

NomoLine™

Airway Adapter Sets and Cannulas

Single-patient use sampling lines

PART NUMBERS: 3801 to 3839, 4367 to 4369



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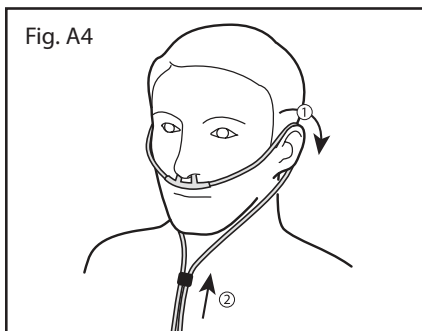
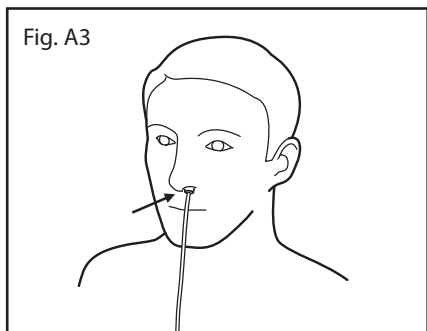
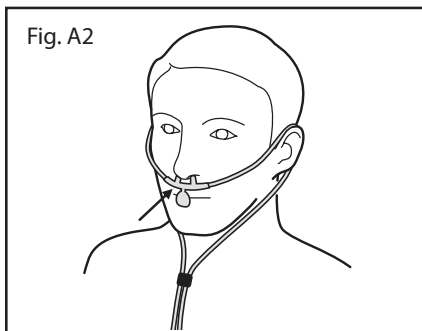
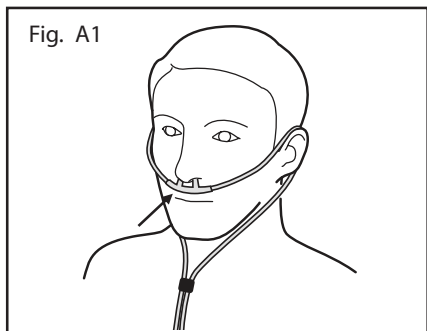
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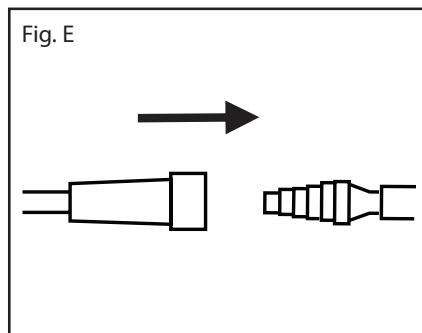
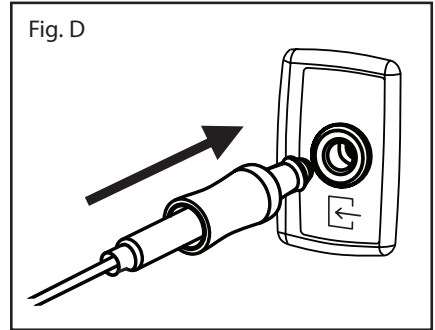
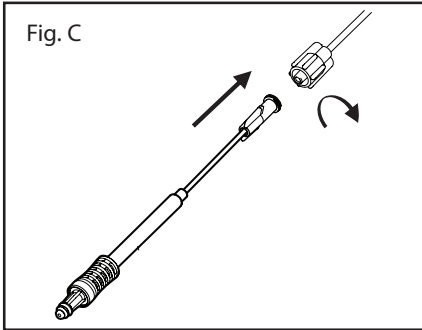
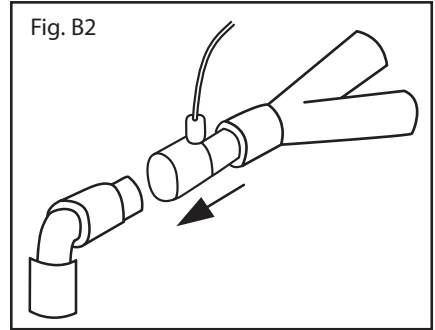
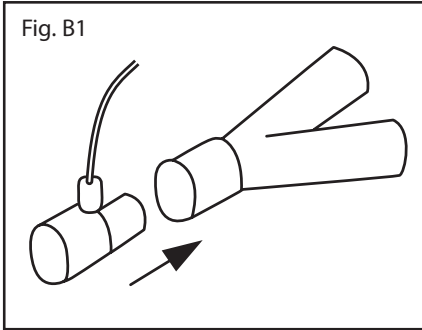


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DIRECTIONS FOR USE

⊗ Single Patient Use Only

⊗ Not made with natural rubber latex

INDICATIONS

The NomoLine™ Product Family is indicated for the measurement of respiratory rate and respiratory and anesthetic gases in adult, pediatric, infant and neonatal patients. The NomoLine Product Family includes single-patient use and multi-use devices for gas sampling and/or oxygen delivery. The NomoLine Product Family is indicated for use by clinical professionals in healthcare environments, including mobile environments.

WARNINGS

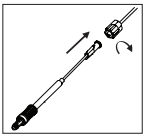
- Carefully route the NomoLine Sampling Line to reduce the risk of patient entanglement or strangulation.
- Do not apply negative pressure to remove condensed water.
- Dispose in accordance with local regulations for biohazardous waste.
- Do not submerge the NomoLine Sampling Line in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method as this may seriously damage the NomoLine Sampling Line.
- Do not re-use due to cross contamination risk.
- Always replace the NomoLine Sampling Line if an occlusion alarm occurs.
- Do not use NomoLine Cannulas on patients with obstructions in one or both nostrils.
- The CO₂ measurement can be diminished if NomoLine Cannulas are used during mouth breathing or on a patient that has a perforated septum.
- Do not use NomoLine Adult/Pediatric Airway Adapter Sets for infants/neonates as the adapter adds 6 ml dead space.
- Do not use NomoLine Infant/Neonatal Airway Adapter Sets for adults/pediatrics as this may cause excessive flow resistance (0.7 ml dead space).
- Do not use NomoLine Airway Adapter Sets with inhalers or nebulized medications as this may clog the bacteria filter.

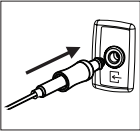
DESCRIPTION

NomoLine Sampling Lines include nasal and nasal/oral cannulas for non-intubated patients and airway adapter sets for intubated patients. The NomoLine Sampling Lines are accessories to the Masimo ISA sidestream gas analyzers. Refer to the ISA User's Guide for technical specification and full system use instructions for the ISA product system.

The table below describes the two groups of NomoLine single-patient use sampling lines:

- Group 1 (part number 3801–3813 and 4368) is intended to be used with NomoLine HH Multi-Patient Use Adapter (part number 3800) that connects to the ISA gas inlet connector. See separate DFU for instructions regarding the NomoLine HH Multi-Patient Use Adapter.
- Group 2 (part number 3814–3839, 4367 and 4369) is intended to be directly connected to the ISA gas inlet connector.

<p style="text-align: center;">NomoLine Airway adapter sets and Cannulas – single-patient use sampling lines PART NUMBER – PRODUCT NAME</p>	<p style="text-align: center;">CONNECTS TO</p>
<p>3801 – NomoLine Adult/Pediatric Airway adapter set with Luer 3802 – NomoLine Adult/Pediatric Airway adapter set 3m with Luer 3803 – NomoLine Infant Airway adapter set with Luer 3804 – NomoLine Adult Nasal CO₂ Cannula with Luer 3805 – NomoLine Pediatric Nasal CO₂ Cannula with Luer 3806 – NomoLine Infant Nasal CO₂ Cannula with Luer 3807 – NomoLine Adult Nasal CO₂ Cannula with O₂ and Luer 3808 – NomoLine Pediatric Nasal CO₂ Cannula with O₂ and Luer 3809 – NomoLine Adult Nasal/Oral CO₂ Cannula with Luer 3810 – NomoLine Pediatric Nasal/Oral CO₂ Cannula with Luer 3811 – NomoLine Adult Nasal/Oral CO₂ Cannula with O₂ and Luer 3812 – NomoLine Pediatric Nasal/Oral CO₂ Cannula with O₂ and Luer 3813 – NomoLine Adult Single Nasal Prong CO₂ Cannula with Luer 4368 – NomoLine Infant/Neonatal Airway adapter set with Luer</p>	<p style="text-align: center;">3800 NomoLine Multi-Patient Use Adapter</p> 

<p style="text-align: center;">NomoLine Airway adapter sets and Cannulas – single-patient use sampling lines PART NUMBER – PRODUCT NAME</p>	<p style="text-align: center;">CONNECTS TO</p>
<p>3814 – NomoLine LH Adult/Pediatric Airway adapter Set 3815 – NomoLine LH Adult/Pediatric Airway adapter set 3m 3816 – NomoLine LH Infant Airway adapter set 3817 – NomoLine LH Adult Nasal CO₂ Cannula 3818 – NomoLine LH Pediatric Nasal CO₂ Cannula 3819 – NomoLine LH Infant Nasal CO₂ Cannula 3820 – NomoLine LH Adult Nasal CO₂ Cannula with O₂ 3821 – NomoLine LH Pediatric Nasal CO₂ Cannula with O₂ 3822 – NomoLine LH Adult Nasal/Oral CO₂ Cannula 3823 – NomoLine LH Pediatric Nasal/Oral CO₂ Cannula 3824 – NomoLine LH Adult Nasal/Oral CO₂ Cannula with O₂ 3825 – NomoLine LH Pediatric Nasal/Oral CO₂ Cannula with O₂ 3826 – NomoLine LH Adult Single Nasal Prong CO₂ Cannula 3827 – NomoLine HH Adult/Pediatric Airway adapter Set 3828 – NomoLine HH Adult/Pediatric Airway adapter set 3m 3829 – NomoLine HH Infant Airway adapter set 3830 – NomoLine HH Adult Nasal CO₂ Cannula 3831 – NomoLine HH Pediatric Nasal CO₂ Cannula 3832 – NomoLine HH Infant Nasal CO₂ Cannula 3833 – NomoLine HH Adult Nasal CO₂ Cannula with O₂ 3834 – NomoLine HH Pediatric Nasal CO₂ Cannula with O₂ 3835 – NomoLine HH Adult Nasal/Oral CO₂ Cannula 3836 – NomoLine HH Pediatric Nasal/Oral CO₂ Cannula 3837 – NomoLine HH Adult Nasal/Oral CO₂ Cannula with O₂ 3838 – NomoLine HH Pediatric Nasal/Oral CO₂ Cannula with O₂ 3839 – NomoLine HH Adult Single Nasal Prong CO₂ Cannula 4367 – NomoLine HH Infant/Neonatal Airway adapter set 4369 – NomoLine LH Infant/Neonatal Airway adapter set</p>	<p style="text-align: center;">ISA gas inlet connector</p> 

INSTRUCTIONS

- Open the bag and remove the NomoLine Sampling Line. For convenient preparations, do not yet remove the tape that keeps the tubing coiled.

A. Fitting a NomoLine Cannula to the patient

- If fitting a NomoLine Nasal CO₂ Cannula refer to **Fig. A1**: Insert the prongs into the nostrils.
- If fitting a NomoLine Nasal/Oral CO₂ Cannula refer to **Fig. A2**: Insert the prongs into the nostrils and position the oral scoop in front of the mouth.
- If fitting a NomoLine Single Nasal Prong CO₂ Cannula refer to **Fig. A3**: Insert the prong in one of the nostrils.
- Refer to **Fig. A4**: Pass the Cannula lines over the ears (1) and adjust the slider for comfort and fit under the chin (2). (This step does not apply to NomoLine Single Nasal Prong CO₂ Cannula.)

B. Connecting a NomoLine Airway Adapter Set to the patient circuit

- Refer to **Fig. B1**: Connect the small diameter end of the Airway Adapter to the Y-piece of the ventilation source.
- Refer to **Fig. B2**: Connect the large diameter end of the Airway Adapter to the patient's endotracheal tube.

C. Connecting a NomoLine Sampling Line with Luer to NomoLine HH Multi-Patient Use Adapter

- Refer to **Fig. C**: Connect the male Luer of the NomoLine Sampling Line to the female Luer of the NomoLine HH Multi-Patient Use Adapter with a twisting motion.

D. Connecting a NomoLine Sampling Line to the ISA gas analyzer

- Refer to **Fig. D**: Remove the tape that keeps the tubing coiled. Connect the NomoLine Sampling Line to the ISA gas inlet connector. A steady green light indicates that the NomoLine Sampling Line is correctly connected to ISA.
- Ensure that the tubing is properly connected and that it is not twisted or crimped.

E. Connecting a NomoLine Cannula to an oxygen source

- Refer to **Fig. E**: Remove the tape that keeps the tubing coiled. Attach the oxygen supply tubing to the oxygen source. Adjust the oxygen flow. (This step applies only to NomoLine Cannulas with O₂.)
- Ensure that the tubing is properly connected and that it is not twisted or crimped.

REPLACEMENT

NomoLine Sampling Lines are single patient use products and should after use be disposed of in accordance with local regulations for biohazardous waste and replaced for each new patient with a maximum of 14 days of use*. They should also be replaced if the sampling line becomes occluded. Occlusion is indicated by a red flashing light on the ISA gas inlet connector. Replace the NomoLine Sampling Line and wait until the gas inlet connector switches to a steady green light.

* *The lifetime of the product depends on the application and product type.*

For NomoLine Sampling Lines with Luer (part number 3801–3813 and 4368) connected to NomoLine HH Multi-Patient Use Adapter (part number 3800) after use:

- Keep the NomoLine HH Multi-Patient Use Adapter connected to the ISA gas inlet connector.
- Remove and discard the disposable, single-patient use NomoLine Sampling Line according to local regulations for biohazardous waste.
- Clean the NomoLine HH Multi-Patient Use Adapter (see separate DFU for cleaning instructions regarding the NomoLine HH Multi-Patient Use Adapter).
- Connect the new Sampling Line to the female Luer of the NomoLine HH Multi-Patient Use Adapter.

For NomoLine Sampling Lines (part number 3814–3839, 4367 and 4369) directly connected to the ISA gas inlet connector after use:

- Remove and discard the disposable, single-patient use NomoLine Sampling Line according to local regulations for biohazardous waste.
- Connect the new Sampling Line to the ISA gas inlet connector.

CLEANING

NomoLine Sampling Lines (part number 3801–3839 and 4367 to 4368) are single-patient use products and should after use be disposed of in accordance with local regulations for biohazardous waste.

To clean the NomoLine HH Multi-Patient Use Adapter (part number 3800) see separate DFU for cleaning instructions regarding the NomoLine HH Multi-Patient Use Adapter.

DISPOSAL

The NomoLine Sampling Line may after use contain accumulated moisture and fluids. Dispose the used product in accordance with local regulations for biohazardous waste.

WARRANTY

MASIMO WARRANTS TO THE INITIAL BUYER ONLY THAT THESE PRODUCTS, WHEN USED IN ACCORDANCE WITH THE DIRECTIONS PROVIDED WITH THE PRODUCTS BY MASIMO, WILL BE FREE OF DEFECTS IN MATERIALS AND WORKMANSHIP FOR A PERIOD OF SIX (6) MONTHS. SINGLE USE PRODUCTS ARE WARRANTED FOR SINGLE PATIENT USE ONLY. THE FOREGOING IS THE SOLE AND EXCLUSIVE WARRANTY APPLICABLE TO THE PRODUCTS SOLD BY MASIMO TO BUYER. MASIMO EXPRESSLY DISCLAIMS ALL OTHER ORAL, EXPRESS OR IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. MASIMO'S SOLE OBLIGATION AND BUYER'S EXCLUSIVE REMEDY FOR BREACH OF ANY WARRANTY SHALL BE, AT MASIMO'S OPTION, TO REPAIR OR REPLACE THE PRODUCT.

WARRANTY EXCLUSIONS






















This warranty does not extend to any product that has been used in violation of the operating instructions supplied with the product, or has been subject to misuse, neglect, accident or externally created damage. This warranty does not extend to any product that has been connected to any unintended instrument or system, has been modified, or has been disassembled or reassembled. This warranty does not extend to products that have been reprocessed, reconditioned or recycled.

IN NO EVENT SHALL MASIMO BE LIABLE TO BUYER OR ANY OTHER PERSON FOR ANY INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION LOST PROFITS), EVEN IF ADVISED OF THE POSSIBILITY THEREOF. IN NO EVENT SHALL MASIMO'S LIABILITY ARISING FROM ANY PRODUCTS SOLD TO BUYER (UNDER A CONTRACT, WARRANTY, TORT OR OTHER CLAIM) EXCEED THE AMOUNT PAID BY BUYER FOR THE LOT OF PRODUCT(S) INVOLVED IN SUCH CLAIM. IN NO EVENT SHALL MASIMO BE LIABLE FOR ANY DAMAGES ASSOCIATED WITH A PRODUCT THAT HAS BEEN REPROCESSED, RECONDITIONED OR RECYCLED. THE LIMITATIONS IN THIS SECTION SHALL NOT BE DEEMED TO PRECLUDE ANY LIABILITY THAT, UNDER APPLICABLE PRODUCTS LIABILITY LAW, CANNOT LEGALLY BE PRECLUDED BY CONTRACT.

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

The following symbols may appear on the product or product labeling:

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Follow Instructions for Use		Masimo reference number
	Manufacturer		Body weight
	Use By YYYY-MM-DD		Less than or equal to
	Do not re-use/Single Patient Use only		Storage Temperature Range
	Not made with natural rubber latex		Storage Humidity Range
Rx ONLY	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician		Storage Atmospheric Pressure Range
	Mark of Conformity to European Medical Device Directive 93/42/EEC		Gas sample
	Keep Dry		Collects water. Short term applications with low humidity
	Lot code		Removes aspirated and condensed water. Long term applications with high humidity
	Catalogue number (model number)		Use with NomoLine HH Multi-Patient Use Adapter
	Do not use if package is damaged		Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs Note: eIFU is not available for CE mark countries.

Patents: <http://www.masimo.com/patents.htm>

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Date of Issue: 2017-11-02

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