

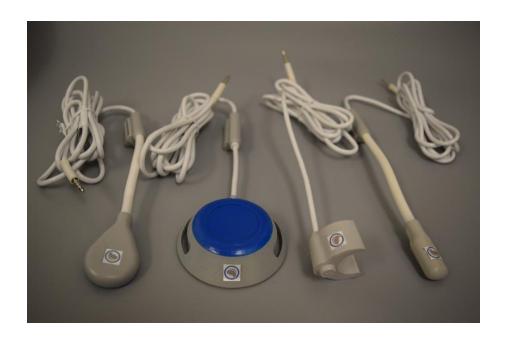
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noddle-mic[™] & noddle-touch[™] Sensor Instruction Sheets

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noddle-mic™ Sensor Instruction Sheet

Included Components

The noddle-mic[™] system consists of the following components and accessories:

noddle-mic[™] cervical collar-mounted sensor

Brand: Voxello™

o Part No.: 03-01-XXX-XXX

noddle-mic[™] Vent line/support arm-mounted sensor

Brand: Voxello™

o Part No.: 04-01-XXX-XXX

Warnings and Safety Notices



WARNING: Do not place noddle-mic[™] sensor in patient's mouth.

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

noddle-mic™ 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. More information on how to determine the patient's most reliable intentional gesture is given above in Patient-side sensor selection and positioning. However, if the patient has good control over tongue clicks and is able to produce four in succession, the noddle-mic[™] may be appropriate.

Some patients, due to their medical status, may benefit from one sensor at one point in time and a different sensor at a later point in time. Thus, it is important to continually check on the patient to ensure a good fit between a patient's abilities and the selected sensor. Voxello has developed two mounting options for patients using the noddle-mic[™].

The mounting options include:

1. noddle-mic™ vent circuit & vent circuit support arm clip mount





2. noddle-mic cervical collar mount





3. noddle-micTM on head band



Mounting noddle-mic[™] to a cervical collar or a headband

The noddle-mic[™] is ideal for mounting on a cervical collar. Their unique mounting system allows for a secure fit that ensures that the sensor does not fall out of reach of the patient while still remaining easily removable for care of the patient. To mount the noddle-mic[™] to a cervical collar please see below (4-7).

4. Unstrap the Velcro® strap on one side of the cervical collar.



5. Place the base of the noddle-mic[™] onto the Velcro® so that the Velcro® is attached.



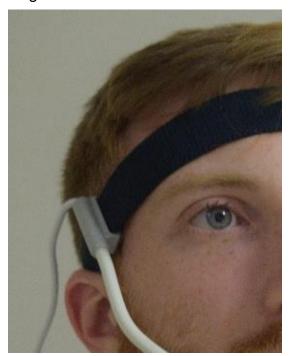
6. Slide the cervical collar's Velcro® strap through the slot at the base of the noddle™ sensor.



7. Secure the cervical collar's Velcro® strap to the Velcro® on the collar itself. The noddle™ sensor should be secure.



The noddle-micTM can also be used with an elastic head band. The head band can be pulled through the slot in the noddle-micTM sensor and adjusted to allow positioning of the sensor so that the patient's tongue clicks activate the noddleTM.



If using the noddle-mic[™] position the sensor near to the patient's mouth so that the microphone will pick up a tongue click. Ensure that the patient is able to activate the noddle[™] easily with a tongue click. Also ensure that the microphone sensor is positioned so that the patient does not breathe against it as this may cause unintentional activations.

8. Positioning microphone



Video Demonstration: Noddle Mic™ to Miami J Collar

Mounting the noddle-mic[™] to a vent line or vent line support arm

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

The noddle-mic[™] is also available in a vent line/support arm mounting option. This option is ideal for patients with a vent-line who may not be wearing a cervical collar. It is easily removable for ease of care for the patient while still maintaining a secure fit to ensure that it will not fall out of reach of the patient.

To install the noddle-mic[™] on a vent line or support arm, see the instructions below.

9. The noddle-mic[™] can only be attached to the vent line for patients who are endotracheally intubated.



10. The noddle-mic[™] should easily snap onto the vent line.



11. The noddle-mic[™] can also be clipped to the vent-line support arm with the supplied adapter.



12. Ensure that the microphone is properly positioned so that the patient can easily activate the noddle™ with a tongue click.

Video Demonstration: Noddle Mic™ to Vent

Disposal

noddleTM transducers are intended for single patient use only and are not to be disinfected and reused on multiple patients. They are to be disposed of following facility protocols for their medical equipment disposal.

Service

The noddle-mic[™] is not user serviceable. Contact Voxello if an issue arises with the noddle-mic[™] sensor.

Warranty

The noddle-mic[™] is free and clear from manufacturing defects for a period of 90 days from the point of sale.

noddle-touch™ and noddle bed-touch™ Sensor Instruction Sheet Included components

The noddle-touch™ system consists of the following component:

noddle-touch[™] sensor

Brand: Voxello™

o Part No.: 02-01-XXX-XXX

noddle bed-touchTM sensor

○ Brand: VoxelloTM

o Part No: 09-01-XXX-XXX

noddle-touch™ 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. More information on how to determine the patient's most reliable intentional gesture is given above in patient-side sensor selection and positioning. However, if the patient is able to put her tongue against her cheek and move it, the noddle-touch™ is the appropriate sensor.

Some patients, due to their medical status, may benefit from one sensor at one point in time and a different sensor at a later point in time. Thus, it is important to continually check on the patient to ensure a good fit between a patient's abilities and the selected sensor. Voxello has developed two mounting options for patients using the noddle-touch™.

Mounting options include:

1. noddle-touch™ cervical collar mount



noddle bed-touch™ can be placed on the bedding.



Mounting noddle-touch™ to a cervical collar

The noddle-touch $^{\text{TM}}$ is ideal for mounting on a cervical collar. Their unique mounting system allows for a secure fit that ensures that the sensor does not fall out of reach of the patient while still remaining easily removable for care of the patient. To mount the noddle-touch $^{\text{TM}}$ to a cervical collar, please see the instructions below.

3. Unstrap the Velcro® strap on one side of the cervical collar.



4. Place the base of the noddle-touch™ onto the Velcro® so that the Velcro® is attached.



5. Slide the cervical collar's Velcro® strap through the slot at the base of the noddle™ sensor.



6. Secure the cervical collar's Velcro® strap to the Velcro® on the collar itself. The noddle™ sensor should be secure.



If using the noddle-touch™ position the sensor near to the patient's cheek and ensure that it can be activated when the patient's tongue is pressed against his or her cheek.

7. Positioning touch sensor





Video Demonstration: Noddle Touch™ to Miami J

Mounting noddle bed-touch™ to bedding,

The noddle bed-touchTM can be clipped to bedding with clips or mounted on a pillow using a band. In both cases, care must be taken to ensure that the patient is able to access the sensor.

- 8. Clipping the sensor to bedding
- 9. Using a band to secure the sensor to a pillow

Disposal

noddleTM transducers are intended for single patient use only and are not to be disinfected and reused on multiple patients. They are to be disposed of following facility protocols for their medical equipment disposal.

Service

The noddle-touch™ is not user serviceable. Contact Voxello if an issue arises with the noddle-touch™ sensor.

Warranty

The noddle-touch™ is free and clear from manufacturing defects for a period of 90 days from the point of sale.