USE AND MAINTENANCE HANDBOOK FOR

NIST TERMINAL UNITS / PROBES AND ACCESSORIES

CONFORM TO EN ISO 18082 AND EN ISO 9170-1 STANDARDS

CE 0476
93/42/EEC

1. General information

1.1 Introduction

Pres Block NIST terminal units are medical devices “CE” marked, built to comply with 93/42/EEC European directive and EN ISO 9170-1 and EN ISO 18082 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 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	(optional)
Symbol of the gas distributed	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	Models
BASE BLOCK	ZARM	Part connected to the distribution system. Please refer to handbook FTGTI05e.	-
SOCKET	VGTN	Part connected to the base block by a gas-specific interface. Contains the gas-specific connection point with the probe.	with UNI gas-specific thread
		Part connected to the system by a copper pipe. Contains the gas-specific connection point with the probe.	VGTN-…-T… with copper pipe
PROBE	IGTN / IGTGN	Male component which is connected into and retained by the socket.	Straight / elbow with barb end

2.2 Technical and Operating characteristics

In compliance with the following standards:	EN ISO 18082 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, Aluminium EN AW-2011 nickel plated, AISI 302, PE, EPDM, Brazing alloy EN1044 – AG102, EN 13348-R290 copper pipe, (PVC: only for the cap that must be removed during installation)	
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 Sockets

Socket VGTN

Perform the following operations in succession:

- Screw the socket onto the base block / equipment (always right-hand screw, excepting socket for AIR, which has left-hand screw).

Socket VGTN-…-T

Perform the following operations in succession:

- weld the terminal unit to the supply copper pipe, according to the standards of good practice;
- clean the line with carbon dioxide or nitrogen;
- fix the socket to the arm of the ceiling pendant, by locking the plate between the body and the nut 24x3 supplied.

3.2 Probes

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.

3.3 Base blocks

Where VGTN socket has UNI thread, please refer to FTGTI05e for the base block handbook.

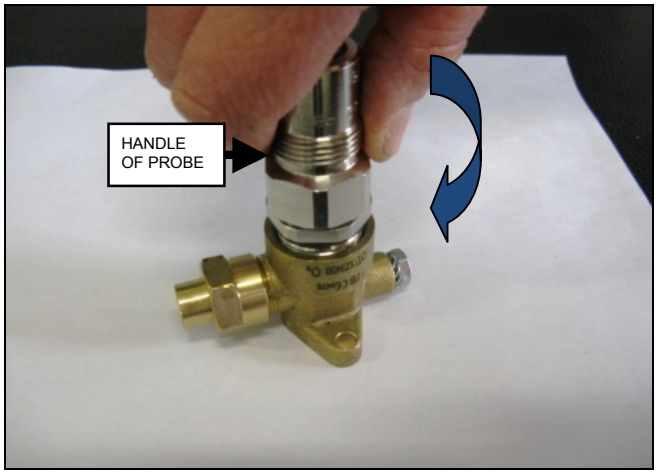
Once installation is completed, verify the tightness: no leakages are allowed.
Afterwards testing required by EN ISO 7396-1 standard must be run.

4. Use

4.1 Functioning

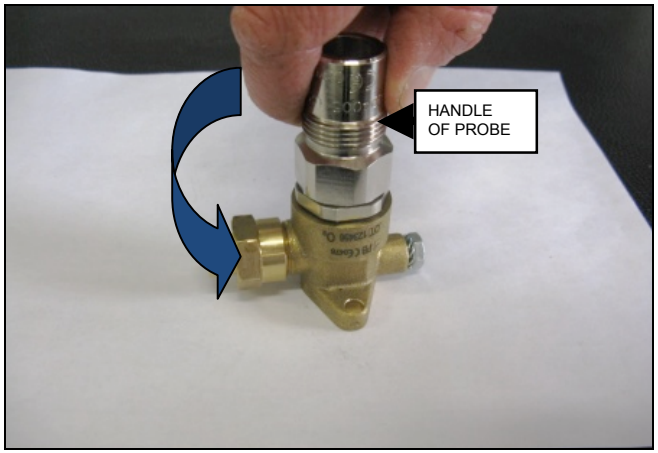
SOCKET / PROBE CONNECTION

1. Verify that the socket and the probe are designed for the same gas and that they comply with the same standard;
2. Grasp the handle of the probe, align it with the socket and screw it clockwise into the socket;
3. Release the probe, verifying that it remains locked in the socket.



SOCKET / PROBE DISCONNECTION

1. Keep the probe, in order to prevent its quick projection;
2. Grasp the handle of the probe and unscrew it anticlockwise, from the socket.



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.

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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