

Intended Use

The Salter Labs BiNAPS Airflow Pressure Transducer is intended for use with polysomnography equipment during sleep disorder studies for the purpose of detecting and amplifying breathing signals and detection of snoring in a sleeping patient. For use in the sleep study environment on pediatric and adult patients. This device is intended to be set-up and maintained by credentialed sleep lab technicians or qualified medical personnel

Caution/Warnings

- The BiNAPS System is for diagnostic purposes only and is not intended to be used as an apnea monitor or in a life sustaining situation.
- This device is not intended to be used with pediatric and infants as a respiratory or SIDS monitoring device.
- Use only with Salter Labs diagnostic cannulas.

Product Use

Airflow Output

Output is a nasal pressure airflow waveform. Output is connected to a polygraph's AC jackbox with 1.5mm safety connectors. Snoring can also be superimposed onto the airflow waveform. This is accomplished by setting higher values for the high frequency filter and the sampling rate for the airflow channel.

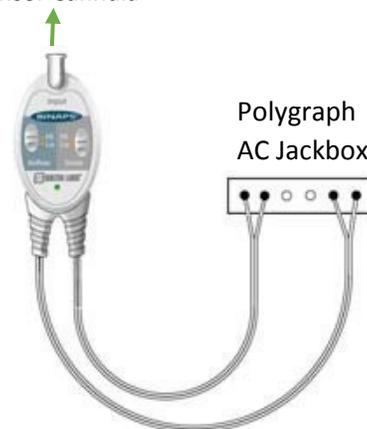
Snore Output

Output is a snoring waveform derived from snore vibrations on the nasal pressure signal. The channel has internal low frequency filter to remove the airflow signal and to provide a flat baseline between snores. Output is connected to a polygraph's AC jackbox with 1.5mm safety connectors.

Hi / Lo Switches

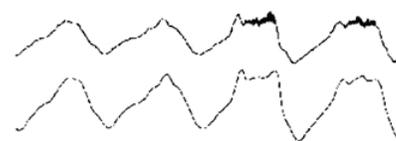
Are used as needed to optimize the airflow and snore signal levels into a polygraph AC jackbox. The "Hi" position will boost signal amplitudes by a factor of four, but will not boost signal amplitudes to DC input levels. The ThermiSense® Thermistor (5700) connects to the ThermiSense® Interface Box, which interfaces with most PSG head boxes.

Connect to
Salter Labs
Filtered Airflow
Sensor Cannula



Snore Output

Airflow output, filtered to allow snoring



Airflow output, filtered to eliminate snoring



Continued on next page.

BiNAPS Technical Bulletin (continued)

Integral Circuit Tester/Indicator

Plug each lead into the side port to verify signal. If a green light fails to illuminate, assume the device is defective and replace the BiNAPS. After testing, remove the leads from the indicator port.

Installation

1. Use Hook and Loop patches to secure the BiNAPS device to the AC jackbox or other convenient location.
2. Connect the "Airflow" leads to the selected polygraph AC jackbox inputs.
3. Connect the "Snore" leads to the selected polygraph AC jackbox inputs.
4. Apply the airflow sensor cannula to the patient similar to an oxygen nasal cannula.
 - a. Insert the prongs into the nares. Loop headset tubing over ears. Slide the bolo toward the neck to a comfortable fit. If needed, secure the cannula using a securement device, e.g. Tender Grip®.
 - b. Ensure the cannula sensor tips do not become blocked during installation or recording.
5. Plug the sensor cannula safety filter into the input of the BiNAPS sensor module with a slight twist to ensure a secure connection.
6. Adjust polygraph settings per the table below. These settings are recommended as starting points. Polygraph and patient variables can significantly influence the settings.

Polygraph Settings

Polygraph & BiNAPS Setting	Airflow	Snoring
High frequency filter	5Hz or higher	70 Hz or higher
Low frequency filter (Time Constant)	0.05Hz or lower (≥ 3 sec)	10Hz or lower (≥ 0.016 sec)
Sample rate	10Hz or higher	70 Hz or higher
Sensitivity	50uV/mm	50uV/mm
BiNAPS Hi/Lo Switch	Adjust for optimal signal amplitude	

Cleaning and Maintenance

The BiNAPS device is reusable and must be cleaned between patients.

1. Wipe the outside surface of the BiNAPS with a damp cloth and mild detergent, or an approved disinfectant. Refer to the table below. Follow the manufacturer's instructions for use and recommended exposure time.
2. DO NOT immerse or soak the BiNAPS device in liquid. DO NOT sterilize.
3. Ensure devices are completely dry before reusing.
4. Salter Labs sleep diagnostic cannulas are disposable and for single-patient use. Do not clean or sterilize or re-use.

Intermediate-Level Disinfectants

Disinfectant Solutions	Brand Name (Examples)
55%-70% Isopropyl alcohol	Super Sani-Cloth Wipes; CavaWipe Cloths
10% household bleach solution	Sani-Cloth® Bleach Disposable Wipes; Diluted household bleach

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