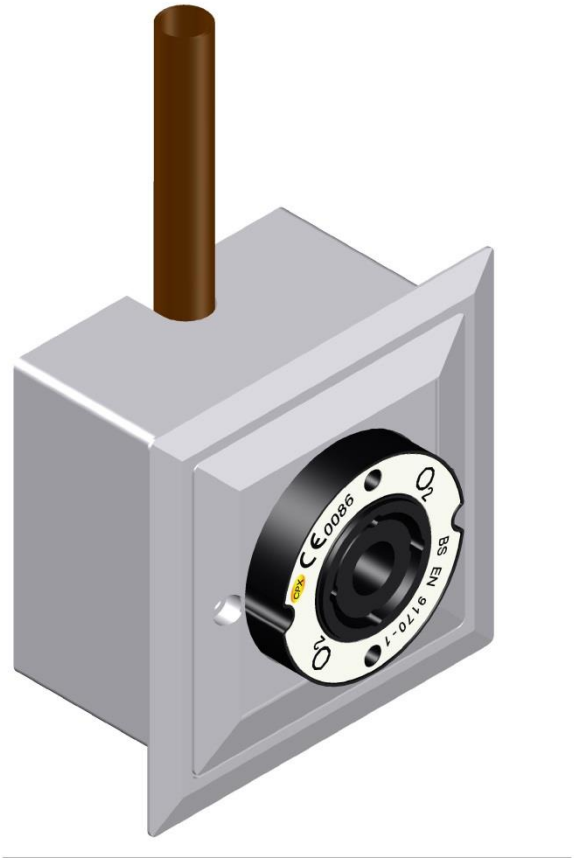
PRECISION UK Ltd

Specialists in HTM02-01 Medical Gas Pipeline Equipment

Technical Specification

Medical Gas Terminal Units (Gas Outlet Points)



EN 9170-1 Terminal Unit

Product Description

CPX Terminal Units comprise a first fix, second fix and check valve. The first fix assembly includes a ø12mm copper pipe for brazing to the fixed pipeline system, a NIST connector for connection to a hose assembly or a permanently crimped hose assembly.

Terminal units are available for oxygen, nitrous oxide, 50% oxygen/50% nitrous oxide mixture, medical air, surgical air and medical vacuum.

Terminal units are available for wall mounting (flush or surface), bedhead trunking and pendant mounting.

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First Fix Assembly

The first fix assembly shall comprise a precision-machined brass block of which the unit includes an indexed pin for each different gas service to prevent interchange ability, plastic components are not acceptable. The unit incorporates a maintenance valve/flutter disc, which will automatically shut off the gas supply if the second fix assembly is removed whilst the pipeline system is under pressure to enable servicing of the 2nd fix and valve without isolation of the gas supply. The terminal unit 1st fix includes mounting positions via M4 tapped holed in 4 positions, allowing the 2nd fix to be installed at any 4 of 90degree increment.

Check Valve Assembly

The check valve assembly comprises of a spring-loaded valve housed in a precision machined brass body. The check valve permits the gas to flow when a probe is connected and seals off the gas flow when the probe is disconnected. The unit is installed between the first fix and the second fix.

Second Fix Assembly

The second fix assembly comprises of a gas specific body, which accepts, retains and releases the probe. It shall be supplied as a complete product with no assembly to be undertaken. The base of the body is indexed to match the first fix assembly. The front face of the second fix assembly incorporates a colour coded gas identity label that indicates the gas type in 2 positions at 180 degrees to each other to allow visual acknowledgment of the gas type.

A stainless steel anti-swivel pin shall be located at 12 o'clock to prevent flow meters from falling over while inserted into the 2nd fix. The unit will only accept the probe for the appropriate service. Gas specific components comprising the terminal unit second fix shall be manufactured from fire retardant polymer compatible with oxygen and for use in MRI. The second fix socket shall incorporate a sheer-plane to safeguard the first fix and pipeline in the event of accidental damage or bed jacking. Gas specific components shall incorporate the Gas Identity marking, EN 9170 and the manufacturer identification mark CPX permanently stamped or cast into the component surface. Probe roller pins shall be manufactured from stainless steel and positioned by the locking ring, these are tamper proof only serviceable using specialist tools. Probe roller pins held captive in cradle designs are not acceptable as this will cause dust settlement and malfunction/sticking.

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Materials

First Fix Assembly

The first fix assembly shall comprise of the following components:

a) 1 no. Brass Block Assembly
b) 1 no. Retainer
c) 1 no. Coding Pin
d) 1 no. Flutter Disc (maintenance valve)
e) 1 no. 'O' Ring
f) 3 nos. Screws

The brass block assembly will comprise of a precision CNC machined brass block with a 12mm diameter x 125mm long copper stub pipe to BS EN 13348 R250 brazed into the brass block using a copper-silver-zinc brazing alloy with minimum 55% silver content and an appropriate flux to BS1044.

The Viton® 'O' ring will be installed within the retainer to provide a 100% seal between the brass block assembly and retainer.

The flutter disc shall enable the second fix assembly and check valve assembly to be removed whilst leaving the pipeline system pressurised. The flutter disc will be manufactured from brass.

The appropriate gas identification for each coding position will be machined into the component. The relevant position of the coding pin is installed during assembly of the first fix assembly. This ensures that the connection interface with the second fix assembly is gas specific. 1=O2, 2=N2O, 3=O2/N2O mix, 4=MA4, 5=SA7, 6=VAC, 7=AGSS, 8 & 9 spare.

The assembly should be capable of withstanding an inlet pressure on 20 bar.

The Gas ID e.g. **O2, BS EN 9170-1:2008** and **CPX** shall be stamped on the 1st fix brass block.

Second Fix Check Valve

The second fix check valve will comprise of the following components;

1 no. Valve Body
1 no. Valve Plunger
1 no. Spring
3 no. 'O' Rings
1 no. Probe Seal

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The valve body and valve plunger will be precision machined brass components.

The diameter of the hole through the valve plunger that permits the flow of gas shall be not less than the minimum diameter allowed through a probe complying with BS 5682:1998.

The spring will be manufactured from stainless steel, the spring shall not compress when the check valve is under vacuum.

The probe seal will be selected to ensure a gas tight seal when a probe is connected.
The Viton® 'O' ring will ensure a gas tight seal when a probe is not connected and the valve plunger is closed.

The valve plunger will be designed to provide a gas tight seal against the probe seal when a probe is not connected in the event of the 'O' ring fail. The probe seal will also ensure that the valve plunger is retained in the valve body if this situation occurs.

The check valve should be capable of withstanding an inlet pressure of 20 bar.
The check valve is installed into the first fix assembly and seals against the retainer at the front of the brass block. The check valve is retained in position by the second fix assembly.

Second Fix Assembly

The second fix assembly will comprise of the following components;

1. 1 no. Body (Gas Specific)
2. 1 no. Locking Ring
3. 1 no. Anti-swivel Pin
4. 1 no. Gas Identity Label (Gas Specific)
5. 1 no. Spring
6. 2 nos. Latch Pin
7. 2 nos. Allen Head Screw, M4 x 16mm long

The body and locking ring will be die cast from zinc alloy and Teflon coated.

The springs, latch pins, anti-swivel pin and Allen head screws will be manufactured from stainless steel.

A body will be die cast for each medical gas detailed above. Each body will incorporate a gas specific connection point to suit the probe collar dimensions as defined in BS 5682:1998. It shall not be possible to insert a probe for a different gas into a body for any particular gas.

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Each body will also incorporate a gas specific coding hole to match the coding pin position in the first fix assembly. It shall not be possible to assemble a second fix assembly for any particular gas onto a first fix assembly for a different gas.

The relevant gas symbol as defined by BS EN 9170-1:2008 will be moulded into the flange of the body e.g. Oxygen=**O2**

The body will incorporate four holes in the probe collar connection point to accept a stainless steel anti-swivel pin installed from the front of the second fix assembly. These four positions will enable to the terminal unit to be installed in the 0º, 90º, 180º & 270º orientations.

The flange of the body will incorporate two holes to enable the first fix assembly and the second fix assembly to be assembled together with the M4 allen head screws.

The body and the locking ring will incorporate "keys" to ensure that the locking ring is assembled in the correct orientation.
The locking ring will incorporate two holes to enable access to the M4 allen head screws to allow for the second fix assembly to be installed and removed from the front of the Terminal Unit without Disassembly of the Terminal Unit.

The spring will retain the locking ring in the extended position ready for probe insertion.
The latch/roller pin retainers locate and retain the latch pins.

A gas identity label will be required for each type of medical gas detailed above. The label will be manufactured from a printed vinyl substrate with a 2 piece protective polypropylene laminate. The label will bear the relevant gas name or symbol, the text "BS EN 9170-1:2008" and be colour coded as a minimum.

Product Variants

The medical gas terminal unit will be available for the following types of gases;

a) Oxygen
b) Nitrous Oxide
c) 50% Oxygen/50% Nitrous Oxide mixture
d) Medical Air
e) Surgical Air
f) Medical Vacuum

The medical gas terminal unit will be available in the following variations;

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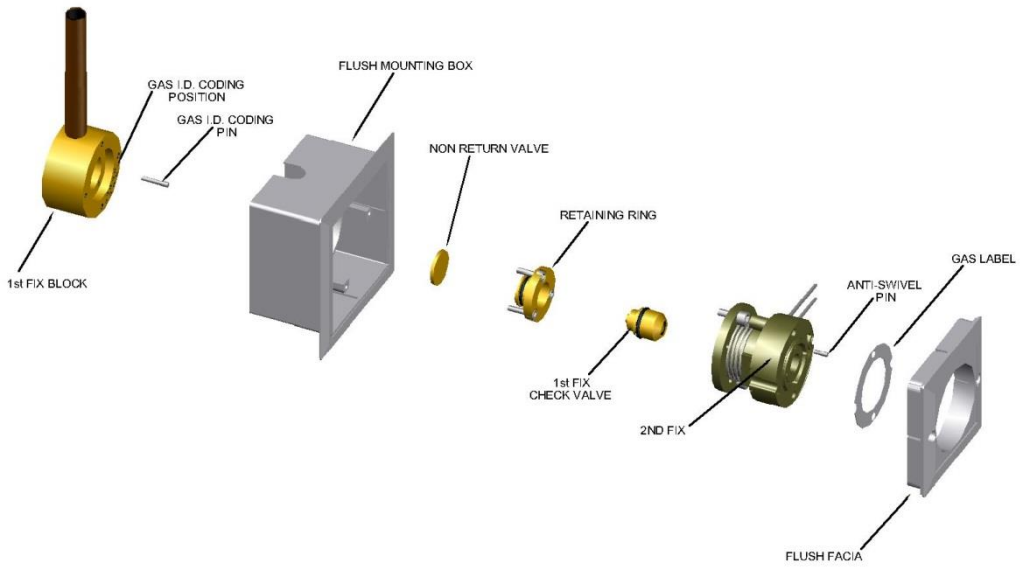
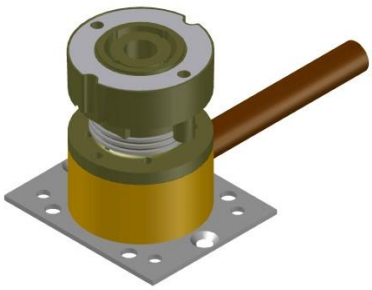
Standard wall mounting

Comprising of a side entry copper stub pipe first fix assembly, a second fix assembly, a check valve assembly and surface or flush mounting box kit.



Standard bedhead mounting

Comprising of a side entry copper stub pipe first fix assembly, a second fix assembly, a check valve assembly and multi positioning bed head mounting plate.



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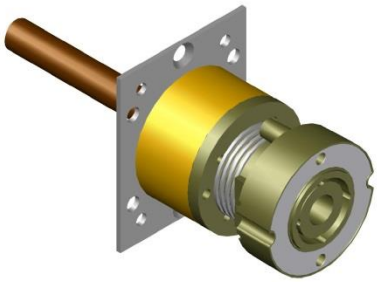
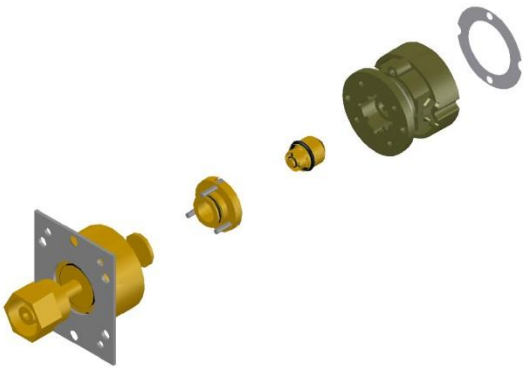
Rear entry bedhead mounting.
Comprising of a rear entry copper stub pipe first fix assembly, a second fix assembly, a check valve assembly and surface or flush mounting box kit.



Pendant mounting with NIST connector.
Comprising of a rear entry first fix assembly with NIST connector, a second fix assembly and a check valve assembly.



Definition of Intended Use
The medical gas terminal unit is intended to be used for the administration of a medical gas from a central supply system via a fixed pipeline in conjunction with other equipment fitted with a probe (quick connector) complying with BS EN 9170-1:2008.

The terminal unit is intended to supply gas to the equipment when the appropriate probe has been correctly inserted and will shut-off the gas supply automatically when the probe is disconnected.

It shall not be possible to connect a probe for a different gas into a terminal unit intended and labelled for another gas.

The terminal units are used to supply gases used during anaesthesia for analgesic purposes and to induce narcosis when used in conjunction with an anaesthetic machine or trolley.

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The terminal units are used to supply the drive gas to support breathing in conjunction with a lung ventilator during anaesthesia and in intensive care and-or neo-natal units.

The terminal units are used to supply gas for oxygen therapy in conjunction with flowmeters, nebulizers, humidifiers and facemasks.

The terminal units are used supply air to drive surgical tools used during operations.

The terminal units are used for the drainage of excess body fluids in conjunction with a suction controller and suitable receiving system.

The terminal units are used in medical engineering workshops for the testing of medical equipment used in conjunction with medical gases.

Medical vacuum terminal units should not be used for the removal of the smoke produced during laser surgery

Quality

CPX Precision UK Medical gas terminal units shall fully comply with the requirements of the UK DoH Health Technical Memorandum HTM2022 and HTM 02-01. Medical gas terminal units shall be CE marked to the Medical Device Directive 93/43/EC as a class IIb medical device. A copy of the certificate authorizing the manufacturer to apply CE marking under the aforementioned directive and a Certificate of Origin must be provided for review.

Medical gas terminal units shall be manufactured under an ISO 13485:2003 quality management system. A copy of the certificate of registration shall be provided for review. Terminal units shall be designed, manufactured and tested to BS EN 9170-1 and BS 6834 shall be marked with this standard and the manufacturer identification mark, all other standards are superseded by this and shall not be present on any part of the terminal unit. Terminal units shall have gas indexing geometry to BS 5682:1998. Other gas specific indexing geometries are not acceptable.

CE Marking

CPX Terminal units are CE marked as a Class IIb Medical Device 93/42/EEC with notified body British Standards Institute and stamped CE 0086.

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Product Cleanliness

CPX terminal units use CPX degreased copper tube which is cleaned and degreased for oxygen service and free from all particulate matter and toxic residues in accordance with BS EN 13348:2001 and has a maximum carbon level of 0.2mg/dm².

Each 1st fix assembly is individually end capped and in sealed polythene bags to maintain cleanliness.

CPX Medical Gas Terminal Units have a guaranteed cleanliness below 0.01 mg/cm² of hydrocarbons on the degreased surface of the product.

Each individual component shall be sealed in a clear polythene bag to protect against external contamination such as water and maintain cleanliness.

Installation Guidelines

Terminal units should be mounted at a height of between 900mm and 1400mm above finished floor level and not less than 200mm from any obstruction.

Where more than one terminal unit is to be mounted in one location, these should be mounted at the following spacing;

- Two terminal units - 150mm centres.
- Three or more terminal units - 135mm centres.

Terminal units mounted in a horizontal array shall be installed in the following sequence when viewed from the front, left to right;

O2; N2O; 50% O2/50% N2O; Medical Air; Surgical Air; Vacuum; AGSS

Determine the required position of the terminal unit and secure the first fix assembly and wall-mounting box, if required, using suitable fixings ensuring that the assembly is horizontal and plumb.

Braze the copper stub pipe to the fixed pipeline system. If the joint to be brazed is close to the brass block, remove the internal components during the brazing operation.
Fit the first fix test plug into the first fix assembly and pressure test the pipeline system.
When the wall is finished, remove the test plug and fit the check valve assembly and second fix assembly.

Fit the fascia and flush surround if required, pressure test and purge the pipeline system.
Remove the anti-swivel pin if this is not required.

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Pipeline Jointing

Copper to copper joints shall be made on site using copper, phosphorus and silver brazing alloy CuP282 to BS EN 17672:2010. Brazing should be carried out using oxygen free nitrogen as an inert gas shield to prevent the formation of oxides on the inside of the pipe. Copper pipes shall be cut square with the pipe axis using a sharp wheel cutter wherever possible, and be cleaned to get rid of any cuttings or burrs.

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