operate with open wounds, or whilst undergoing invasive medical treatments. Strangulation hazard Grid Pad is supplied with a power cable and can be used with cabled accessories. These can present a strangulation hazard.

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 Grid Pad, particularly if you are using it

with an eye gaze camera, move away from the device and consult a medical professional.

Warranty

Your Grid Pad is covered under the standard <X> year warranty from the time of purchase.

Repairs and Maintenance

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

Smartbox will provide information such as circuit diagrams and component lists to maintenance personnel when necessary.

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.

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.

Disposal

Please dispose of in line with local electronic waste regulations.

Refurbishment

If the device is in need of 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.

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.

Battery warnings

Do not dismantle, open or shred the battery.

Do not expose the batteries to heat or fire, and avoid storage in direct sunlight.

Do not short-circuit the battery.

Do not store the battery haphazardly in a box or drawer where it may be short-circuited by other metal objects.

Do not subject the battery to mechanical shock.

In the event of a battery leaking, do not allow the liquid to come in to contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.

The charger is an important part of the equipment, do not use any charger other than that specifically (Model: XXXXXX) provided for use with the equipment, and refer to the manufacturer’s instructions or equipment manual for charging instruction.

Do not use any other battery with the equipment unless approved by Smartbox.

Battery usage by children should be supervised.

Keep the battery clean and dry.

Do not leave a battery on prolonged charge when not in use.

After extended periods of storage, it may be necessary to charge and discharge the battery several times to obtain maximum performance.

Retain the original product literature for future reference.

Only use the battery in the application for which it was intended.

Dispose of the battery according to local regulations.

Statement of compliance

Requirements in UK
5150MHz~5350MHz is for indoor use only.

SAR is measured with the device at 0 mm to the body, while transmitting at the highest certified output power level in all frequency bands of the device. The maximum SAR value is 0.324W/kg (body) averaged over 10 gram of tissue. This equipment should be installed and operated with a minimum distance of 0 cm between the radiator and your body.

EU / CE Statement

Hereby, Smartbox Assistive Technology Ltd. declares that this radio equipment complies with Directive 2014/53/EU. The frequencies used by the wireless networking feature of this product are the 2.4 GHz range.

The full text of the EU declaration of conformity is available here:
<thinksmartbox.com/GP10s-DOC >

Applicable Legislation

This equipment complies with the requirements of:
• EU harmonised legislation
• Medical Device Regulation (EU) 2017/745 (including EMC Directive 2014/30/EU and LVD Directive 2014/35/EU)
• RoHS Directive 2011/65/EU
• WEEE Directives 2012/19/EU

Harmonised Standards
EN 60601-1:2006/A1:2013

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

EN 60601-1-2:2015
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

EN ISO 14971:2012
Medical devices - Application of risk management to medical devices

EN 61000-3-3:2013
Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection

EN 50581:2012
Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.

FCC Statement

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

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, and
(2) this device must accept any interference received, including interference that may cause undesired operation.
For use in North America

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.

RF warning for Portable device:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End user must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The mobile device is designed to meet the requirements for exposure to radio waves established by the Federal Communications Commission

(USA). These requirements set a SAR limit of 1.60W/kg averaged over one gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the body is 0.826 W/ kg.

For body operation, this device has been tested and meets FCC RF exposure guidelines when used with any accessory that contains no metal and that positions a minimum of 0mm from the body. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

For use in Canada

Industry Canada Class B Emissions Compliance Statement This Class B digital apparatus complies with Canadian ICES003.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotopically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This device complies with Industry Canada licence-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.

Conformément à la réglementation d’Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d’un type et d’un gain maximal (ou inférieur) approuvé pour l’émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l’intention des autres utilisateurs, il faut choisir le type d’antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l’intensité nécessaire à l’établissement d’une communication satisfaisante.

Le présent appareil est conforme aux CNR d’Industrie Canada applicables aux appareils radio exempts de licence. L’exploitation est autorisée aux deux conditions suivantes : (1) l’appareil ne doit pas produire de brouillage, et (2) l’utilisateur de l’appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d’en compromettre le fonctionnement.

The device is designed to meet the requirements for exposure to radio waves established by the Innovation, Science and Economic Development Canada’s. These requirements set a SAR limit of 1.60W/kg averaged over

one gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the body is 0.826 W/ kg.

Le dispositif est conçu pour répondre aux exigences de l’exposition aux ondes radio créée par la science et l’innovation, développement économique Canada. Ces exigences limite de sar de 1.60W/kg en moyenne pour un gramme de tissu. La valeur de r - s en vertu de cette norme plus élevée au cours de la certification de produits déclarés pour une utilisation bien portés sur le corps est 0.826 W/kg.

EMC Declarations

TBC