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noddle™

User Manual

07-100004, Rev. 07

Table of Contents

General description

Intended use

The noddle™ is intended to be used by patients who cannot either access a standard nurse call and/or communicate traditionally. The noddle™ is used for alternate access to a nurse call and/or access to assistive and augmentative communication devices (speech generation devices) to communicate with caregivers.

Indications for use

The noddle™ is indicated for use by patients who have physical limitations, weaknesses and/or limited communication abilities in order to assist them with summoning and communicating with their caregiver by controlling other devices such as the nurse call and speech generation devices. To use the noddle™ patients should be sufficiently cognitively intact so that they can produce intentional gestures and intend to communicate with caregivers.

Caregiver installation

The noddle™ can be installed in hospital, long-term care and home environments. In order to install the noddle™ the caregiver must have knowledge of the procedure for installing equipment in each environment. Installation of the noddle™ in conjunction with a nurse call system requires knowledge of or training in the specifications of that particular nurse call system. Installation of the noddle™ in conjunction with a speech generating device requires knowledge of or training in the specifications and operation of that particular speech generation device.

The caregiver can safely set up the following functions of the noddle™:

- Power on and off the noddle™
- Fasten the noddle™ to a pole, bed headboard or headwall rail using the built-in clamping system: Do not attach the noddle™ to the bed rail.
- Pair the noddle™ with a speech generating device via hardwired outputs or Bluetooth®

The caregiver can perform the following maintenance with the noddle™:

- Charge the noddle™
- Clean the noddle™ enclosure

Patient operation

The noddle™ is intended to be operated by a patient.

The patient can safely operate the following functions of the noddle™:

- Activate the noddle™ with a switch (e.g. noddle-touch™ or noddle-mic™)

- Activate the nurse call by using the noddle™
- Navigate a speech generating device by using the noddle™

Neither the patient nor the caregiver should perform the following maintenance with the noddle™:

- Remove and/or replace any portion of the noddle™ that is or was at any point in time fixated by screws
- Remove and/or replace the rechargeable battery inside of the noddle™

Safety sign and symbol definitions

Symbol	Identity
	Risk of fire
	General warning
	Non-ionizing radiation
REF	Device catalog number
LOT	Manufacturing lot number
	IEC 60601-1 Electrical Shock Protection Class II
RoHS	Reduction of Hazardous Substances Conformance
	Do not dispose of equipment in household refuse
	IEC 60601-1 Type B applied part
	FCC Certified Components
	Upper/lower limits of temperature
	DC Power input
	Bluetooth wireless standard symbol
	Manufacturer

Warnings and safety notices

WARNING: Battery can explode if mishandled. Only to be accessed by trained service personnel.

WARNING: RF emissions may cause interference. Maintain 1m radius from other electromechanical equipment.

WARNING: The noddle™ shall not be serviced and maintenance shall not be performed while it is in use.

WARNING: Do not clean with bleach solution.

WARNING: To avoid the risk of accidental decannulation, noddle™ sensors must not be mounted on ventilation circuits of patients with tracheotomies.

WARNING: The noddle™ is not to be used for patient self-administration of any medication, including pain medication.

WARNING: The noddle™ should not be serviced or maintained while equipment is connected to a power source, turned on, or in use.

WARNING: 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.

WARNING: 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.

WARNING: Interference between the noddle™ and devices with which it is intended to communicate could impair the operator's ability to operate such devices. To minimize this risk please follow guidelines for optimal RF performance.

WARNING: 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 the noddle™, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: The noddle™ should not be placed or used near magnetic resonance imaging machines.

WARNING: Operator or caregiver should not attempt to remove or replace the internal battery. Improper care or installation of the lithium-ion battery may result in fire or explosion. Service only by trained technical personnel.

WARNING: Do not use any external power source to charge or power the noddle™ other than the DC charging module and USB cable provided. Incompatible chargers could damage the internal circuitry or damage the

battery.

WARNING: Do not autoclave or burn for disposal. This product contains a lithium-ion battery that can explode upon exposure to excessive heat.

WARNING: This portable RF communications equipment can affect medical electrical equipment

WARNING: Use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Voxello as replacement parts for internal components, may result in increased emissions or decreased immunity of the noddle™.

WARNING: This system may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

WARNING: If enclosure is damaged discontinue use and send to a technician for repair or assessment.

WARNING: Do not touch frayed wires. If touched, electrical current could leak and potentially cause injury. If any wires become frayed, they must be disposed of and replaced. Contact Voxello for replacement.

CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

California Proposition 65 Warning: This product may contain chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

Compatible accessories and cables should use shielded cable of length no longer than 10 feet.

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.

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.

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.

Product identification

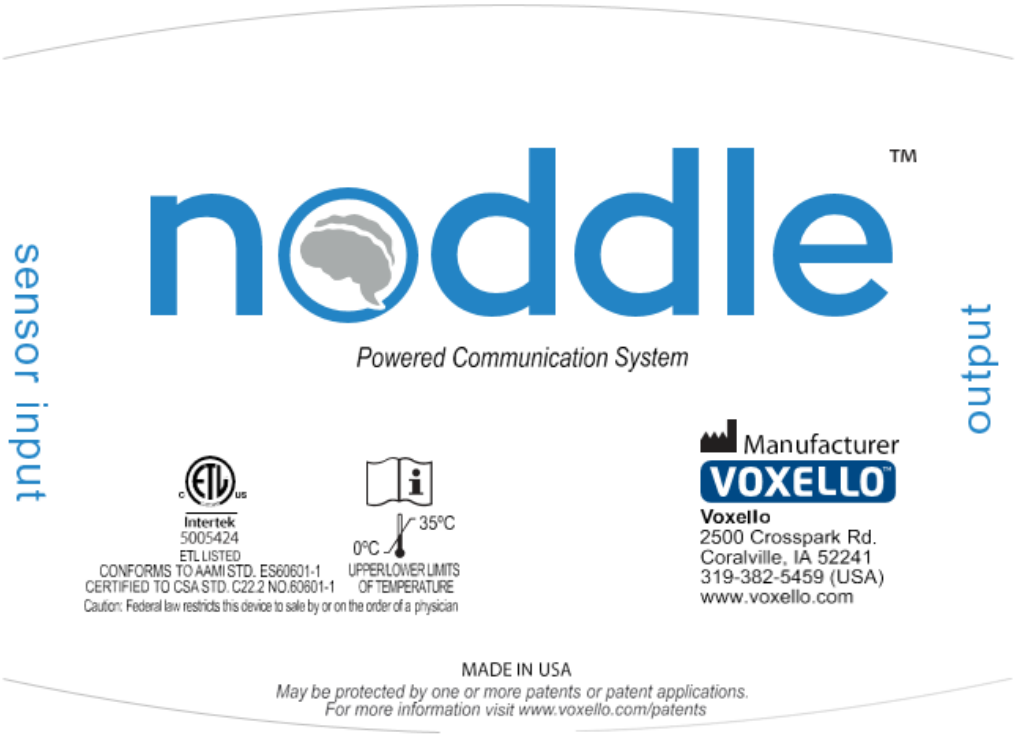

Figure 1a: Front label

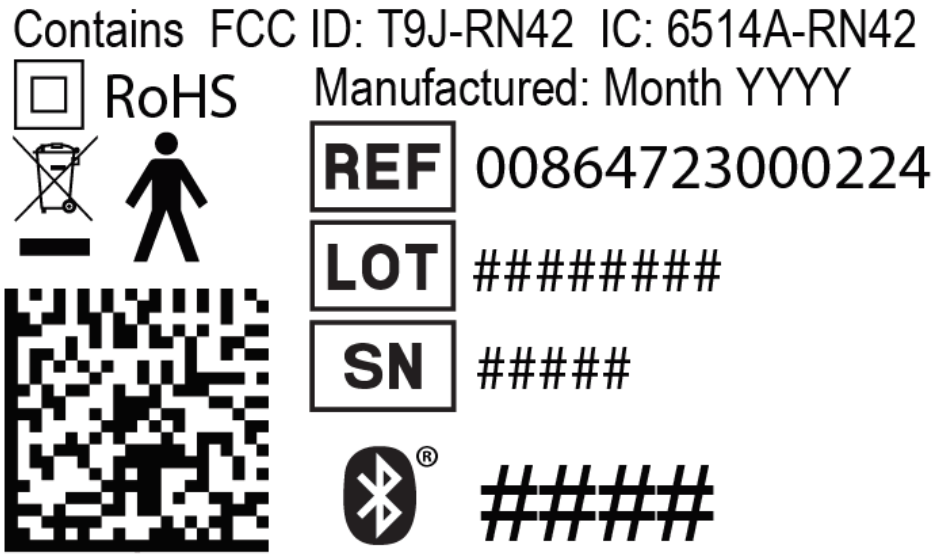

Figure 1b: Back Label with product identification information

The noddle™ is listed under the FDA Unique Device Identifier (UDI) system. Each noddle™ can be individually identified by its serial number, its lot number, and its Bluetooth® code.

Included components

The noddle™ system consists of the following components:

- noddle™
  - Brand: Voxello
  - Part No.: 01-10-XXX-XXX
- 6 ft. USB power cord (standard-A to micro-B)
  - Brand: Globtek
  - Part No.: USBA6F0MICROB-WH(R)
- 6W DC power adapter (5V/1.2A)
  - Brand: Globtek
  - Part No.: WR9QA1200USBNMEDRVW (with US plug insert)
- 10 ft. 1/4” to 1/8” output interconnect cable
  - Brand: Hosa Technologies, Inc.
  - Part No.: CMS-310

Function

General function

The noddle™ is designed to respond to input from a single transducer and provide the user with control of multiple outputs. It can take an input from a microphone, proximity detector, or any sensor/switch with a switch-closure output, and allow the user to use a single intentional gesture (e.g. tongue click, tongue in cheek gesture, button push) to control multiple devices (e.g. nurse call system, speech generating device or environmental control unit).

Gesture detection

The noddle™ uses patent-pending methods to identify/isolate the user’s intentional gesture from extraneous signals/noise. For example, when used with the accessory sensor noddle-mic™, the noddle™ is designed to identify the particular “tongue clicking” sound that even a user who is intubated can make. Thus, it does not respond to sounds of others speaking or any of the sound coming from a user’s physical environment (e.g. ventilator sounds, alarms, background music). A similar approach is used with the noddle-touch™ accessory sensor so that a particular gesture towards the sensor will trigger a response from the noddle™. If a patient’s head continually rests against the sensor, it will not trigger a response from the noddle™.

Video Demonstration: Noddle Mic™

Video Demonstration: Noddle Touch™

Gesture counting

The noddle™ counts the number of sequential intentional gestures to activate one of three connected functions or devices that the user wishes to control. The noddle™ also provides Bluetooth® outputs to permit wireless connectivity.

The front of the device (Figure 2) has a port for connecting the input sensor and LEDs that indicate the device is on and the status of the input. If no input is connected the Selection LED will be red. When an input sensor is connected the selection LED will indicate whenever a gesture has been detected. It will first blink (blue) to indicate a detected gesture and then blink (green) to indicate that the output port has been triggered. The device also provides audio feedback in the form of beeps to indicate that gestures have been detected.

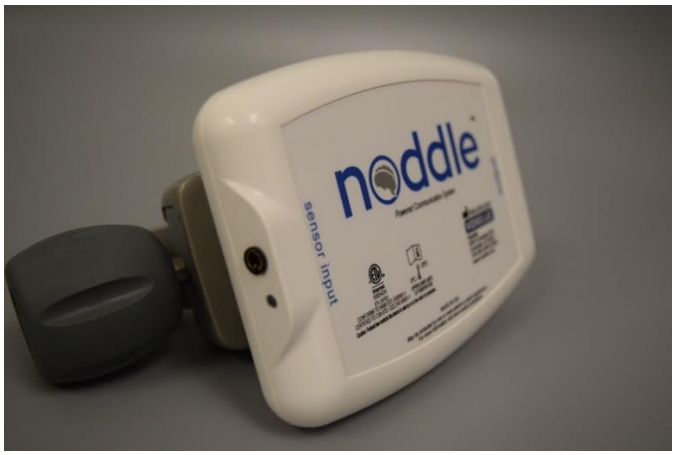

Figure 2: Front side of noddle with input jack and selection indicator light

The back of the device (Figure 3) has a jack connected to the charging module, an on- off power switch, three jacks for the output relays and a Bluetooth® pairing button. The output relays can be connected to any device accepting a switch closure.

Figure 3: Rear side of noddle™ with (left to right) power jack, charging indicator light, power on/off indicator light. power switch, input jacks 1-3 and Bluetooth® pairing button.

Setup

Powering the noddle™

The noddle™ is powered from either the electrical mains using the provided DC power adapter or secondarily by the internal rechargeable battery (Figure 4).

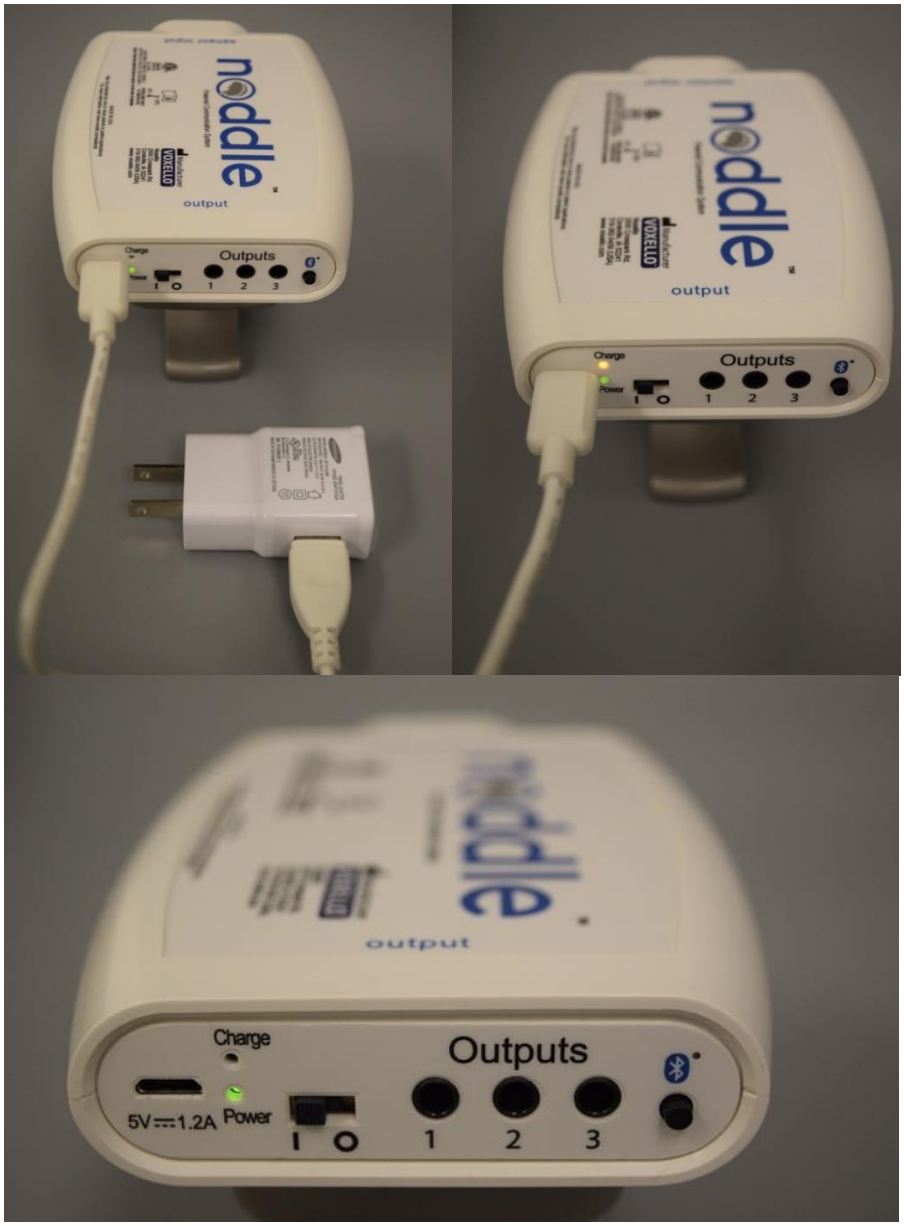

Figure 4: noddle™ Power; Connection to power adapter via mini USB (upper left), power and charge indicators (upper right); battery operated (bottom).

Powering from electrical mains

The noddle™ can be powered and the battery be charged by connection to the provided external DC power supply. To charge and/or power the noddle™ plug the provided DC charging module (5V/1.2A DC) into the micro-USB jack on the back of the device.

WARNING: Do not use any external power source to charge or power the noddle™ other than the DC charging module and USB cable provided. Incompatible chargers could damage the internal circuitry or damage the battery.

Powering from internal rechargeable battery

The noddle™ has a secondary power source, an internal Lithium-Ion rechargeable battery (3.7V, 580 mAh). The approximate power cycle length is 15 hours. The noddle™ battery can be charged by connecting the provided charging module to the noddle™. The noddle™ may be used while the battery is charging.

While in operation under battery power, the noddle™ should be periodically checked for low battery charge. This is indicated by a repeated red flashing of the main indicator light accompanied by a long alert tone.

WARNING: Operator or caregiver should not attempt to remove or replace the internal battery. Improper care or installation of the lithium-ion battery may result in fire or explosion. Service only by trained technical personnel.

WARNING: If the battery is not likely to be used for an extended period of time the battery should be removed from power by trained technical personnel.

WARNING: The battery should be periodically checked for ability to hold charge by operating the powered device while disconnected from the power supply.

Positioning the noddle™ and sensors

The noddle™ case has been designed to allow for alternative mounting solutions so that the noddle™ can be used at the hospital bedside as well as on a wheel chair (Figure 5). The included combination post/rail clamp allows for a wide range of compatible mounts.

Post/rail clamp specifications

- Post grip range: 19 mm – 39 mm (0.75 in – 1.50 in)
- Rail grip size: 10 mm x 25 mm
- Maximum rated force: 13.6 kg (30 lbs) at the clamp base

Figure 5: noddle™ with attached IV pole-clamp

Positioning the noddle™ in the hospital room

Attach the noddle™ to the IV pole using the IV pole clamp attached to the noddle™. The noddle™ should be positioned so it is securely fastened to a post or rail.

The noddle™ should be positioned within 1.8 meters (6 feet) of a standard U.S. 120V AC power outlet so that the provided power cord can reach between the outlet and the noddle™. When selecting this outlet, ensure that the cord will not pose a tripping hazard or create a physical obstruction around the patient. It is recommended that the noddle™ is placed on the patient's IV pole and the power cord is plugged into the hospital approved IV pole power strip.

In addition, the noddle™ should be positioned so that it is within 1.5 meters (5 feet) of the patient-side mounting site of the accessory sensor (e.g. noddle-mic™ or noddle- touch™; Figure 6).

Figure 6: Nurse attaching noddle-mic™ on patient-side mounting site of the sensor.

Video Demonstration: Positioning noddle™ and SGD

Patient-side sensor selection and positioning

Key to the successful use of any switch or sensor involves an assessment of the patient's ability to produce an intentional gesture reliably. The assessment should identify the residual motor abilities of the patient as well as the patient's cognitive status to ensure that the patient fits the criteria for indications for use (see indications for use below).

To determine the appropriate sensor for a given patient, ask the patient to produce a gesture intentionally, on command. This may include the patient moving her finger or toe or her cheek with her tongue or making a clicking sound with the tongue. It is crucial that the patient produce this gesture up to four times in succession with no more than 750 milliseconds between iterations. Some patients, due to their medical status, may benefit from one sensor at one point in time and may later benefit from a different sensor, so it is important to continually check on the patient to ensure a good fit between a patient's abilities and the selected sensor.

To accommodate a wide range of patients, the noddle™ has been designed to accept a variety of accessory switches and sensors. Below are examples of Voxello proprietary switches (Figure 7) as well as third party switches that Voxello has tested and validated with the noddle™. All certified compatible sensor accessories will be listed on our website at www.voxello.com/support.

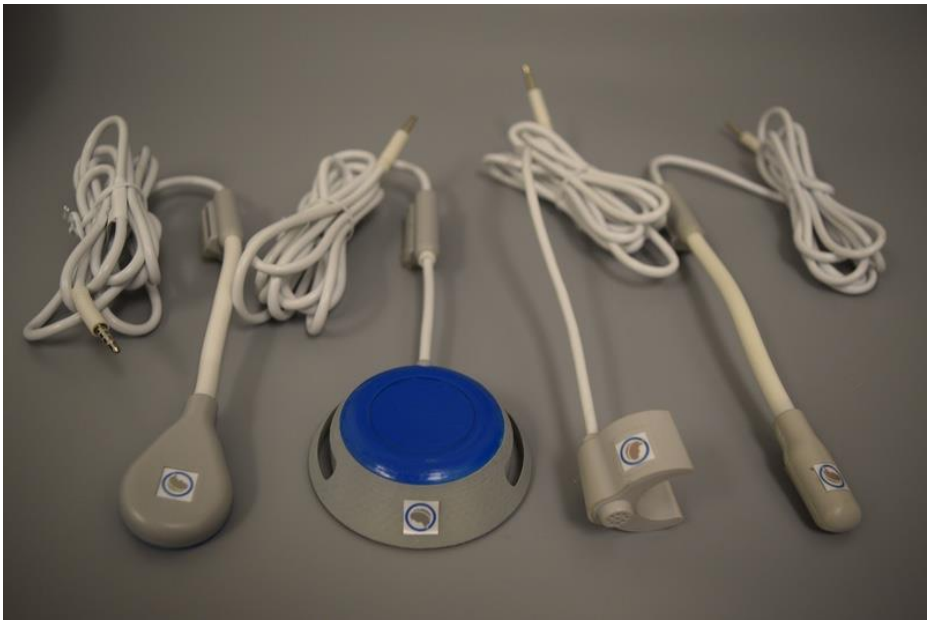

Figure 7: (Left to right) Cervical collar-mounted noddle-touch™, noddle bed-touch™, noddle vent-mic™, cervical collar mounted noddle-mic™. **WARNING:** noddle vent-mic™ should not be used with patients with a tracheostomy.

However, it is equally important that one develop a switch mounting strategy that will ensure that the user can always access the switch. Voxello has developed mounting systems for the noddle-mic™ and noddle-touch™ auxiliary sensors. When mounting a sensor, it is best to mount it on the same side as the noddle™ device so as to minimize obstructing the patient with the cord. This may be unavoidable in some circumstances, but it should be minimized. Please see the noddle-mic™ and noddle-touch™ instruction sheets for more detailed information regarding mounting options and instructions on how to mount a noddle™ accessory sensor. The noddle bed-touch™ sensor can also be placed on the bedding to allow activation with a small finger movement (Figure 8).

Figure 8: noddle bed-touch™ sensor

Connecting the noddle™ to wired switched output connections

The noddle™ uses standard 3.5 mm mono connections to control a wired switched device. An interconnect cable is provided along with each noddle™. When connecting the outputs to a nurse call system, select the appropriate jack on the other end of the cable. Most nurse call systems use a standard ¼-inch phono jack. Most switch activated AAC/Speech-Generating Device (SGD) systems require standard mono 3.5 mm (mini phono) jacks (Figure 9).

The noddle™ sends a pulsed signal to the nurse call system. This requires a “latching” nurse call. That is, the nurse call system will receive a short pulse and remain “on” until the nurse resets the system on the patient’s headboard. The noddle™ does not control how the nurse call system is deactivated once it is activated by the noddle™.

Figure 9. Left: Nurse call cable plugged into the back of the noddle™; Right: Nurse call cable plugged into headwall.

Bluetooth® wireless setup

The noddle™ also provides Bluetooth® connectivity for each output. In order to use the noddle™ with an iPad or other SGD, such a device must have a Bluetooth® connection.

Pairing

Pairing mode may be initiated on the noddle™ by depressing the Bluetooth® pairing button on the back of the noddle™ for at least 2 seconds (Figure 10).

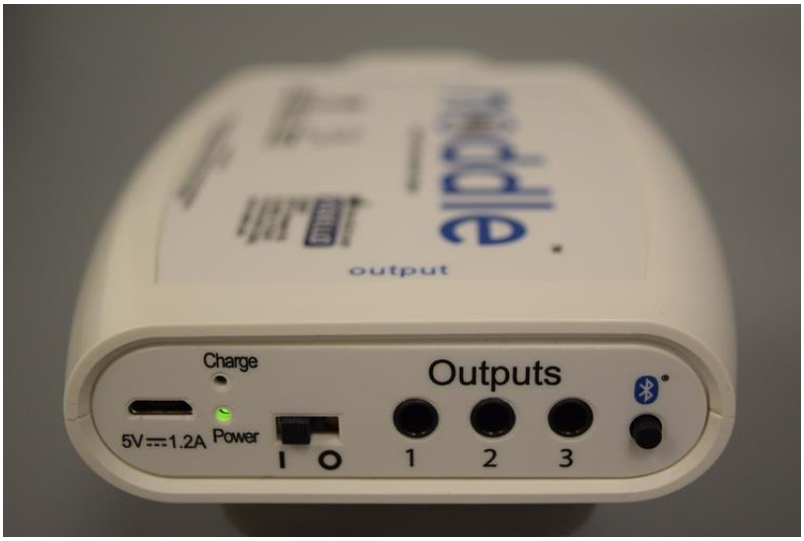

Figure 10: Depressing the Bluetooth® pairing button on the back of the noddle™

The front indicator light will flash to blue (Figure 11) and the noddle™ will then be visible as an option for pairing on a tablet or SGD. The front indicator light will flash blue until a connection has been established.

The tablet may ask the user to confirm a passcode, in which case the user should simply accept the passcode provided by the tablet.

Note: If the noddle™ is currently paired with a Bluetooth tablet, it must first be disconnected. The noddle™ will automatically re-connect to a paired device when disconnected or powered on, so the disconnection must be initiated from the tablet.

Figure 11: Selection indicator light flashes blue to indicate that the noddle™ is now in Bluetooth® pairing mode

Bluetooth® output

The noddle™ sends a space character in response to a single gesture, newline/return character in response to two successive gestures, and a lowercase ‘u’ in response to three successive gestures. It is essential that those match the expected characters on the application running on the paired device. Character input can be changed on some SGDs and other devices. However, the noddle™ character output is fixed and cannot be changed.

Using the noddle™ with a SGD and Nurse Call

The noddle™ can be paired with a speech generating device (SGD) and the nurse call system by utilizing all three outputs on the back of the noddle™. This can be accomplished by pairing the SGD with the noddle™ via the Bluetooth® connection or via wires from the SGD to the noddle™. For Bluetooth® connection, first enable Bluetooth® settings on the SGD and then press the Bluetooth® button on the back of the noddle™. Connecting the Bluetooth® to the noddle™ will utilize two of the three outputs on the noddle™. These two outputs are used for two-switch scanning on the SGD, which is explained in more detail in the noddle-chat™ User Manual. To connect the noddle™ to the nurse call system, plug the nurse call cord into the back of the noddle™ in Output 1 or Output 3 and then plug the other end into the headwall in the room. With the nurse call plugged into Output 1, the nurse call is activated with one gesture and the SGD is activated with two and three gestures. With the nurse call plugged into Output 3, it is activated with three gestures and the SGD is activated with one and two gestures. With a SGD that does not have Bluetooth® capability but does have switch input, plug one to two switches into the noddle™. The nurse call can then be connected to Output 3 of the noddle™.

Please refer to the noddle-chat™ User Manual for more detailed information regarding the noddle-chat™ software that is used with a SGD tablet.

Patient Inclusion/Exclusion Criteria

Patient selection is a crucial component to successful noddle™ use. Patients must meet the following criteria to make maximum use of the noddle™:

- Patient must be conscious
- Patient must be severely limited in his/her mobility and unable to access standard nurse call system
- Patient must be able to produce an intentional gesture (e.g. tongue in cheek, tongue click, finger tap) reliably
- Patient must respond appropriately to yes/no questions

Some patients will not be good candidates for noddle™ use and this includes:

- Patients who are heavily sedated or unconscious
- Patients who are able to access the nurse call independently and communicate without assistance

Patients on sedation medications may benefit from the noddle™ once they are no longer on these medications and/or when their medical status improves to the point where they are conscious and able to produce intentional gestures. These patients should be closely monitored by nursing staff and re-assessed as their medical status changes. The same is true for patients who have benefitted from one sensor at one point during their hospitalization but whose medical condition may change during their stay and may benefit from a different sensor or sensor positioning at a later time. These patients should be monitored regularly as well to ensure appropriate sensor fit throughout the patient's hospitalization.

To decide which patients may benefit from the noddle™ to access the nurse call system, answer the questions in the Nurse Call Access Decision Tree (Figure 12). Or, if the patient may have difficulty with spoken language, answer the questions in the Communication Decision Tree (Figure 13).

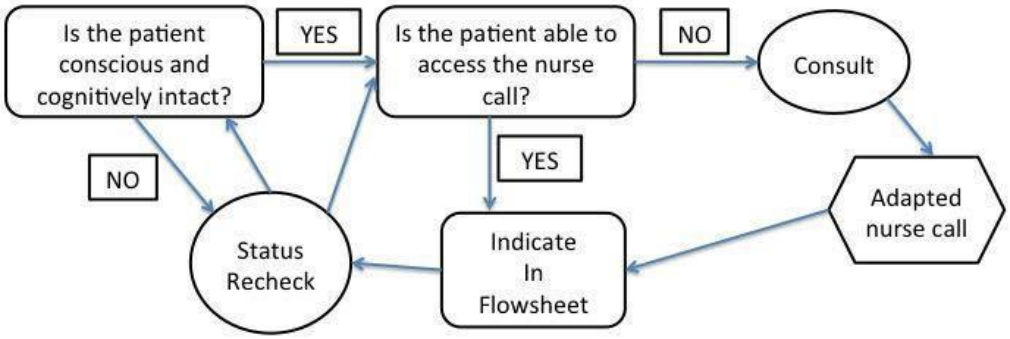

Figure 12: Nurse Call Access Decision Tree

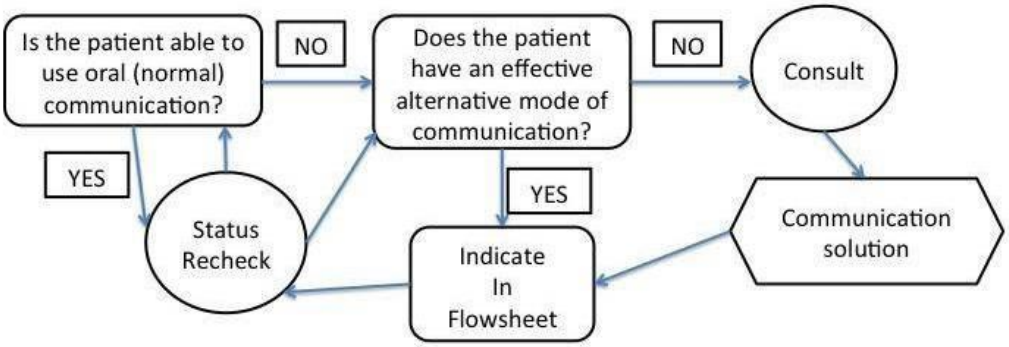

Figure 13: Communication Decision Tree

Operation

Connecting a sensor

The selection indicator light will remain red until a sensor is plugged into the input jack on the front of the noddle™ (Figure 14). Once a sensor is plugged in, the selection indicator light will flash green once and then turn off.

Figure 14: noddle™ waiting for a sensor to be plugged in (left), and with sensor plugged in (right)

Activating an output to control a function or device

When a user intentionally activates a sensor (e.g. with a tongue click) the noddle™ will begin waiting for sequential activations for a period of 0.75 seconds. A tone will sound indicating a selection while the selection indicator light will flash green. The selection indicator light will remain blue while waiting for sequential intentional gestures (Figure 15). During this period, the user may make up to two more sequential intentional gestures in order to activate different outputs/functions:

If output/function 1 is desired, the user performs only the initial intentional gesture.

If output/function 2 is desired, the user performs two sequential intentional gestures.

If output/function 3 is desired, the user performs three sequential intentional gestures.

Figure 15: The noddle™ responds to an intentional gesture by flashing green (left) and then blue (right) for each activation.

Once the selection time period is completed the noddle™ will sound a tone and flash green and blue sequentially once to indicate the activation of output/function 1, twice to indicate the activation of output/function 2, or three times to indicate the activation of output/function 3.

If the user intentionally gestures to activate the device but wishes to cancel the selection immediately afterwards then continuing to make 4 or more sequential intentional gestures will cancel the selection and no outputs/functions will be activated. In this case a long tone will sound and the indicator light will flash yellow (Figure 16). The indicator light will also flash yellow in the case of a detected unintentional gesture.

Figure 16: The noddle™ indicating that the response has been cancelled after being activated 4 or more times by intentional gestures.

Shutdown procedure

The noddle™ may be shut down by sliding the power switch to the off position. Before placing in storage all cords should be unplugged from the noddle™.

WARNING: If the battery is not likely to be used for an extended period of time the battery should be removed from power by trained technical personnel.

Indicator lights and alerts

The main indicator light next to the input jack indicates the function of the device. Upon certain operational conditions the light, accompanied by the buzzer, may alert the user of such conditions. Table 1 below outlines the indicator light/buzzer patterns and their meanings:

Table 1: Indicator patterns and meanings

Light pattern	Buzzer pattern	Meaning
Flashing red 2 times per second for 2 seconds	Alternating high-low beeps 2 times per second for 2 seconds	Battery is low. Connect to power immediately.
Solid red[a]	None	Sensor is unplugged. Patient unable to use device.
Flash green, then remains blue	Single beep	Patient gesture detected, waiting for further gestures.
Flash green once	Single beep	Output 1 triggered.
Flash green twice quickly[a]	2 beeps	Output 2 triggered.
Flash green three times quickly[a]	3 beeps	Output 3 triggered.
Flash yellow once	None	Patient cancelled output sequence. No output.
Solid yellow[a]	None	Patient gesture detected, but outside time limit. Check to ensure that sensor is not inadvertently being triggered.
Solid blue[a]	None	User is pressing the Bluetooth® pairing button
Flash blue 3 times quickly (5 Hz)	None	Bluetooth® pairing mode entered.
Flash blue slowly[a]	None	Currently in Bluetooth® pairing mode and discoverable. Waiting to pair.
Flash between red and green quickly for less than one second	1 beep at each color change	Factory testing mode inadvertently entered. Restart the device to resume normal operation.

[a] *"Quickly" means 5 Hz, "Slowly" means 1 Hz, "Solid" means continuously*

Maintenance

Routine and preventative maintenance to be performed by hospital staff

A. Cleaning and Sterilizing
   a. The noddle™ can be cleaned and sterilized with PDI Germicidal Disposable Wipes (http://pdihc.com/all-products, or equivalent). Follow instructions for use of the wipes for appropriate germicidal effect. Care should be taken to prevent excess liquid from spilling into the connector jacks on the noddle™.
   b. The power cord and module can be cleaned and disinfected with PDI Germicidal Disposable Wipes (http://pdihc.com/all-products, or equivalent). Follow instructions for use of the wipes for appropriate germicidal effect.
   c. To avoid fluid accumulation on the noddle™, a dry wipe should be used after each application of a PDI Germicidal Disposable Wipe.

WARNING: Do not autoclave. This product contains a lithium-ion battery that can explode upon exposure to excessive heat.

WARNING: Do not clean with bleach solution.

B. Check the power cable and cables used to connect the noddle™ to the nurse call system are properly connected and that the noddle™ can activate the nurse call system.
   a. Determine that the power module is charging the noddle™
   b. Determine that the noddle™ is providing the requisite relay closure to activate the nurse call system.

C. Check that the noddle™ Bluetooth® is paired with the speech-generating device (SGD) the patient is using.
   a. Determine that the noddle™ is paired with the patient's SGD.
   b. Determine that the noddle™ is providing the SGD the Bluetooth® signals to control the SGD's switch selection scanning.

Routine and preventative maintenance to be performed by service personnel

1) noddle™ battery check and replacement
2) noddle™ software updates

Troubleshooting

Power

The noddle™ runs on either the supplied power adapter or its internal rechargeable battery. If the device power light is not illuminated, make sure that the power switch is turned to the 'On' position. Check that the power module is properly connected to the noddle™ in the micro-USB power port. The battery will be charged if the AC module is properly connected. If the noddle™ does not power up on the battery, or the battery does not appear to hold a charge, check that the power connection is secure and that the battery is charged. Depending on the age of the battery (and number of charging cycles) it may be necessary to replace the battery. If it is determined that the battery has reached its end of life, the battery *must* be replaced by Voxello technical repair staff. Do not attempt to change the battery.

Sensor

If the noddle™ does not appear to respond to signals from the sensor, check that that sensor is properly connected. If the sensor is not plugged in or improperly plugged in, then the Selection LED will continuously be illuminated red. If the connections are secure and there is still no response, replace or reposition the transducer.

Output connections

Cable to Nurse Call

If the noddle™ is responding to the sensor (the Selection LED is blinking appropriately) but is not activating the nurse call system, check the cable connection on the output of the noddle™ and at the headwall connection to the nurse call system. If the connections are secure but there is still no activation of the nurse call, replace the cable or reset the noddle™.

Cables to SGD

If a SGD is being used that does not have Bluetooth® connectivity and the noddle™ is responding to the sensor (the Selection LED is blinking appropriately) but is not activating the SGD, check the cable connection in the output connectors on the rear of the noddle™. If the connections are secure but there is still no activation of the SGD, replace the cable or reset the noddle™.

Bluetooth®

If the devices linked to the noddle™ via Bluetooth® are not responding, check that the Bluetooth® is connected. To prevent losing the connection with a paired device, it is important to set the AutoLock on those devices to the "Never" setting. Many devices drop their Bluetooth® connection when they go into sleep mode or are turned off. In those cases, it may be necessary to re-connect the noddle™ with those devices (see instruction on pairing above).

Technical Description

Application	
Indications for use	The noddle™ is intended for use by patients who have physical limitations or weaknesses and limited communication abilities in order to assist them with summoning and communicating with their caregiver by controlling other devices such as the nurse call and speech generation devices. To use the noddle™ patients should be sufficiently cognitively intact so that they can produce intentional gestures and intend to communicate with caregivers.
Applied standards	
IEC 60601-1:2005	
IEC 60601-1-2:2007	
ISO 14971:2007	
Dimensions of the noddle™	
Height x Width x Depth	14.2 cm x 8.9 cm x 8 cm
Weight	525 g
Power	
Power supply	5V, 1.2A DC USB power supply
Battery	3.7V, 580 mAh internal lithium-ion rechargeable battery
Classifications	
Protection against electric shock	IEC 60601-1 Class II, Type B
Protection against harmful ingress of water or particulate	IP00 (None)
Method of sterilization	PDI Germicidal Disposable Wipes
Mode of operation	Continuous
Wireless communication range	
After One Wall	16 meters
After Two Walls	18 meters
After Three Walls	10 meters
NOTE These values are approximate and may vary depending upon the RF environment.	
Wired output port specifications	
The output ports are designed to perform a switch closure in response to activation of the input sensor.	
Rated switching voltage	24 VDC
Rated switching current	1 A
Length of closure	100 ms
Expected operation lifetime	100,000 cycles

Operating environment	
Temperature	0 – 35 ºC
Humidity	10 – 75 %
Storage/transport environment	
Temperature	-20 – 45 ºC
Humidity	10 – 75 %
Manufacturer	
	Voxello 2500 Crosspark Road Coralville, IA 52241 USA

Guidance and manufacturer's declaration – electromagnetic emissions		
The noddle™ is intended for use in the electromagnetic environment specified below. The customer or the user of the noddle™ should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 2	The noddle™ must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The noddle™ is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The noddle™ is intended for use in the electromagnetic environment specified below. The customer or the user of the noddle™ should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the noddle™ requires continued operation during power mains interruptions, it is recommended that the noddle™ be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The noddle™ is intended for use in the electromagnetic environment specified below. The customer or the user of the noddle™ should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the noddle™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	0.058 m
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	d = 0.058 80 MHz to 800 MHz d = 0.12 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

			Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by and reflection from structures, objects and people.

a	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the noddle™ is used exceeds the applicable RF compliance level above, the noddle™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the noddle™.
b	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the noddle™.

The noddle™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the noddle™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the noddle™ as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
0.01	d = 0.12	d = 0.12	d = 0.23
0.1	d = 0.37	d = 0.37	d = 0.74
1	d = 1.2	d = 1.2	d = 2.3
10	d = 3.7	d = 3.7	d = 7.4
100	d = 12	d = 12	d = 23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The essential performance of the noddle™ for EMC testing was as follows:

- It is acceptable under immunity testing for the noddle™ to respond to spurious activation signals from the sensor. As a result of these spurious activations the noddle™ may send ‘space’, ‘newline’, and ‘u’ characters over Bluetooth® connection, which may activate speech generation functions on a connected

speech generation tablet. Also as a result of these acceptable spurious sensor activations the output ports 1, 2 or 3 may also switch closed.

- noddle™ may disconnect temporarily from Bluetooth® host if connected, but must re-connect to Bluetooth® host within 30 seconds after immunity testing is completed.
- noddle™ must retain power throughout test as indicated by lighted “Power” green LED next to USB power cable.
- noddle™ components must not sustain permanent damage from test.

Frequency band information						
Mode		**Min**		**Max**		
Receive (GHz)		2.402		2.480		
Transmit (GHz)		2.402		2.480		
Parameter	**Freq. (GHz)**	**Min.**	**Typ.**	**Max.**	**Bluetooth® Specification**	**Units**
Sensitivity at 0.1 BER	2.402	-	-80	-86	≤ -70	dBm
	2.441	-	-80	-86		dBm
	2.480	-	-80	-86		dBm
RF Transmit Power[1]	2.402	-	4	-		dBm
	2.441	-	4	-		dBm
	2.480	-	4	-		dBm
Initial Carrier Frequency Tolerance	2.402	-	4	-		kHz
	2.441	-	4	-		kHz
	2.480	-	4	-		kHz
20-dB Bandwidth for Modulated Carrier	-	-	900	1000	≤ 1000	kHz
Drift (Five Slots Packet)	-	-	15	-	40	kHz
Drift Rate	-	-	13	-	20	kHz
$\Delta f1_{avg}$ Maximum Modulation	2.402	140	165	175	>140	kHz
	2.441	140	165	175		kHz
	2.480	140	165	175		kHz
$\Delta f2_{avg}$ Minimum Modulation	2.402	140	190	-	115	kHz
	2.441	140	190	-		kHz
	2.480	140	190	-		kHz
[1] Normal mode						

WARNING: Service other than that expressed in the technical service manual should not be performed without authorization from the manufacturer.

Mains isolation

The power supply used for the noddle™ is certified to meet the requirements of 60601-1 mains isolation.

Service

Expected service lifetime

The noddle™ is intended as a durable medical device and should provide up to 5 years of service.

Checking device performance

In addition to the routine checks that are performed by hospital staff as part of setup, hospital technical maintenance staff should perform the following maintenance once every 6 months. Technical service personnel are required to be competent in basic electrical knowledge and testing.

Battery performance

1. Plug noddle™ into its power supply.
2. Ensure that the “Charge” LED illuminates. If it does not illuminate, leave noddle™ powered on and unplugged for one hour, then repeat step 3 and check LED again.
3. Allow noddle™ to fully charge, as indicated by the charge LED illuminating then shutting off.
4. Unplug noddle™ power to on position and unplug power cord.
5. Ensure that the LED next to the power switch labeled “Power” remains illuminated.
6. noddle™ must remain powered for at least one hour after full charge.
7. If the battery either does not charge or does not supply enough power to the device for one hour, please contact Voxello for troubleshooting, repair or replacement. Service fee may apply if device is outside of the warranty period.

Firmware version check

Voxello may occasionally update the noddle™ firmware. If an update is available a notification will be listed on the Voxello website along with compatible hardware versions, and the priority of the update. If a firmware update is desired or required noddle™ may then be sent to a service location for a firmware upgrade. Service fee may apply if device is outside of the warranty period.

Input performance check

Technical maintenance staff should check that all three modes of input operation – microphone tongue click detection, capacitive touch, and switch closure – are functional.

1. Power on noddle™.
2. Plug in approved microphone accessory.
3. Produce acceptable input gesture, and ensure that the noddle™ main indicator LED and piezo buzzer both activate.
4. Plug in approved capacitive touch accessory.
5. Produce acceptable input gesture, and ensure that the noddle™ main indicator LED and piezo buzzer both activate.
6. Plug in approved switch closure accessory.

7. Produce acceptable input gesture, and ensure that the noddle™ main indicator LED and piezo buzzer both activate.
8. If any of the input tests fail please contact Voxello for troubleshooting, repair or replacement. Service fee may apply if device is outside of the warranty period.

Output performance check

Technical maintenance staff should check that all outputs are functional.

1. Plug a supplied output connection cord into the output 1 jack. Using a multi-meter switched to Continuity Test Mode, connect one of the multi-meter leads at the tip and the other at the sleeve of the output connection cord. There should not be continuity.
2. Activate the single-gesture input. The continuity indicator buzzer on the multi- meter should sound for approximately 100 ms.
3. Plug a supplied output connection cord into the output 2 jack. Using a multi-meter switched to Continuity Test Mode, connect one of the multi-meter leads at the tip and the other at the sleeve of the output connection cord. There should not be continuity.
4. Activate the 2-gesture input. The continuity indicator buzzer on the multi-meter should sound for approximately 100 ms.
5. Plug a supplied output connection cord into the output 3 jack. Using a multi-meter switched to Continuity Test Mode, connect one of the multi-meter leads at the tip and the other at the sleeve of the output connection cord. There should not be continuity.
6. Activate the 3-gesture input. The continuity indicator buzzer on the multi-meter should sound for approximately 100 ms.
7. Connect to a Bluetooth® device as indicated in the instruction manual. Activate each of the 3 input gestures until a response is seen on the tablet.
8. If any of the output tests fail please contact Voxello for troubleshooting, repair or replacement. Service fee may apply if device is outside of the warranty period.

Replacement of components

Components should not be replaced with parts other than those specified in the manual. For replacement parts, please contact Voxello. Voxello may make available upon request circuit diagrams, component part lists, descriptions, calibration instructions or other information that will assist service personnel to repair the parts of the noddle™ that are designated by Voxello as repairable by service personnel.

WARNING: Use of components other than those specified could result in damage to the noddle™, patients, operators, or other equipment.

Disposal

Disposal of the noddle™

The noddle™ is intended for multiple uses. Cleaning should follow the facility's protocol for medical equipment cleaning and disinfecting. The noddle™ is intended to be used

through its intended service lifetime of 5 years. At the time of the expiration of its service lifetime, please return the noddle™ to Voxello for proper disposal. Do not dispose of the noddle™ in a landfill or in household refuse.

WARNING: Do not autoclave or burn for disposal. This product contains a lithium-ion battery that can explode upon exposure to excessive heat.

Further assistance

Online Tech Support

For online technical support, please visit www.voxello.com/support

Phone Tech Support

For assistance over the telephone please call 319-382-5459 between the hours of 8 AM and 5 PM CST Monday through Friday.

Warranty Information

Voxello provides a 1 year warranty on purchased devices through Voxello or authorized Voxello distributors and resellers. Voxello offers service contracts which may extend this warranty coverage up to 5 years. Contact Voxello or your local distributor for information regarding extended warranty coverage.