USE AND MAINTENANCE HANDBOOK FOR

AIR MOTOR TERMINAL UNITS AND PROBES

CONFORM TO ENV 737-6 AND EN ISO 9170-1 STANDARDS

0476

93/42/EEC

1. General information

1.1 Introduction

Pres Block AIR MOTOR terminal units and probes are medical devices "CE" marked, built to comply with 93/42/EEC European directive and EN ISO 9170-1 and ENV 737-6 standards.
Before using the device, please read this handbook and ensure it is read by authorized operators.

1.2 Destination of use

Pres Block terminal units and probes have been designed to connect in a safe way medical equipment to the medical gases distribution system.

1.3 Classification and information under 93/42/EEC directive

The medical device:

- is identified with class of risk IIb, according to rule 11 of Annex IX of directive 93/42/EEC;
- 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.

1.5 Marking

Markings on every device are:

"PB" or "Pres Block"	Identifies Pres Block as the manufacturer
"CE 0476"	Identifies the Notified Body that approved the CE certification for the device
"LOT XXYYZZ"	Batch number, where "XX" identifies the year of manufacture
Referenced standard	

Other markings per component:

Terminal Units	
"AIR MOTOR"	according to EN ISO 9170-1 standard
Name of the Customer	(optional)

2. Technical information

2.1 Components

Available components are:

Name	Code (initial part)	Description
TERMINAL UNIT	VAM737	Part connected to the distribution system. Contains the gas-specific connection point with the probe.
PROBE	IAM737	Male component which is connected into and retained by the terminal unit.

2.2 Technical and Operating characteristics

In compliance with the following standards:	ENV 737-6 and EN ISO 9170-1	
Transport, storage and working temperatures range:	-20 ÷ +60° C	
Transport, storage and working humidity range:	10 ÷ 90 %	
Atmospheric pressure limits:	700 ÷ 1060 hPa	
Materials used:	Brass (type CW614N) with and without nickel plating, EN 13348-R290 copper pipe, Aluminium EN AW-2011, AISI (302/304/420), EPDM	
Lubricants:	Compatible with O2	
Distributed gases and relative working pressures:	Air motor	from 560 kPa to 1200 kPa

2.3 Transport and storage

The original packaging is designed to guarantee the proper transport and storage of the product, in compliance with the requests of EN ISO 15001 standard.

The device must be transported and stored in its original packaging; any damage to the packaging may be detrimental to the functioning or safety of the product.
The device must be protected from atmospheric agents (rain, snow, etc.): water may cause malfunctioning.

3. Installation

The medical device must be installed only by expert and authorized operators. The installation must strictly follow these instructions and the requests of EN ISO 7396-1 standard.
The medical device must be installed at an easily accessible height, reducing as much as possible the risk of damages, due to furniture or other medical devices, and granting a distance ≥ 100 mm between 2 consecutive terminal units.
All the materials used during installation must be compatible with the gases supplied and the materials of the device.
Every precaution must be taken to guarantee and maintain the cleanliness of the device according to EN ISO 15001 standard.
Before installation, verify that the device is compatible with the devices it must be connected with, especially if supplied by different manufacturers.
Before use, connect the device to equipotential earth.

3.1 Terminal units

Terminal units VAM737-PG6

Perform the following operations in succession:

- braze-weld the terminal unit to the scavenging copper pipe (O/D 15 mm.) according to the standards of good practice (e.g. absence of oxides on the surfaces to be welded, silver solder, quenching without thermal shocks, etc.);
- clean the line with nitrogen;
- fix the terminal unit on the wall / trunking / ceiling pendant using the 3 supplied M4x8 screws;
- fix the barb end to the flexible hose (I/D 6 mm.) with a suitable single-use clip or crimped ferrule, according to EN ISO 5359 standard.

Terminal units VAM737-TL

Perform the following operations in succession:

- braze-weld the terminal unit to the scavenging copper pipe (O/D 15 mm.) and the supply copper pipe (O/D 8 mm.) according to the standards of good practice (e.g. absence of oxides on the surfaces to be welded, silver solder, quenching without thermal shocks, etc.);
- clean the line with nitrogen;
- fix the terminal unit on the wall / trunking / ceiling pendant through the plate using 2 suitable screws;
- fix the terminal unit to the lid using the 3 supplied M4x8 screws.

3.2 Probes

Perform the following operations in succession:

- fix to the inlet flexible hose (I/D 6 mm.) onto the internal barb end with a suitable single-use clip or crimped ferrule, according to EN ISO 5359 standard;
- fix to the outlet flexible hose (I/D 32 mm.) onto the external barb end with a suitable single-use clip or crimped ferrule, according to EN ISO 5359 standard.

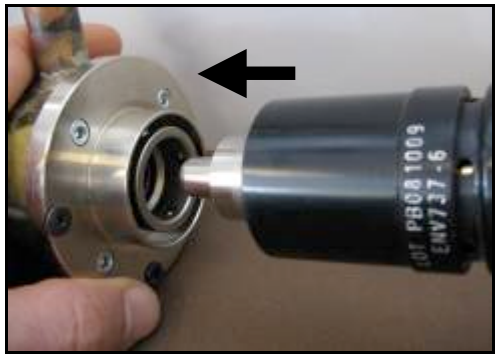
Once installation is completed, verify the tightness: no leakages are allowed.
Afterwards testing required by EN ISO 7396-1 standard must be run.

4. Use

4.1 Functioning

TERMINAL UNIT / PROBE CONNECTION

1. Verify that the terminal unit and the probe are designed for the same gas and that they refer to the same standard;
2. Grasp the probe and align it with the terminal unit;
3. Insert the probe into the terminal unit with enough force to oppose the upstream pressure, until the release sleeve of the terminal unit clicks into place;
4. Release the probe verifying that it remains anchored into the terminal unit.



TERMINAL UNIT / PROBE DISCONNECTION

1. Keep the probe, in order to prevent its quick projection;
2. Push the release sleeve of the probe, outwards the terminal unit.

4.2 Cleaning

For cleaning use only distilled water or diluted ethyl alcohol.

4.3 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 those for which it is designed.
Do not crash the probe, in order not to spoil its functionality.
Do not try to insert probes designed for a different gas and/or different standard into the terminal units. This may damage both devices.

5. 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.

Every precaution must be taken to maintain the cleanliness of the device.
Do not use lubricants that aren’t compatible with oxygen at the operating pressures of this medical device.
During maintenance and repair only original parts must be used.
Once maintenance is completed, testing required by EN ISO 7396-1 standard must be run again

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