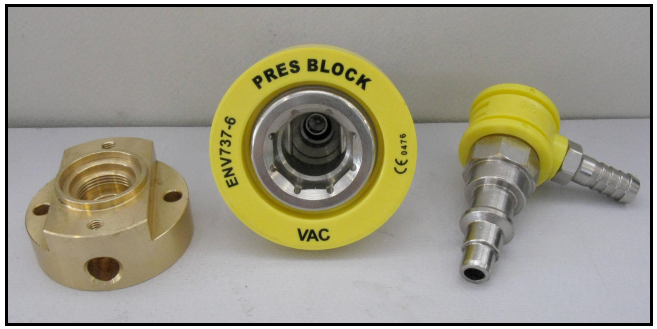
USE AND MAINTENANCE HANDBOOK FOR

ENV737-6 TERMINAL UNITS AND ACCESSORIES

CONFORM TO EN ISO 9170-1 STANDARD



CE 0476
93/42/EEC

1. General information

1.1 Introduction

Pres Block ENV 737-6 terminal units and accessories 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 accessories have been designed to connect in a safe way medical equipments 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.

1.4 Markings

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
Symbol of the gas distributed	according to EN ISO 9170-1 standard

Batch Numbers and other markings per component:

Sockets	
Referenced standard	
Batch number: either as a data stamp [XXYY], followed by one or two letters identifying the gas [ZZ] or as "LOT XXYYZZ". In both cases "XX" stands for the year of manufacture	
Name of the Customer	(optional)
Base Blocks: Please refer to handbook FTGTD05Ze and to FTGTI05e	
Probes and Adaptors	
"LOT XXYYZZ"	Batch number, where XX identifies the year of manufacture
Referenced standard	(optional)
Name of the Customer	(optional)

2. Technical information

2.1 Components

Available components are:

Name	Code (initial part)	Description
BASE BLOCK	ZARMOR ZARM	Part connected to the distribution system. Please refer to handbook FTGTD05Ze for ZARMOR and to handbook FTGTI05e for ZARM.
SOCKET	VGTE - OR / VGTEM - OR	Part connected to the base block by a gas-specific interface. Contains the gas-specific connection point with the probe.
	VGTE	Part connected to the base block by a gas-specific thread. Contains the gas-specific connection point with the probe.
PROBE	IGTE / IGTGE	Male component which is connected into and retained by the socket.

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, Zamak (Zinc alloy), AISI (302/304/420), ABS, PA66, PE, POM, EPDM
Lubricants:	Compatible with distributed gases (especially for O2)
Distributed gases and relative working pressures:	O2; N2O; CO2; Air, mixtures — from 320 kPa to 600 kPa
	Vacuum — from -10 kPa to -60 kPa
	N2; Air-800 — 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

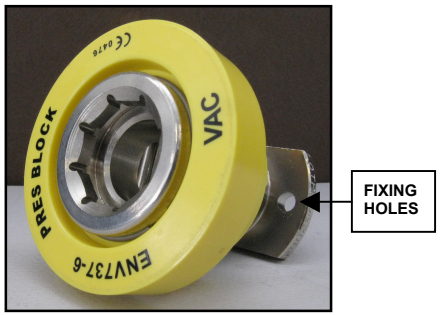
The medical device must be installed only by expert and authorized operators. The installation must strictly follow these instructions and the requests of EN ISO 7396-1 standard.
The medical device must be installed at an easily accessible height, reducing as much as possible the risk of damages, due 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 Base blocks

Please refer to handbook FTGTD05Ze for ZARMOR base blocks and to handbook FTGTI05e for ZARM base blocks.

3.2 Sockets

Socket VGTE-OR and VGTEM-OR



Perform the following operations in succession:

- align the 2 fixing holes I/D 4,5 mm. with the 2 females M4 threaded of the base block,
- fix the socket onto the base block tightening at the same time the

2 M4 screws (supplied with the base block) with an Allen wrench;
- apply the red label “NOT OPERATIVE”, taking it away only when all final tests of the system have been performed.

Socket VGTE
Perform the following operations in succession:
- tighten the socket onto the base block, with a 30 mm. pipe wrench (always right-hand screw, except for the socket for AIR which has left-hand screw);
- point out that the socket cannot be used, because final tests on the system must be run, before its use.

3.3 Probes

Probe with barb end terminal IGT…PG…
Perform the following operations in succession:
- fix the barb end to the flexible hose (I/D 6 or 8 mm.) with a suitable single-use clip or crimped ferrule, according to EN ISO 5359 standard.

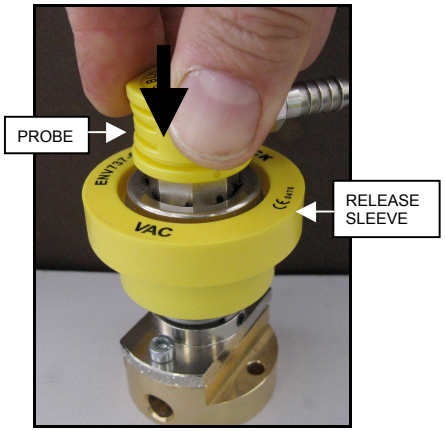
Probe with threaded terminal IGT…F… and IGT…M…
Perform the following operations in succession:
- fix the threaded terminal granting the tightness with a suitable O-ring or PTFE tape.

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

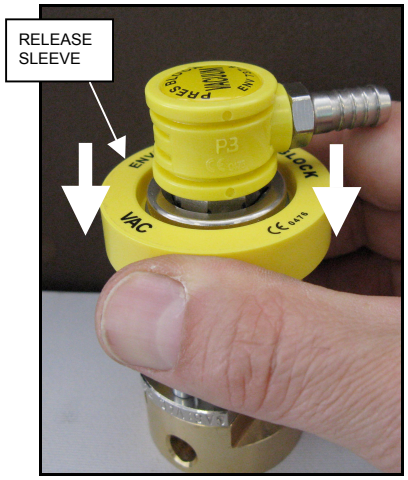
4.1 Functioning

SOCKET / PROBE CONNECTION
1. Verify that the socket and the probe are designed for the same gas and that they refer to the same standard;
2. Grasp the probe and turn it aligning its profile with the corresponding profile of the socket;



3. Insert the probe into the socket with enough force to oppose the upstream pressure, until the release sleeve of the socket clicks into place;
4. Release the probe verifying that it remains anchored into the socket.

SOCKET / PROBE DISCONNECTION
1. Keep the probe, in order to prevent its quick projection;
2. Push the release sleeve of the socket, towards the base block.



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 sockets. 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.
Following maintenance kits are available for the sockets model VGTEM:
- VGTE-OR-RIC.

Every precaution must be taken to maintain the cleanliness according to the requests of EN ISO 15001 standard.

During maintenance and repair only original parts must be used.
Do not use lubricants that aren’t compatible with the distributed gases at their operating pressures. Especially in the case of contact with oxygen there might be safety issues relating to fire or explosion, if an incompatible lubricant is used.
Once maintenance is completed, testing required by EN ISO 7396-1 standard must be run again

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