DRAFT

NeoPIP™ Resuscitation Unit

Instructions for Use

NOT FOR SALE

PENDING 510(k) and CE Mark

Read this manual carefully before operating the unit

After reading this manual, keep it readily available for reference

NeoForce Group Inc

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1 Introduction

This Manual deals with the specifications, operation and maintenance of the NeoForce NeoPIP™ Infant Resuscitator Unit. NeoForce is not responsible for any product issue arising from a user ignoring the instructions for operation and maintenance as described in this manual; or for any accident attributable to repair by someone other than an authorized service representative.

Read this manual carefully and familiarize yourself thoroughly with its contents before operating the unit. Keep this manual where it is readily accessible for reference by end users. If any technical problems should arise, please contact your local NeoForce Sales or Service Representative at 215-672-6800. Additional copies of this manual are available on request.

CAUTION – this product is shipped without being disinfected. Be sure to clean and disinfect the unit before using it for the first time after purchase.

Disposable and used parts as well as other products past their useful lives should be disinfected or sterilized and disposed of as medical wastes according to your institution policy and procedures.

2 Intended Use

The NeoPIP™ Infant Resuscitator Unit is intended to deliver oxygen or blended gas to a neonate while controlling peak inspiratory pressure (PIP). NeoPIP™ is intended to be used in conjunction with the NeoPEEP™ Patient Circuit which provides positive end expiratory pressure (PEEP) control. The NeoPIP™ device provides, as a safety measure, an adjustable maximum pressure relief (Pop-Off) valve.

3 Basic Instructions

1 – Follow these instructions for the safe use of the device
2 – Inspect the unit on a routine basis to ensure optimal performance
3 – Never use the unit if it is damaged or malfunctions in any way. Stop using the unit as soon as possible, remove the unit from service and contact your NeoForce service representative at 215-672-6800.

4 Symbol Definition

Attention: Consult Accompanying Documents

WARNING – identifies situations or actions that may affect patient or user safety. Disregarding a warning could result in patient or user injury.

CAUTION – points out special procedures or precautions that personnel must follow to avoid equipment damage.
NOTE – a statement that provides additional information intended to clarify points, procedures or instructions.

5 Warnings and Cautions

Warning - Please read and understand the instructions fully before using the NeoPIP™ infant resuscitator and related accessories. The NeoPIP™ is intended to be used only by personnel who have been trained in infant resuscitation.

Warning - It is the responsibility of the purchaser to ensure that all users of this device have been adequately trained in resuscitation techniques and guidelines.

Warning - The NeoPIP™ resuscitator should only be used after completing a pre-use check to ensure that correct pressures will be delivered to the patient. If the device fails to operate as intended during pre-use checks remove the device from use and contact your NeoForce representative for service.

Warning: Release the T-Piece as soon as the breath is delivered. Extended occlusion of the T-Piece may result in over inflation of the patients lungs.

Warning - Ensure that there are no sources of ignition present when the device is in use.

Warning - NeoPIP™ may only be used with flow regulated medical gases. Ensure that the range of supply pressures is regulated to 50 psi.

Warning - Recommended gas flow range is 1 – 15 L/min. DO NOT USE FLOW GREATER THAN 15 L/min.

Warning - The Maximum Pressure relief is factory set to 40 cm H2O and can be adjusted up to a nominal 80 cm H2O. This should only be done in exceptional circumstances by persons trained in infant resuscitation. DO NOT ATTEMPT TO SET THE Max Pressure Relief ABOVE 80 cm H2O.

Warning - Use only the NeoPEEP™ patient circuit and T-Piece.

Warning – Ensure all oxygen and air supplies are turned off and disconnected from the NeoPIP™ prior to cleaning of the device. Fire hazards are possible in oxygen enriched environments.

Caution – US Federal Law restricts this device to sale on or by the order of a physician.

Note – Ensure that the oxygen concentration is either monitored using an oxygen analyzer or preset using oxygen / air flow rate graphs.

Note – The Maximum Pressure Relief valve acts as an overall pressure limit. Pressure above 40 cm H2O cannot be achieved unless the Maximum Pressure Relief valve limit is adjusted to greater than 40 cm H2O.

Note – The Maximum Pressure and Peak Inspiratory Pressure valves are in the same circuit. The PIP valve is intended for frequent use to adjust and control the desired patient supply pressure up to the pressure set by the Maximum Pressure valve.

Note – The NeoPIP™ is intended to be used with single use patient circuits to minimize the potential for cross-contamination and eliminating the need for time-consuming and costly reprocessing.

6 Controls and Indicators (see Figure 1)

	Front Panel Item	Description
A	Pressure Manometer Gauge	Displays Maximum Pressure Relief value during setup procedure, displays Peak Inspiratory Pressure and Positive End Expiratory Pressure during setup, checkout and with each inspiratory/expiratory cycle.
B	Maximum Pressure or Pop-Off Control	Adjustment of knob will allow changing the pop-off set point.
C	PIP Control	Peak Inspiratory Pressure. Adjustment knob will allow changing the PIP set point.
D	Gas Inlet	Tapered barbed fitting for attachment of oxygen hose.
E	Patient Circuit	Fitting to receive the standard 15 mm NeoPEEP™ patient circuit connector.

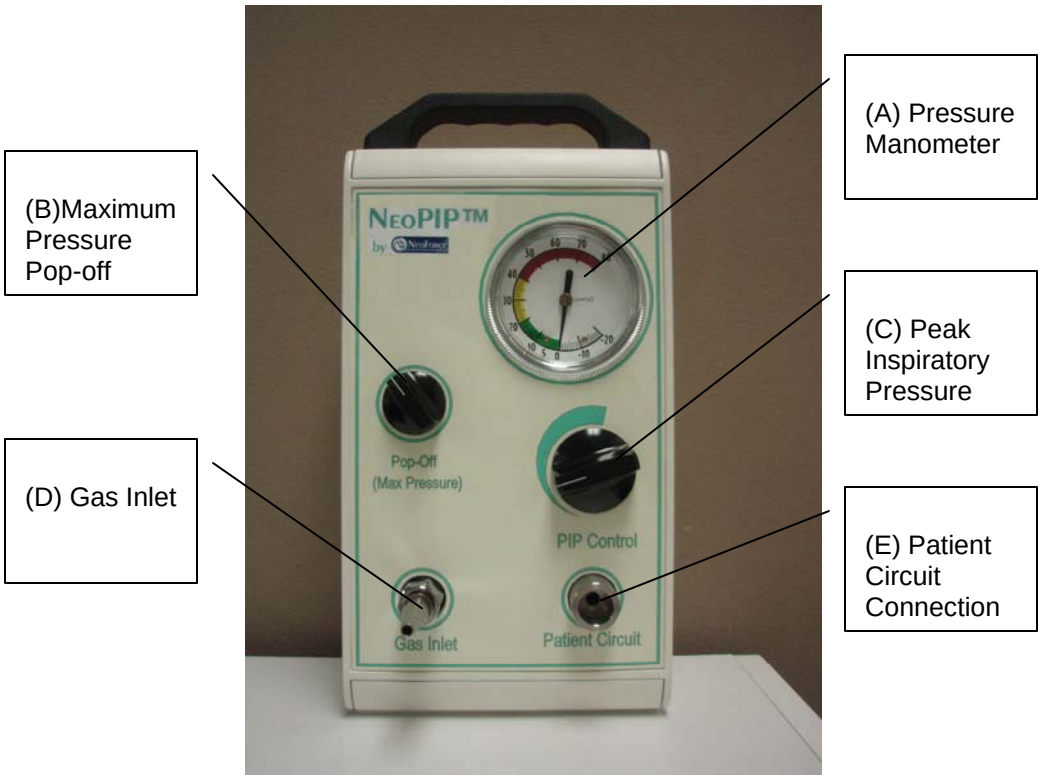

Figure 1

7 Features and Specifications

The NeoPIP™ Infant Resuscitator Unit is intended for emergency manual resuscitation of neonates and infants. The device is used in conjunction with a flow meter to control the gas inlet and a blender if blended air and oxygen is desired. Breathing frequency is controlled by the caregiver's rate of occlusion and release of the T-Piece port which directs the flow to and away from the patient.

PIP – Peak Inspiratory Pressure can be set by the PIP Control knob over a range of 2 to 80 cm H2O as a function of flow rate. The value is displayed on the manometer.

PEEP – Positive End Expiratory Pressure can be set over a range of 1 to 25 cm H2O as a function of flow rate. This is set by adjusting the knob on the top of the breathing circuit T-piece. The value is displayed on the manometer

Maximum Pressure Relief – can be set by adjusting the control knob over a range of 2 to 80 cm H2O. The value is displayed on the manometer.

Gas Inlet connections – medical gas can be provided by tank or by wall outlet. Gas from the source will pass through the blender, then flow meter and into the NeoPIP™ device. The gas inlet connection is a standard ¼ in tapered barb fitting.

Patient Circuit – the patient circuit is disposable with a standard 15 mm ID x 22 mm OD fitting.

Description	Specification
Maximum Pressure Relief.	Setting between 5 cm and 80 cm H2O/mbar, factory setting is 40 cm H2O/mbar
Peak Inspiratory Pressure (PIP)	2 – 80 cm H2O at 6 L/min
Positive End Expiratory Pressure (PEEP)	At 6 L/min PEEP = 2 to 5 cm H20 At 8 L/min PEEP = 2 to 6 cm H2O At 10 L/min PEEP = 2 to 8 cm H2O
Dead Space	< 7 mL
Expiratory Resistance	< 5 cm H2O
Inspiratory Resistance	< 5 cm H2O
Height Width Depth	26 cm (10.25 in) 15.25 cm (6 in) 9 cm (3.5 in)
Weight	2.8 kg (6.2 lbs)
Mounting	IV pole, F-rail, wall mount, free standing with handle for transport
Manometer	-20 to 80 cm H2O +/- 2
Gas Inlet flow range (accessory flow meter)	1 L/min to 15 L/min
Oxygen Concentration (accessory blender)	21 – 100% based on gas supply
Operating Temperature Operating Humidity Operating Altitude **Storage /Transportation** Temperature Storage Humidity	10 – 40 deg C up to 90% RH non-condensing 0 – 10,000 ft -20 deg C to 60 deg C up to 90% RH non-condensing
Immersion Resistant	Temporary Submersion will not affect functionality
Cleaning Recommendations	Clean with warm soapy water. For surface disinfection use NeoKleen (NK12-024) a quaternary ammonium solution

8 Installation

NeoPIP™ is designed to mount to an IV pole, radiant warmer rail adapter, or wall. NeoPIP™ may also be used as a free standing device on a shelf. Once the desired location for the NeoPIP™ is determined setup may be initiated.

9 Setup

The NeoPIP™ **must** be used in conjunction with a flowmeter with a range of 0 – 15 L/min.

NeoPIP™ may be used with a blender if a range of oxygen concentration between 21% and 100% is desired.

If a blender is used:

First attach the air and oxygen gas sources to the appropriate blender ports. If the blender and flow meter are separate devices, then attach them according to manufacturers instructions. Attach the blender gas outlet to the inlet of the flow meter.

If a blender is not used then attach the gas supply directly to the inlet of the flow meter.

Attach standard medical gas tubing from the outlet of the flow meter to the GAS INLET tapered barb on the front of the NeoPIP™.

Connect the patient circuit to the Patient Circuit outlet on the front bottom of the NeoPIP™ device.

Connect the test lung to the patient circuit T-Piece.

10 Pre-Use Check

Adjust the gas supply to the desired flow rate between 5 and 15 L/min.

To check/set Maximum Pressure:

- ✓ Occlude PEEP valve at the distal end of the patient circuit

- ✓ Turn PIP control knob on the front of the device two full turns clockwise.

- ✓ Adjust the Maximum Pressure control knob to set the desired maximum pressure pop-off.

To set the PIP

- ✓ While still occluding the PEEP valve, turn the PIP control Knob counter-clockwise to set the desired peak inspiratory pressure which is displayed on the manometer.

To set the PEEP

- ✓ Release the PEEP valve and adjust to set the desired positive end expiratory pressure which is displayed on the manometer.

Turn off the gas supply and remove the test lung from the patient circuit T-Piece.
If the device fails to operate as intended during pre-use checks remove the device from use and contact your NeoForce representative for service.

11 Instructions for Resuscitation

(1) Adjust gas supply to desired flowrate and set PIP and PEEP pressures, verify settings on manometer display.

(2) Fit T-piece to neonatal resuscitation mask and place over the patients mouth and nose or fit patient T-piece to the endo-tracheal tube.

(3) Resuscitate by placing and removing the thumb or index finger over the PEEP valve port at the top of the T-Piece to allow inspiration and expiration at the desired breath rate.

12 Cleaning and Servicing

The NeoPEEP™ patient circuit is disposable, discard according to local requirements for bio-hazardous waste.

Clean the external surfaces of the NeoPIP™ Infant Resuscitator with a damp cloth and mild soapy water. To disinfect use NeoKleen a quaternary ammonium solution.

Dry all surfaces after cleaning with a clean soft cloth or paper towel

NeoPIP™ does not require service or maintenance under normal use conditions and when pre-use checks are conducted. If the device fails to operate as intended during pre-use checks remove the device from use and contact your NeoForce representative for service. Do not disassemble the NeoPIP device.

13 Troubleshooting

Trouble	Possible Cause	Action to take
No gas flow to the patient	Not connected to gas supply source	Connect hose to Wall or Tank gas supply source
	Gas supply source is depleted	Replace tank
	Hose from gas supply is not connected to flow meter / blender	Secure connection to flow meter / blender
	Hose from flow meter to NeoPIP™ is not connected	Secure connection between flow meter and NeoPIP™ Gas Inlet
	Patient circuit is not connected to NeoPIP™	Secure patient circuit to NeoPIP™ Patient Circuit connector
	Hose or patient circuit is kinked or occluded	Unkink or replace kinked or occluded item.
	Maximum pressure valve or PIP control valve are fully closed	Open valves and perform check out procedure. If this does not resolve the problem, remove the unit from service.*
Insufficient gas flow to the patient	Leak in one of the connections	Check and secure all hose connections, perform checkout. If this does not address leak, remove the unit from service.*
Control knobs do not function	Damage to knob or valve	Remove the unit from service.*
Display does not function	Damage to gauge	Remove the unit from service.*

*In all cases where the unit is removed from service, immediately contact NeoForce Group Service at 215-672-6800.

14 Supplies

Part Number	Description
TBD TBD	7 ft Oxygen Tubing 4 ft Oxygen Tubing
800150	NeoPEEP™ Single Patient Use Resuscitation Circuit
200600D	Single Patient Use Round Face Mask, Size 0
NK12-024	NeoKleen Surface Disinfectant

Note: all supplies are available from our on-line store at www.neoforcegroup.com

Contact Us

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