



AeroSwitch[®]

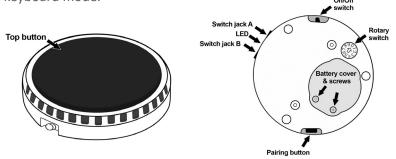
A Universal Bluetooth[®] Switch



18660 Version 1.03

AEROSWITCH

The AeroSwitch[®] is a wireless switch that can be used to control electronic speech generating devices. It has two ports that allow for the connection of wired switches (mono or dual). A rotary dial allows you to set up options for sending in broadcast mode or keyboard mode.



TURNING THE AEROSWITCH ON

Slide the power switch to the on position*. The blue LED will flash to indicate the remaining battery charge. You may need to wait a few seconds before the LED begins to flash.

NUMBER OF FLASHES	REMAINING BATTERY CHARGE	
4 flashes	76% - 100%	
3 flashes	50% - 75%	
2 flashes	25% - 49%	
1 flash	Less than 25%*	
1 very short flash	Less than 10%*	
*Consider getting a replacement battery		

*To turn the AeroSwitch on, slide the power switch to I. To turn the AeroSwitch off, slide the power switch to O.

DECIDING ON BROADCAST MODE OR KEYBOARD MODE

The AeroSwitch has two connection options: Broadcast mode and keyboard mode. The switch ships in broadcast mode. There are two deciding factors that determine if Broadcast or Keyboard mode is used.

- If you are scanning inside and out of the app or just within the app
- Which device you are using

Not all devices are compatible with Broadcast mode. See the chart in the next section, "Setting the Switch Mode".

BROADCAST MODE	KEYBOARD MODE
Limited to scanning WITHIN the communication software (Empower [®] , NuVoice [®] , Chat software, TouchChat [®] , LAMP Words for Life [®] , or Dialogue [®] AAC)	Able to run scanning both WITHIN and OUTSIDE the communication software

BROADCAST MODE	KEYBOARD MODE
Longer battery life (1-3 years, depending on use)	Shorter battery life (2-3 months, depending on use)—replace with rechargeable batteries
If you have a choice between broadcast and keyboard mode AND want to stay strictly within the communication software, this is the better option.	If you have a device that's not compatible with broadcast mode AND/OR want to use the switch outside the communication software, this is the better option.

SETTING THE SWITCH MODE

Set the AeroSwitch rotary dial to broadcast mode or keyboard mode using the following guidelines.

DEVICE	BROADCAST	KEYBOARD
Accent [®] 800-40	 ✓ 	V
Accent 1000-40	 ✓ 	V
Accent 1400-30	 ✓ 	V
NovaChat [®] 5 · 4 th generation		 ✓
NovaChat 8 · 5 th generation	 ✓ 	V
NovaChat 10 · 7 th generation	 ✓ 	V
Via [®] Pro	 ✓ 	 ✓
Via Mini	V	V

DEVICE	BROADCAST	KEYBOARD
Other devices with Bluetooth®		\checkmark
4.1 and higher		

For information on older PRC-Saltillo devices, please go to **prc-saltillo.com/co-branded-products** and select the AeroSwitch User's Guide link under AeroSwitch.

USING THE ROTARY DIAL

Use the 10-position rotary dial on the bottom of the AeroSwitch to change the switch mode. A small screwdriver is included to adjust the rotary dial.

If a keyboard mode is selected, the switch essentially sends that specified keystroke (for example, "one" or "enter") to the communication device.



0-Broadcast	5-Keyboard = One
1-Broadcast	6-Keyboard = Two
2-Broadcast	7-Keyboard = Tab
3-Keyboard = Space	8-Keyboard = Left-click
4-Keyboard = Enter	9-Keyboard = Right-click

Important! After you change the switch mode, turn the AeroSwitch off and back on.

If you are using multiple AeroSwitches in a common area:

Make sure they are set to different modes to ensure there is no interference. For example, John and Doug are in the same classroom. John could be using an Accent 1400-30 in Broadcast mode 0 and Doug could be using a NovaChat 10.7 in Broadcast mode 1.

SETTING UP AN ACCENT DEVICE IN BROADCAST MODE

- 1. Ensure the AeroSwitch is turned off
- 2. Set the rotary dial to broadcast mode 0
- 3. Turn the AeroSwitch on
- 4. If your Accent device is running NuVoice software:
 - Go to the Toolbox and select Access Method Menu
 - If switch scanning is not already selected, select Choose Different Access Method, select 1 Switch or 2 Switch, and select a specific switch scanning method
 - From the Access Method Menu, select Connect AeroSwitch
- 5. If your Accent device is running Empower software:
 - Select Menu > Toolbox > System Settings > Devices & Connections
 - Select the Switches tab
 - Select the Connect Switch **Connect** button; a message will prompt you to press the switch to pair it
- 6. Within 10 seconds: Press and release the AeroSwitch top button
- 7. To connect a second AeroSwitch, set its rotary dial to broadcast mode 1 and repeat steps 3 through 6
- 8. Select OK twice (NuVoice) or Close (Empower)

Note: To set up switch scanning, download the NuVoice Software Manual or the Accent User's Guide available from **prentrom.com/support.**

SETTING UP AN ACCENT DEVICE IN KEYBOARD MODE

- 1. Ensure the AeroSwitch is turned off
- 2. Set the rotary dial to the keyboard mode you'd like to use and turn the AeroSwitch on
- 3. On the device, open the Bluetooth settings in Windows
- 4. Select Add Bluetooth or other device
- 5. Select Bluetooth
- 6. Press and release the AeroSwitch pairing button; the blue LED must be blinking to pair the switch; this makes the AeroSwitch discoverable to your device
- On the device, select the AeroSwitch from the list of discoverable devices; you may need to scroll down in the window to find it
- 8. If you are prompted for a code, enter **000000**.
- 9. Select **Connect**; you may need to scroll down to find the Connect button
- 10. Adjust additional switch settings as needed within the software

SETTING UP A NOVACHAT DEVICE IN BROADCAST MODE

- 1. Ensure the AeroSwitch is turned off
- 2. Set the rotary dial to the broadcast mode you'd like to use and turn the AeroSwitch on

- 3. Choose Menu > Application Settings > Input > Scanning > Enable Scanning
- Choose Switch Access > Switch Configuration and select One Switch or Two Switch
- 5. If you selected **One Switch**, the prompt "Press any switch" will appear; press and release the preferred switch
- 6. If you selected **Two Switch**, select **Switch 2** and press and release the second switch

Note: To set up switch scanning, refer to the NovaChat User's Guide provided with your device or available from

saltillo.com/support/downloads.

Note: If you are using an Android[™] 10 or higher device without an amplifier connected, open the Android settings and turn the Location setting On.

SETTING UP A NOVACHAT DEVICE IN KEYBOARD MODE

- 1. Ensure the AeroSwitch is turned off
- 2. Set the rotary dial to the keyboard mode you'd like to use and turn the AeroSwitch on
- 3. On the device, select Menu > Application Settings > System > Bluetooth Settings > Connect to Switch
- 4. Press and release the AeroSwitch pairing button; the blue LED must be blinking
- 5. Select AeroSwitch from the listing
- 6. If you are prompted for a code, enter **000000**
- 7. Tap Pair
- 8. Choose Menu > Application Settings > Input > Scanning > Enable Scanning

- Choose Switch Access > Switch Configuration and select One Switch or Two Switch
- 10. If you selected **One Switch**, the prompt "Press any switch" will appear; press and release the preferred switch
- 11. If you selected **Two Switch**, select **Switch 2** and press and release the second switch

Note: To set up switch scanning, refer to the NovaChat User's Guide provided with your device or available from **saltillo.com/support/downloads.**

If you are using an Android 11 or higher device:

- 1. Ensure the AeroSwitch is turned off
- 2. Set the rotary dial to the keyboard mode you'd like to use and turn the AeroSwitch on
- 3. Press and release the AeroSwitch pairing button; *the blue LED must be blinking*
- On the device, open the Android settings and select Connections > Bluetooth
- 5. Select AeroSwitch from the listing
- 6. If you are prompted for a code, enter **000000**
- 7. Tap Pair

Note: To set up switch scanning, refer to the NovaChat User's Guide provided with your device or available from **saltillo.com/support/downloads.**

SETTING UP A VIA PRO OR VIA MINI DEVICE

If you are using scanning within TouchChat, LAMP Words for Life (WFL), or Dialogue AAC:

Set up your Via Pro or Via Mini device in broadcast mode

- 1. Ensure the AeroSwitch is turned off
- 2. Set the rotary dial to the broadcast mode you'd like to use and turn the AeroSwitch on
- In TouchChat HD, choose Menu > Settings > Input> Scanning and ensure that Scanning Enabled is selected
- 4. Choose Scanning > Configure Switches > Switch Configuration and select One Switch or Two Switch
- 5. If you selected **One Switch**, the prompt "Press any switch" will appear; press and release the preferred switch
- 6. If you selected **Two Switch**, select **Switch 2** and press and release the second switch

If you are using iOS scanning:

Set up your Via Pro or Via Mini device in keyboard mode.

- 1. In the iOS settings on your device, open the Bluetooth settings
- 2. Ensure the AeroSwitch is turned off
- 3. Set the rotary dial to the keyboard mode you'd like to use and turn the AeroSwitch on
- 4. Press and release the AeroSwitch pairing button; *the blue LED must be blinking*

Note: This makes the AeroSwitch discoverable to your device.

- 5. On the device, select **AeroSwitch** in the device's Bluetooth settings
- 6. If you are prompted for a code, enter **000000**
- 7. Tap Pair

Note: To set up switch scanning, refer to the documentation available for your device.

SETTING UP AN IPAD[®] IN BROADCAST MODE WITHIN A PRC-SALTILLO APP

This section applies if you are using an iPad[®] with TouchChat, LAMP Words for Life (WFL), or Dialogue AAC.

- 1. Ensure the AeroSwitch is turned off
- 2. Set the rotary dial to the broadcast mode you'd like to use and turn the AeroSwitch on
- In TouchChat, WFL, or Dialogue, choose Menu > Settings > Input> Scanning and ensure that Scanning Enabled is selected
- Choose Scanning > Configure Switches > Switch Configuration and select One Switch or Two Switch
- 5. If you selected **One Switch**, the prompt "Press any switch" will appear; press and release the preferred switch
- 6. If you selected **Two Switch**, select **Switch 2** and press and release the second switch

SETTING UP DEVICES NOT LISTED ABOVE

- 1. Open the Bluetooth settings on your device
- 2. Ensure the AeroSwitch is turned off
- 3. Set the rotary dial to the keyboard mode you want to use and turn the AeroSwitch on
- 4. Press and release the AeroSwitch pairing button; the blue LED must be blinking
 - *Note:* This makes the AeroSwitch discoverable to your device

- 5. On the device, select the AeroSwitch In the device's Bluetooth settings
- 6. If you are prompted for a code, enter **000000**
- 7. Tap Pair
- 8. To connect a second AeroSwitch, set the rotary dial to a different keyboard mode and repeat the steps above

Note: To set up switch scanning, refer to the documentation available for your device.

WAKING THE AEROSWITCH (APPLIES TO KEYBOARD MODE ONLY)

After 30 minutes of no activations, AeroSwitch will go to sleep. Press the switch to wake it up. It will take a few seconds to wake. Your first switch press might be missed and need to be repeated.

USING THE AEROSWITCH WITH WIRED SWITCHES

Important! Before connecting a wired switch, turn the AeroSwitch off.

You can use single or dual wired switches with the AeroSwitch for 2-switch scanning.

- 1. Make sure the AeroSwitch is turned off
- 2. Plug in the wired switch or any combination of single and dual switches into switch jacks A and B
- 3. Turn the AeroSwitch back on
- 4. Set up the AeroSwitch as described under the appropriate "Setting up" section above

DISCONNECTING AND/OR UNPAIRING THE AEROSWITCH AND DEVICE

If you want to use the AeroSwitch with a different device, unpair it from the original device.

Accent Device with NuVoice in Broadcast Mode

- 1. In NuVoice, go to the Toolbox and select Access Method Menu
- 2. Select Disconnect ALL AeroSwitch
- 3. Select **OK** twice

Accent Device with Empower in Broadcast Mode

- 1. In Empower, select Menu > Toolbox > System Settings > Devices & Connections
- 2. Select the Switches tab
- 3. Select the Connect Switch **Disconnect all** button; "Do you want to disconnect all of the switches?" will appear
- 4. Select **Okay**; "Unpairing Switches" will appear; when the message disappears, the switch has been disconnected
- 5. Select Close

Accent Device with NuVoice or Empower in Keyboard Mode

- 1. On the device, open the Bluetooth Settings in Windows
- 2. Select the AeroSwitch from the list of devices connected
- 3. Select Remove Device and click Yes

NovaChat Device

If you connected the AeroSwitch in broadcast mode, you do not need to disconnect it from the device.

If you connected the switch in keyboard mode, disconnect it by selecting Menu > Application Settings > System > Bluetooth Settings > Connect to Switch and then selecting AeroSwitch. Via Pro and Via Mini Devices

If you connected the AeroSwitch in broadcast mode, you do not need to disconnect it from the device.

If you connected the switch in keyboard mode, disconnect it by selecting **iOS Settings** > **General** > **Bluetooth** > **AeroSwitch** and then selecting **Forget This Device**.

Devices not listed above

Open the Bluetooth settings on your device and disconnect/unpair according to your operating system documentation.

CUSTOMIZING THE APPEARANCE OF YOUR AEROSWITCH

Customize the appearance of your AeroSwitch with a picture or with one of the colored cap covers provided with the switch.

- 1. Remove the retaining ring by rotating it counterclockwise; lift off the clear cap cover
- 2. Place a small picture on the black cap and place the clear cap cover over it or place a colored cap cover on the black cap
- 3. Screw the retaining ring on to hold the cap cover in place

REPLACING THE BATTERY

AeroSwitch is powered by a lithium coin cell battery. How long the battery lasts will depend on how much the AeroSwitch is used and whether it is in broadcast mode or keyboard mode.

Replacement batteries are available in stores. Look for a CR2032 lithium coin cell battery. Rechargeable options are available.

- 1. Turn the AeroSwitch off
- 2. Remove the battery cover screws and cover; use the screwdriver included with the switch
- 3. Remove the battery
- 4. Insert the replacement battery with the + (positive) facing up toward you
- 5. Turn the AeroSwitch on; if the blue LED flashes 4 times, you have inserted the battery correctly
- 6. Replace the cover and screws

FOR ADDITIONAL INFORMATION

To view the AeroSwitch User's Guide, videos, FAQs, troubleshooting tips, and other information about using your AeroSwitch, visit **prc-saltillo.com/aeroswitch.**

FOR TECHNICAL ASSISTANCE

- NovaChat or Via Technical Support: 1-800-382-8622, option 1
- Accent Technical Support: 1-800-262-1990

\triangle SAFETY INFORMATION

- Any mounts used should be fitted by a qualified person; failure to install the mounting system according to the manufacturer's instructions may result in an injury to the user
- Analysis of positioning by a qualified person is required to prevent repetitive stress injuries to the user
- Cables are a potential entanglement or strangulation hazard
- Do not immerse the switch in water
- When removed, the battery can be a choking hazard or could pose a hazard if ingested; keep the replacement battery in a

safe location until used and properly dispose of the old battery according to local, state, and/or country regulations

- The battery cover screws can be choking hazards; keep them in a safe location if removed and refasten the cover securely
- The screwdriver provided with the switch could be a hazard for poking an eye; store it in a safe location when not in use

Implantable Medical Devices: A minimum of six (6) inches should be maintained between a handheld wireless mobile device and an implantable medical device, such as a pacemaker, implantable cardioverter defibrillator, vagus nerve stimulator, shunt, or stent, to avoid potential magnetic interference with the medical device. Persons who have such devices:

- Should ALWAYS keep the mobile device a minimum of six (6) inches from their implantable medical device
- Should not carry the mobile device in a breast pocket
- Should move the mobile device away from themselves immediately if there is any reason to suspect that it is interfering with the implantable medical device
- Should read and follow the directions from the manufacturer of the implantable medical device; if you have any questions about using your wireless mobile device with an implantable medical device, consult your health care provider

COMPLIANCE INFORMATION

Electronic Interference Information

This switch complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This switch may not cause harmful interference, and (2) this switch must accept any interference received, including interference that may cause undesired operation. **Warning!** Changes or modifications to this switch not expressly approved by PRC-Saltillo could void the user's authority to operate the equipment.

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

Third Parties

PRC-Saltillo assumes no responsibility for any loss or claims by third parties which may arise through the use of this product.

Switch Intended Purpose

AeroSwitch is a wireless remote switch that can be used to wirelessly control electronic speech generating devices. The AeroSwitch can be hand-held, operated on a table surface, or mounted to a wheelchair. The switch does not incorporate in any way medicinal substances, human blood or plasma derivatives, nor is it manufactured using tissues of animal origin.

Expected Service Life

The expected service life of the switch is five years. If you replace the battery in your switch, dispose of the old battery in accordance with your local, state, and/or country regulations. If you dispose of your switch, please dispose of it in accordance with your local, state, and/or country electronic recycling laws.

Intended Operators

The individual using the switch along with a device to communicate, the individual's communication partner, and/or the person changing device settings, maintaining software files, etc. are the intended operators of the switch.

Expected Position of Operators

In normal use, the device and switch are expected to be within easy reach of the individual. The position will vary if the device is mounted on a wheelchair or table.

Special Skills, Training, or Knowledge Required

No special skills or training are required to operate or maintain the switch. The pictures and text in this document will help the operators acquire the knowledge to achieve the intended use of the switch.

Instructions for Use

- All functions of the switch are safe for use by the user. For best results, follow the instructions in this manual
- To report any serious incident associated with the switch, contact PRC-Saltillo and your national authority

Instructions for Storage

Turn the AeroSwitch off if it is going to be stored or not used for an extended period of time.

Explanation of Symbols

This section explains the symbols that appear on PRC-Saltillo devices, accessories, or packaging.

Symbol	Explanation
FC	The device is Federal Communications Commission (FCC)-compliant.
CE	The device conforms to European Union health, safety, and environmental standards.
UK CA	The device conforms to the requirements of the UK MDR 2002.
IC	The device complies with Innovation, Science and Economic Development Canada license- exempt RSS standard(s).
Ŕ	The entire device and accessories, excluding the adapter, are type BF applied parts. "Applied part" refers to the part of the device with which the user comes into physical contact when using it for its intended function.
	The device complies with applicable ACMA technical standards for telecommunications, radiocommunications, EMC, and EME.
\wedge	Caution! Use caution when operating the device to avoid undesirable consequences.

Symbol	Explanation
(((;;))	The device emits generally elevated, potentially hazardous, levels of non-ionizing electromagnetic radiation.
X	Recycle electronic equipment. Do not throw the device in the trash.
IP44	The device is protected against solid objects over 1mm and water splashed in all directions.
Ť	Keep dry. The device needs to be protected from moisture.
X	The range of temperatures to which the device can be exposed while in use. Caution: If the device has been stored in an environment in which the temperature range is different from "the range of temperatures to which the device can be exposed while in use", let the device stand for at least 30 minutes before using it. While in transport or storage, the range of temperatures to which the device can be exposed.
<u>%</u>	The range of humidity to which the device can be exposed while in use.

Symbol	Explanation
A	The range of atmospheric pressure to which the device can be safely exposed while in use, transport, or storage.
8	Follow the instructions for use. Refer to the instruction manual.
i	Consult the instructions for use.
*	The device employs Bluetooth wireless technology.
#	The device model number.
SN	The device serial number.
	The date of manufacture of the device and the name and address of the manufacturer.
MD	Indicates a medical device.
ECREP	The authorized representative in the European Community.
UK REP	The responsible person in the United Kingdom.

Specifications

Dimensions	2.99 in. (76 mm) in diameter and 0.8 in. (20 mm) in height
Battery life	Varies by user, switch mode setting, and how much the AeroSwitch is used

Environmental Conditions for Operating, Transport, and Storage

	Operating	Transport and Storage
Temperature	5°C to 40°C or	-25°C to 70°C or
	41°F to 104°F	-13°F to 158°F
Humidity	15% to 90%	10% to 90%
Atmospheric	70 kPa to 106	50 kPa to 106 kPa
Pressure	kPa	

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DECLARATION OF CONFORMITY

We, Prentke Romich Company, hereby declare that the product mentioned below conforms to the regulation mentioned below. We further declare that we are solely responsible for issuing this Declaration of Conformity.

Manufacturer's Name and Address:	Prentke Romich Company dba PRC-Saltillo 1022 Heyl Road Wooster, OH 44691 USA
Manufacturer's SRN (Single Registration Number):	US-MF-000018695
Authorized Representative's Name and Address:	Jürgen Babst Prentke Romich GmbH Karthäuserstr. 3 D-34117 Kassel, Germany
Authorized Representative's SRN: DE-AR-000005106	Basic UDI-DI: 81648602SwitchQK
Product Type: Bluetooth Switch	UDI-DI Code: 00816486020650
Trade Name: AeroSwitch	Product Code: F18204
Product Name: AeroSwitch	Model Number: F18204

Product Description, Intended Use, and Reasonably Foreseeable Misuse (Ref. EN ISO 14971:2019): The AeroSwitch[™] is a wireless switch based on the Silicon Labs BGM115 Bluetooth[®] SiP Module. This switch can be used to control electronic speech generating devices. It has two ports that allow for the connection of wired switches (mono or dual). A rotary dial allows the customer to set up options for sending in broadcast mode or keyboard mode. It can be hand-held, operated on a table surface, or mounted to a wheelchair. The switch does not use animal tissue or incorporate a substance or human blood derivative. The device with an AeroSwitch is not intended to be used as a sole communication aid; it is not intended to be an emergency call device; and it is not intended to hold information critical to care of the user.

Conformity Assessment Route: This Declaration of Conformity is issued in accordance with Regulation EU MDR 2017/745, Article 19, and the conformity assessment performed in accordance with article 52 (7); the Radio Equipment Directive (RED) 2014/53/EU; and 768/2008/EC, Annex II, Module A(2), (4.2).

Classification is declared according to Annex VIII of EU MDR 2017/745: Class 1

Standards to which Conformity is Declared:

IEC 60601-1:2005	AS/NZS 3200.1.2:2005
IEC 60601-1-2:2014	FCC CFR 47 Part 15, subpart B:2017, Class B
EN 60601-1-2:2015	ICES-003, Issue 6:2016, Class B ITE
CAN/CSA-C22.2 No. 60601-1-2:2016	AIM 7351731 Rev. 2.00 (2017-02-23)
IEC 60601-1-11:2015	IEEE/ANSI C63.27-2017
IEC/EN 60529:2013 (IP44)	ACMA Radiocommunications Standard 2014
EN 301 489-17 V3.2.0:2017	

I, the undersigned, hereby declare that the product specified above is designed to conform to the above regulation, directive(s), and standards.

+ ALAS

Date: 19 July 2023

Dustin Welty VP of Engineering Prentke Romich Company dba PRC-Saltillo Wooster OH 44691 USA

DECLARATION OF CONFORMITY

We, Prentke Romich Company, hereby declare that the product mentioned below conforms to the regulation mentioned below. We further declare that we are solely responsible for issuing this Declaration of Conformity.

Manufacturer's Name and Address:	Prentke Romich Company dba PRC-Saltillo 1022 Heyl Road Wooster, OH 44691 USA
UK Responsible Person and Address:	Liberator Ltd "Whitegates", 25-27 High Street Swinstead, Lincolnshire NG33 4PA UK
Product Type: Bluetooth Switch	Basic UDI-DI: 81648602SwitchQK
Trade Name: AeroSwitch	UDI-DI Code: 00816486020650
Product Name: AeroSwitch	Product Code: F18204

Model Number: F18204

Product Description, Intended Use, and Reasonably Foreseeable Misuse (Ref. EN ISO 14971:2019): The AeroSwitch[™] is a wireless switch based on the Silicon Labs BGM115 Bluetooth[®] SiP Module. This switch can be used to control electronic speech generating devices. It has two ports that allow for the connection of wired switches (mono or dual). A rotary dial allows the customer to set up options for sending in broadcast mode or keyboard mode. It can be hand-held, operated on a table surface, or mounted to a wheelchair. The switch does not use animal tissue or incorporate a substance or human blood derivative. The device with an AeroSwitch is not intended to be used as a sole communication aid; it is not intended to be an emergency call device; and it is not intended to hold information critical to care of the user.

Conformity Assessment Route: This Declaration of Conformity is issued in accordance with Regulation UK MDR 2002 and The Radio Equipment Regulations 2017.

Classification is declared according to UK MDR 2002: Class 1

Standards to which Conformity is Declared:

IEC 60601-1:2005 IEC 60601-1-2:2014 EN 60601-1-2:2015 CAN/CSA-C22.2 No. 60601-1-2:2016 IEC 60601-1-11:2015 IEC/EN 60529:2013 (IP44) EN 301 489-17 V3.20:2017 AS/N2S 3200.1.2:2005 FCC CFR 47 Part 15, subpart B:2017, Class B ICES-03, Issue 6:2016, Class B ITE AIM 7351731 Rev. 2.00 (2017-02-23) IEEE/ANSI C63.27-2017 ACMA Radiocommunications Standard 2014

I, the undersigned, hereby declare that the product specified above is designed to conform to the above regulation, directive(s), and standards.

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Date: 19 July 2023

Dustin Welty VP of Engineering Prentke Romich Company dba PRC-Saltillo Wooster OH 44691 USA

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DOCUMENT VERSION

18660 Version 1.03 · 12/07/2023 · Applies to model F18204

UK

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EC REP EU Authorised Representative

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