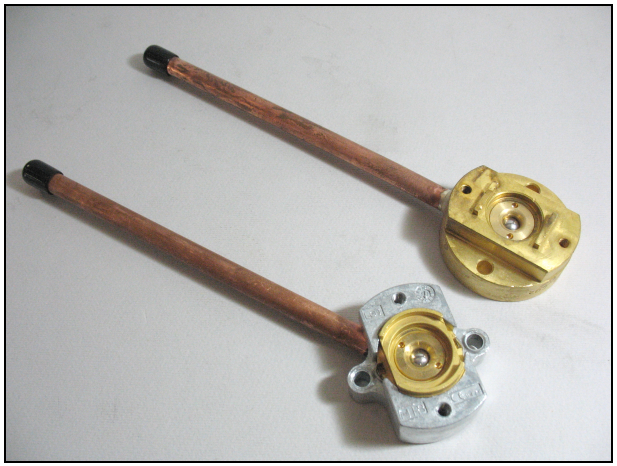
USE AND MAINTENANCE HANDBOOK FOR

BASE BLOCKS OR RANGE

CONFORM TO EN ISO 9170-1 STANDARD



CE 0476

93/42/EEC

1. General information

1.1 Introduction

Pres Block base blocks OR range are medical devices "CE" marked, built to comply with 93/42/EEC European directive and EN ISO 9170-1 standard.
Before using the device, please read this handbook and ensure it is read by authorized operators.

1.2 Destination of use

Pres Block base blocks OR range 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.

1.4 Markings

Markings on every device are:

"PB"	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 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	

2. Technical information

2.1 Components

Available components are:

Name	Code (initial part)	Description
BASE BLOCK	ZARMOR	Part connected to the distribution system.

2.2 Technical and Operating characteristics

In compliance with the following standards:	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), Brazing alloy EN1044 – AG102, EN 13348-R290 copper pipe, Zamak (Zinc alloy), AISI (302/304/420), PA66, PE, (PVC: only for the cap that must be removed during installation)	
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.

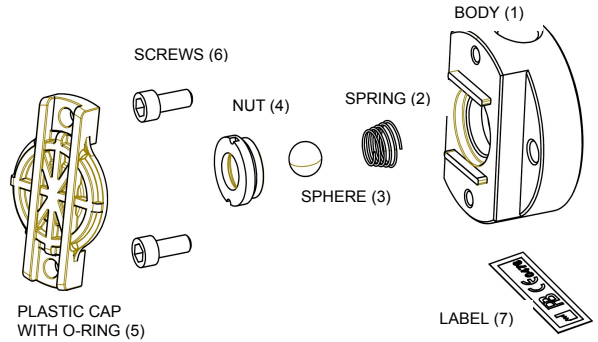
3. Installation

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.

Base block with terminal for copper pipe to be welded

Perform the following operations in succession:

- braze-weld the base block to the supply copper pipe, 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.) and apply the ultra-destructible label for the identification of the product;
- clean the line with nitrogen;



- connect the base block to the wall, using suitable screws and an adequate box;
- assemble into the body (1) of the base block, the maintenance valve supplied in a separate plastic bag, first putting the spring (2) inside the body (1), then placing the sphere (3) on the nut (4) and finally tightening the nut (4) onto the body (1) with a wrench (not required for base blocks for vacuum);

This step must be performed on all the base blocks where a copper pipe still has to be welded

- apply the label (7) on the body (1) for its identification;
- seal the base block for the tightness test, with the supplied plastic cap with O-ring (5) fixing it with the supplied screws (6).

Base block with barb end terminal

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;
- connect the base block to the wall, using the supplied screws and an adequate box;
- assemble into the body (1) of the base block, the maintenance valve supplied in a separate plastic bag, first putting the spring (2) inside the body (1), then placing the sphere (3) on the nut (4) and finally tightening the nut (4) onto the body (1) with a wrench (not required for base blocks for vacuum);
- apply the label (7) on the body (1) for its identification;
- seal the base block for the tightness test, with the supplied plastic cap with O-ring (5) fixing it with the supplied screws (6).

Base block for ceiling pendants
Please refer to base block with barb end terminal.

Base block with copper pipe
Please refer to base block with terminal for copper pipe to be welded.

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 Operation

Pres Block base block is used to connect terminal units to the medical gases distribution plant and grant a gas-specific connection to the socket.
Every base block has a maintenance valve which permits the maintenance of the terminal unit, without shutting down the pipeline system and other terminal units, as required by the EN ISO 9170-1 standard. For terminal units for vacuum, this maintenance valve is available only upon request.

4.2 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.

5. Maintenance

The maintenance program must envisage a minimum of biannual inspections with particular reference to:
- wear or damage;
- contamination;
- marking – labelling;
- tightness;
- flow rate according to EN ISO 7396-1.

These operations must be recorded.
The following maintenance kits are available:
- ZARMOR/VNR.

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.
Once maintenance is completed, testing required by EN ISO 7396-1 standard must be run again

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