LOW-PRESSURE HOSE ASSEMBLY. Useand maintenance handbook

Conform to en iso 9170-1 standard

General information

Introduction

Pres Block low-pressure hose assembly is a medical device “CE” marked, built to comply with 93/42/EEC European directive and EN ISO 5359 standard.
Before using the device, please read this handbook and ensure it is read by authorized operators.

Warranty

Pres Block guarantees the medical devices for 24 months from thedate of delivery.
This warranty covers exclusively the repair or free replacement ofany components defective for manufacturing reasons.
The replacement or repair of the parts covered by this warrantydoes not extend the validity of the warranty itself.
The medical device has an expected life of 8 years in normalworking conditions, during which 10.000 couplings socket/probecould be done.

Purpose of the manual

Purpose of this handbook is to give indications for the safe use andmaintenance of the device.

Destination of use

Pres Block terminal units and accessories have been designed toconnect in a safe way medical equipments to the medical gasesdistribution system.

Marking

Marks on every device are:

• Pres Block logo “PB”, preceded by manufacturer symbol “ ” according to CEI EN 980 standard;

• “CE” marking followed by the number “0476”, which identifies thenotified body that has approved the “CE” certification of thedevice; • batch number “XXYYZZ” preceded by the word “LOT”, where “XX” identifies the year of fabrication;

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• “symbol of the gas” distributed, according to EN ISO 9170-1 standard;

• possible name of the Customer.

Traceability

Pres Block guarantees the traceability up to its direct Customer, who is liable for guaranteeing the same up to the end user.

Classification and information under 93/42/EEC directive

The medical device:

• is identified with class of risk IIa, according to 93/42/EEC European directive – Annex IX – Rule 11;

• is neither for single use, nor sterile;

• does not intentionally contain latex;

• does not incorporate neither medicinal substances, nor biological or animal tissues, nor human blood;

• does not contain phthalates classified as carcinogenic, mutagenic or toxic to reproduction, by EC Regulation 1907/2006 (REACh).

Technical information

Components

The main components are:

• inlet connector (NIST or EN ISO 9170-1 probe);

• flexible hose;

• outlet connector (NIST or EN ISO 9170-1 probe/socket).

Materials used are:

• Brass EN12164 - CW614N nickel plated;

• AISI 302;

• ABS / PA / PE / POM;

• NBR / FPM / EPDM;

• PVC;

• Aluminium type 2000 or 6000.

Technical specs

According to ENV 737-6 and EN ISO 9170-1 standards.

Transport and storage

Transport and storage temperatures: -15 ÷ +50 °C

Working temperatures according to EN ISO 9170-1: -20 ÷ +60 °C

Humidity: 10 ÷ 90 %

Atmospheric pressure: 700 ÷ 1060 hPa.

Installation

The medical device must be installed only by expert personnel,strictly according to these instructions.
All the materials used during installation must be compatible withthe gases supplied and the materials of the device.
Every precaution must be taken to guarantee and maintain thecleanliness of the device.
Before installation, verify that the device is compatible with thedevices connected, especially if supplied by differentmanufacturers.
Before use, connect the device to equipotential earth.

Functioning

Socket/Probe connection

1. Visually inspect the assembly for wear and damage.
2. Verify that the socket and the probe are designed for the same gas and that they refer to the same standard.
3. Connect the probe into the socket with enough force to oppose the upstream pressure.
4. Release the probe verifying that it remains connected.

Socket/Probe disconnection

1. Keep the probe, in order to prevent its quick projection.
2. Disconnect the probe from the socket.

Safety

Before use, personnel must familiarize with the control devices and their operation.
If the medical device is out of order or in maintenance, disconnect the gas supply and place a visible sign stating “NOT IN SERVICE. DO NOT USE”.
Do not use the medical device for gases or pressures different from that for which it is designed.
Do not crash the probe, in order not to spoil its functionality.
For cleaning use only distilled water or diluted ethyl alcohol.

Maintenance

The maintenance program must envisage a minimum of biannual inspections with particular reference to:
• easy coupling and disconnection;
• wear or damage;
• contamination;
• marking – labelling;
• tightness;
• flow rate according to EN ISO 7396-1.
These operations must be recorded.

During maintenance and repair only original parts must be used.
Every precaution must be taken to maintain the cleanliness.
Once the maintenance is completed, please do all the tests required by EN ISO 7396-1 standard.