Parker Hannifin Corporation
245 Township Line Road
Hatfield, PA 19440 USA
Office 215-723-4000

Disposable Medical Breathing Circuit, Second Generation

Instructions for Use and Installation Guide

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https://www.porterinstrument.com/

Representation

	**Legal Manufacturer**	Parker Hannifin Corporation Precision Fluidics Division 245 Township Line Road Hatfield, PA 19440 USA Office: (215) 723-4000
	**European Communities Authorized Representative**	EMERGO Europe Westervoortsedijk 60 6827 AT Arnhem, The Netherlands Tel: +31 70 345 8570
	**Conformité Européenne (CE) Mark**	Compliance with conformity assessment on quality management system and technical documentation per Regulations (EU) 2017/745 for Medical Device, Annex IX Chapters i & III
	**Switzerland Authorized Representative**	Medenvoy Gotthardstrasse 28 6302 Zug Switzerland +41 41 562 01 42

READ INSTRUCTIONS FOR USE COMPLETELY BEFORE OPERATING THIS DEVICE

This document contains warnings, cautions, instructions for use, and maintenance information that the user must completely comprehend before using this device. Failure to properly operate and maintain this device may result in patient/user harm and/or damage to equipment.

Table of Contents

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

Visit our website: www.porterinstrument.com/medical for additional information.

To download Instructions for Use: visit https://www.porterinstrument.com/medical-support
Choose “Breathing Circuits” from the dropdown within the “Product Download” section.

1. Device Information

1.1. Intended Use/Intended Purpose

The Disposable Medical Circuit (DMC) is intended to deliver a mixture of nitrous oxide and oxygen gases to a patient through an inhalation route and scavenge waste analgesic gas through an exhalation route.

1.2. Models

The DMC is a dual limb circuit available in 2 lengths, 6 feet or 10 feet, and require an anaesthetic mask or a mouthpiece to be attached prior to patient use (see options below). All instructions and information are the same for all models unless specified otherwise.

Device Model Table

Model Type	Model Number	Model Description
Disposable Medical Circuits	DMC-12-6*	Porter Disposable Medical Circuit, Pack of 20, 6 Feet
	DMC-12-10*	Porter Disposable Medical Circuit, Pack of 20, 10 Feet

*Denoted as CE Certified and available on European Market. Other models may be available on other international markets.

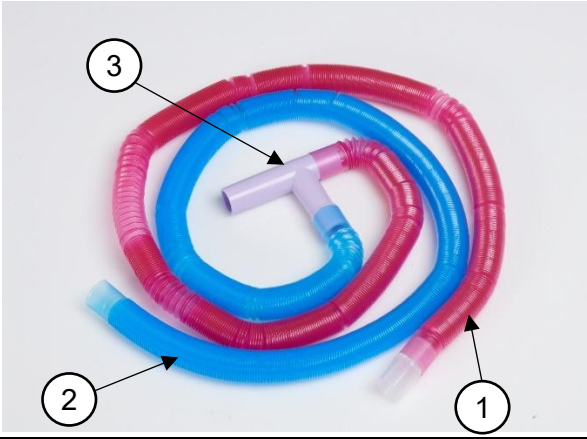
Accessories Model Table

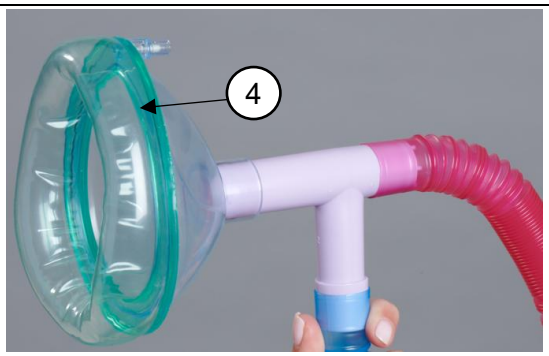
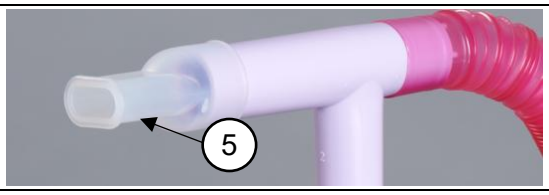
Model Type	Model Number	Model Description
Face Masks	DMC-LARGE*	Porter Disposable Mask Large
	DMC-MEDIUM*	Porter Disposable Mask Medium
	DMC-SMALL*	Disposable Mask Small
	DMC-PEDO*	Disposable Mask Pediatric
Mouthpiece	61988000*	Disposable Mouthpiece
Vacuum Controllers	5400SCAVPLUS*	Scavenger Plus

*Denoted as CE Certified and available on European Market. Other models may be available on other international markets.

1.3. User Interface

#	Description
1	Vacuum tubing / Exhalation Tubing (Magenta)
2	Fresh Gas Tubing (Blue)
3	T-Handle



4	Face Mask (not included)	
5	Mouthpiece (not included)	

1.4. General Description/Principles of Operation

The DMC is a device composed of an inhalation tubing line, exhalation tubing line, and face mask or mouthpiece. The device features a single tube (blue) that delivers oxygen or a mixture of nitrous oxide (N_2O) and oxygen (O_2) to the patient and evacuates the patient exhalation through exhalation tubing line (magenta). The magenta hose connects to the vacuum control interface. The device features a one-way valve that prevents patient rebreathing. The blue tube is connected to the port perpendicular to the vacuum and breathing port of the T-handle. The face mask is provided in four different sizes (pediatric, small, medium, large) for proper fit on the patient's nose and mouth. The mouthpiece is available in one size and is meant for mouth breathing only.

The DMC is connected to a N_2O and O_2 gas mixing, conscious sedation device and a vacuum control device. The mixed gas is delivered to a patient either through continuous flow or demand flow through the inhalation line with the use of a face mask or mouthpiece. The patient is able to inhale the mixed gas using normal respiratory effort.

The exhalation line of the device is connected to a vacuum source, which removes the exhaled waste analgesic gas and any gas that was not inhaled by the patient from the face mask or mouthpiece component. The vacuum source then removes the gas from the healthcare facility. Scavenging of waste analgesic gas ensures that the healthcare practitioner's exposure to nitrous oxide is limited to low levels of parts per million.

The DMC is equipped with safety features described in Section 1.8.

1.5. Use of the Device

The DMC is to be used by a healthcare professional trained in the use and administration of N_2O and O_2 gases. The device is designed for use in a gas delivery and scavenging system for pain management and / or minimal conscious sedation, which is ideal for short, minimally invasive procedures to alleviate patient anxiety or minor pain and discomfort. It is the responsibility of the medical professional to consider the side effects, contraindications, and risks associated with administration of N_2O and use of conscious sedation.

The DMC is not used for the administration of general anesthesia or as part of, or in conjunction with, a general anesthesia administration system. The user should observe the patient to prevent over sedation in the event of an O_2 failsafe malfunction or crossed lines. If a patient becomes overly sedated when being delivered 100% O_2, immediately remove the face mask or mouthpiece, and encourage

mouth breathing. This is an indication of a failsafe malfunction or crossed lines; in this case, only deliver pure O_2 from an independent source.

WARNING: Do not use this device for the administration of general anesthesia or as part of, or in conjunction with, a general anesthesia administration system.

NOTE: If a serious incident (death or any intervention) has occurred while the device was in use, it should be reported to the manufacturer immediately and the Competent Authority of the member state in which the serious incident occurred.

1.6. Patient Population

The patient population includes conscious, spontaneously breathing, awake, alert, and cooperative patients.
Patients are selected by a medical professional trained in the use and administration of nitrous oxide and oxygen gases. The medical professional must consider patients who are able to receive the gas mixture based on the risks associated with conscious sedation.

1.7. Warnings and Cautions

Warnings and cautions are listed where relevant to a certain section of this document.

A **WARNING** is an instruction, procedure, or explanation of hazards that may result in injury.

A **CAUTION** is an instruction, procedure, or explanation of hazards that may result in damage to a product, equipment, or the environment.

WARNINGS and **CAUTIONS** are presented throughout the document along with this symbol to alert the reader of their presence.

1.8. Safety Features

One-way Valve:

The Disposable Medical Circuit includes a flapper valve that prevents the patient from re-breathing exhaled waste analgesic gas.

Single-Use Disposable Design:

The entire circuit, face mask, and mouthpiece are all designed to be single-use and are completely disposable to prevent cross-contamination between patients.

WARNING: The Disposable Medical Circuit is not intended or expected to be used during an MR exam and has not been evaluated for safety and compatibility in the MR environment. The safety of the Disposable Medical Circuit in the MR environment is unknown, but due to the presence of materials in the device's accessories that may be ferromagnetic, the Disposable Medical Circuit should be considered "MR Unsafe" and should be kept outside of any MRI scanner rooms.

WARNING: Workers exposed to nitrous oxide may suffer harmful effects. The healthcare professional is responsible for employing proper techniques, such as scavenging, room ventilation, system maintenance, and patient compliance to reduce exposure (ACGIH recommends a Threshold Limit Value of 50 parts per million over an 8-hour time-weighted average)

WARNING: The Disposable Medical Circuit is used with the delivery of Oxygen (O_2). Therefore, when this device is used in conjunction with energy producing devices (such as lasers, radio frequency sources, or other heat sources), the user must adhere to the instructions for use of those devices to avoid ignition of combustible materials.

1.9. Delivery Protocols

It is the responsibility of the medical establishment and the healthcare professional to develop specific delivery protocols for administration of N_2O using the DMC. Specific delivery protocols for adult and pediatric patients should be developed.

The DMC is considered transient (less than 60 minutes) in terms of continuous use when providing analgesia (minimal sedation). Procedures that occur intermittently over the course of many hours may also be considered transient. The upper limit of use duration is at the discretion of the medical professional.

1.10. Safe Combination of devices

The DMC is designed to be used within a nitrous oxide/oxygen conscious sedation delivery and scavenging system to deliver an accurate mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device system is also used to remove exhaled waste analgesic gas through a vacuum control interface. The system is comprised of a series of devices and accessories, which includes a demand or continuous flow system, breathing circuit with face mask or mouthpiece, vacuum control interface, mounting stand, and gas supply hoses.

To ensure safe combination of device, user should follow the installation instructions in **Section 2** below and ensure all connections are secure and tight.

1.11. Specification

Dimensions

Tubing (model dependent): 70.867 in (180.00 cm)
OR 118.11 in (300 cm)
T-Handle: 3.8 in L x 3.0 in H x 0.9 in W
(9.65 cm L x 7.62 cm H x 2.29 cm W)
Connector: 1.75 in L (4.45 cm L)

Face Mask Sizing

Pediatric
Small
Medium
Large

Connections

Mixed Gas Inlet: Fresh Gas Tube connect to 22mm connection.

Vacuum: Fresh Gas and Vacuum Tube connect to 19mm connection.

Face Mask/Mouthpiece Connection: 22mm

Weight

DMC-12-6: 0.292 lbs. (0.132 kg)
DMC-12-10: 0.529 lbs. (0.240 kg)

Atmospheric Pressure

1 atm ± 0.2 atm (101 kPa ± 20 kPa)

Environmental

Temperature

Storage/Transport: 23°F - 86°F
(-5°C - 30°C)
Operational: 23°F - 86°F
(-5°C - 30°C)

Relative Humidity

Storage/Transport: ambient
Operational: ambient, non-condensing

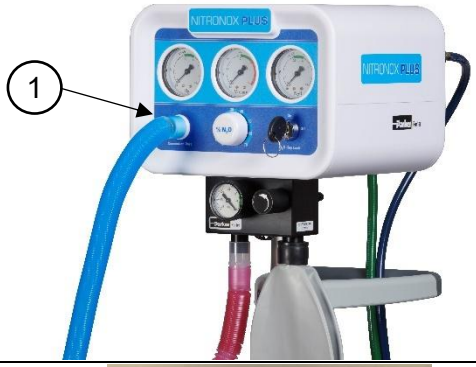
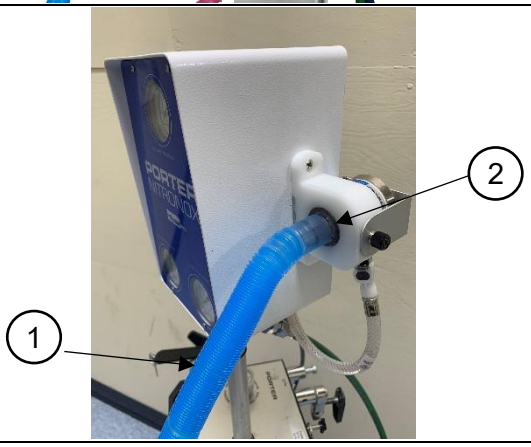
2. Installation Instructions

WARNING: For centrally piped facilities, properly connected gas pipelines are essential to patient safety. The ultimate responsibility of assuring that lines are not crossed rests with the user. Per NFPA 99, the certified medical gas plumber, and verifier, should provide written documentation that all gas pipelines are connected properly and that all use points of the system have been tested prior to use. It is important that the user verify by their own test that all gas pipelines are connected properly prior to using the system.

2.1. Expanding Tubing Instructions

1	When expanding the tubing of the circuit, ensure to hold the tubing below the T-Handle.	

2.2. Connecting the Conscious Sedation Device

Conscious Sedation Device Connection		
1	Ensure tubing is expanded to desire length before connecting to vaccum controller. Refer to section 2.1 for expanding instructions.	
2	**Connecting to Nitronox Plus Models** Connect the Fresh Gas Tubing (Blue) of the **Disposable Medical Circuit** to the **Connection Port** (1) on the front of the Nitronox Plus	
3	**Connecting to Nitronox HD Models** Connect the Fresh Gas Tubing (Blue) of the **Disposable Medical Circuit** (1) to the to the **Connection Port** (2) on the side of the Nitronox HD	
4	Connect the **magenta scavenging hose** to the scavenging device; if not using a scavenger, the magenta hose may hang freely.	

2.3. Compatible Vacuum Controller Accessories

Nitronox Scavenger Plus


2.3.1. Connecting the Vacuum Controller

Nitronox Scavenger Tube		
1	Ensure tubing is expanded to desire length before connecting to vaccum controller. Refer to section 2.1 for expanding instructions.	
2	**Connecting to Nitronox Scavenger Plus Models** Connect the **Magenta Hose** to the scavenger port on the **Nitronox Scavenger Plus** (1).	
3	Ensure all connections are tight and secure	

3. Instructions for Use

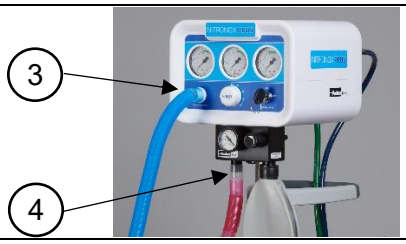
3.1. Setup and Prechecks

WARNING: The user should observe the patient to prevent over sedation in the event of an O_2 failsafe malfunction or a crossed lines situation. If a patient becomes overly sedated when being delivered 100% O_2, immediately remove the mask and encourage mouth breathing. This is an indication of a failsafe malfunction or crossed lines. In this case, only deliver pure O_2 from an independent source.

WARNING: Always use clean, dry, medical grade gases, and never oil or grease any part of the device.

1	Ensure device is properly connected (described in **Section 2 Installation Instructions**).
2	Before using the DMC, check the following: • Face Mask and Mouthpiece connections are secure. • Hose connections are secure. • The circuit is free of physical damage
3	Ensure vacuum system is operating. **Note:** The American Dental Association recommends 45 LPM scavenging flow.

3.2. Operating Instructions for Disposable Medical Circuit

1	Before the procedure starts, if desired, adjust the conscious sedation device to 100% O2 ensuring the patients first breaths are 100% O2.	
2	When expanding the tubing of the circuit, ensure to hold the tubing below the T-Handle.	
3	Attach the **face mask** (1) or mouthpiece (both not included) to the **T-Handle** (2) of the Disposable Medical Circuit. **Note:** Do not use strap on face mask. **Note:** If tube is removed from T-Handle connection, reattach the tubing.	
4	Attach the **fresh gas tubing** (3) of the circuit (Blue Tube) to the delivery system.	
5	Attach the **waste gas tubing** (4) of the circuit (Magenta Tube) to the Scavenger Control Device.	
6	Instruct the patient to inhale through the face mask or mouthpiece. Patient should also be instructed to exhale through the face mask or mouthpiece to achieve effective scavenging.	
7	Monitor the vacuum conditions during the procedure and adjust vacuum flow as necessary to maintain effective scavenging.	
8	If patient shows signs or communicates conditions of over-sedation, adjust the conscious sedation device to 100% O_2 or encourage room air breathing.	
9	At The completion of the procedure, administer 100% O_2 for several minutes to remove excess N_2O and prevent N_2O exposure in the environment. Remove the breathing circuit from the patient and dispose of.	

4. Maintenance

The DMC is a single-use disposable device and does not require maintenance. The DMC can be used for a maximum of three (3) years after the date/lot: YYYY-MM-DD found on the device label.

WARNING: Proper inspection of this device is essential to prevent gas leaks. All hoses, fittings, and connections should be inspected.

WARNING: Do not modify this equipment without authorization of the manufacturer.

WARNING: Proper inspection of this device is essential to prevent gas leaks. All hoses, fittings, and connections should be inspected.

WARNING: Do not use or replace any components or accessories, except those specified in these instructions for use and installation guide.

4.1. Cleaning

The DMC is a single-use disposable device and should not be cleaned.

WARNING: When using single-use breathing circuit components, dispose of after the procedure to prevent patient cross-contamination. Do not attempt to clean, sterilize, sanitize, or reuse.

1	**Disposal (no cleaning)** Disposable components listed below are Single Use Only: ▪ Disposable Medical Circuit ▪ Face Mask ▪ Mouthpiece	

4.2. Disposal

It is best practice to inquire with local authorities for proper disposal guidelines, if applicable

5. Symbols Glossary

The following symbols may use throughout this document, as well as on device labels and packaging.

Symbol	Title of Symbol	Description of Symbol
	**Manufacturer Information**	Indicates the medical device manufacturer and is accompanied by the name and address of the manufacturer. [EN ISO 15223-1:2021, clause 5.1.1]
	**Date of manufacture and Country of Manufacture**	Indicates the country where the device was manufactured. Also Indicates the date when the device was manufactured. This symbol is accompanied by four digits for the year the device was manufactured. (EN ISO 15223-1:2021, clause 5.1.3, 5.1.11]
	**Catalog Number**	Indicates the manufacturer's catalog number of the device and is used for identification of the device. [EN ISO 15223-1:2021, clause 5.1.6]
	**Serial Number**	Indicates the manufacturer's serial number of the device and is used for identification of the specific device. [EN ISO 15223-1:2021, clause 5.1.7]

Symbol	Title of Symbol	Description of Symbol
	**Unique device identifier**	Indicates a carrier that contains unique device identifier information [EN ISO 15223-1:2021, clause 5.7.10]
	**Prescription device**	Indicates that federal law restricts this device to sale by or on the order of a physician or dentist.
	**Medical Device**	Indicates the item is a medical device. [EN ISO 15223-1:2021, clause 5.7.7]
	**Do not re-use**	Indicates a medical device that is intended for one single use only. [EN ISO 15223-1:2021, clause 5.4.2]
	**Consult Instructions for Use**	Indicates the need for the user to consult the instructions for use. [EN ISO 15223-1:2021, clause 5.4.3]
	**Caution**	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot be presented on the medical device itself. [EN ISO 15223-1:2021, clause 5.4.4]
	**Caution/Warning**	Indicates important cautionary or warning information to the user that is presented in the instructions for use that accompanies explanatory instructions to the user. [EN ISO 15223-1:2021, clause 5.4.4]
	**European Community Authorized Representative**	Indicates the authorized representative in the European Community (European Union) [EN ISO 15223-1:2021, clause 5.1.2]
	**Switzerland Authorized Representative**	Indicates the authorized representative in Switzerland. [MU600_00_016e / V3.0]
	**Conformité Européenne (CE) Mark**	Indicates that the product may be traded freely in any part of the European Economic Area, regardless of its country of origin. Note the number below the CE Mark does not appear for low-risk devices. [2017/745 EU Annex V]
	**Does not contain DEHP**	Indicate a medical device does not contain the phthalate plasticizer DEHP. [BS EN 15986 Annex A.2]

Symbol	Title of Symbol	Description of Symbol
	**Does not contain natural rubber latex**	Indicate a medical device or its packaging is "not made with natural rubber latex. [EN ISO 15223-1:2021, clause 5.4.5]
	**Non-sterile**	Indicates a medical device that has not been subjected to a sterilization process. [EN ISO 15223-1:2021, clause 5.2.7]
	**Do not use if package is damaged and consult instructions for use**	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information. [EN ISO 15223-1:2021, clause 5.2.7]
	**Keep away from sunlight**	Indicates a medical device that needs protection from light sources. [EN ISO 15223-1:2021, clause 5.3.2]
	**Keep Dry**	Indicates a medical device that needs to be protected from moisture. [EN ISO 15223-1:2021, clause 5.3.4]

6. Warranty

CERTIFICATE OF WARRANTY

THIS WARRANTY IS GIVEN IN PLACE OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE.

Under no circumstances shall Parker Hannifin Corporation be liable for incidental or consequential damages as those terms are defined in the uniform commercial code.

Parker Hannifin Corporation, Porter Instrument warrants that each product or part shall be free from defects in workmanship and materials, under normal use and with appropriate maintenance, for one (1) year from the date of delivery to customer unless otherwise specified in writing. All rubber and plastic parts and accessories are warranted under the same conditions for a period of ninety (90) days from date of purchase.

No statement or claim about the product by any employee, agent, representative, or dealer of Parker Hannifin Corporation shall constitute a warranty by Parker Hannifin Corporation or give to rise to any liability or obligation of Parker Hannifin Corporation.

Parker Hannifin Corporation shall not be liable for any damage, injury or loss arising out of the use of the product, whether as a result of a defect in the product or otherwise, if, prior to such damage, injury or loss, the product was (1) damaged or misused; (2) repaired, altered or modified by persons other than Parker Hannifin Corporation; (3) not installed in strict compliance with applicable codes and ordinances; or (4) not installed by an authorized Parker Hannifin Corporation dealer. Parker Hannifin Corporation's obligation for breach of this warranty, or for negligence or otherwise, shall be strictly and exclusively limited to the repair or replacement of the product or part. This warranty shall be void on any product on which the serial number has been altered, defaced, or removed.

ORDERS All orders are to be made through authorized Parker Hannifin Corporation distributors. All billing will be done through said distributors. Direct orders will be handled through the authorized local dealer as determined by Parker Hannifin Corporation.

RETURNS All returned merchandise will be handled through authorized Parker Hannifin Corporation distributors. No returns will be accepted unless authorized in writing by Parker Hannifin Corporation and accompanied by the original shipping invoice. All returns are subject to restocking charge.

Policies subject to change without notice.

To register your product: visit https://www.porterinstrument.com/dental-support and click on Warranty Registration Form button.