

PRODUCTS COVERED	92516 CAPNO POD, 92517 CAPNO MODULE, 92518 MULTIGAS MODULE
TITLE	CALIBRATION GASES NO LONGER AVAILABLE WITH CE MARK
SUBTITLE	N/A
NUMBER	077-0671-00 Rev. A
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## 1 Purpose

This document is intended to provide information on handling of calibration and accuracy checks for the 92516 CAPNO POD, 92517 CAPNO MODULE, 92518 MULTIGAS MODULE where 712-1032-00 and 712-1037-00 Calibration gases are unable to be acquired due to removal of CE mark.

## 2 Solution

Due to regulatory changes our supplier for the 712-1032-00 and 712-1037-00 calibration gases have removed their CE mark. Spacelabs has attempted to source alternative suppliers for this demand without success and therefore these calibration gases are no longer available in countries where the CE mark is required.

Servicing of the devices where calibration gas is required but unable to be obtained will instead need to be performed by the Equipment Service Center in Snoqualmie, WA (USA) where calibration gas can be used.

## 3 Background Information

- 3.1 92517 and 92516 internal NomoLine ISA CO2 bench assemblies 010-1948-10 are permanently factory calibrated and do not require any routine user calibration, zeroing is also performed automatically.
- 3.2 92517 and 92516 ISA CO2 benches 010-1948-04 and below still require annual calibration and performance checks, these benches will need to be sent to the Equipment Service Center.
- 3.3 92518 ISA AX+ Multigas bench assemblies 010-1924-XX, span calibration is not required but may be performed as an optional calibration or check, should this need performed these devices will have to be sent to the Equipment Service Center.
- 3.4 92518 Multigas Module, Oxygen Calibration should be completed on first installation and once a year thereafter, should this need performed it should be done with 100% O2 using a hospital supplied source, alternative 55% source using the 712-1032-00 Calibration gas will not be available where CE mark is required. If no 100% source is available for performing the recommended annual maintenance device should be sent to the Equipment Service Center.

## 4 Procedure

Should End User want to perform accuracy check the gas mixture may be acquired from the vendor of your choice, provided the following gas concentrations and accuracies are met. Depending on your application, either a CO2 (92516 and 92517) or Multigas (92518) gas mixture should be used. (see Figure 1 – Figure 4)

Should device require calibration or service, please contact your Spacelabs Service representative for additional information regarding sending your device to the Equipment Service Center.

Multigas Mixture	
GAS	Concentration
CO2	4%-11%
N2O	30%-100%
Desflurane	2%-12%
O2	46%-100%
N2	Balance %

Figure 1

Accuracy of mixture for all gases is +/- .03 vol% or +/- (.02 vol% + .1% of reading), whichever is greater. Oxygen concentration must be a whole percent (%).

Multigas Reading Measurement Values	
GAS	Accuracy
CO2	+/- (0.3 vol% + 4% of reading)
N2O	+/- (2 vol% + 5% of reading)
Desflurane	+/- (0.2 vol% + 10% of reading)
O2	+/- (2 vol% + 2% of reading)

Figure 2

\*See service manual p/n 070-2362-00 for instructions in addition to gas data considerations for further information about effects of humidity and interfering gas and vapor effects.

Capnography Mixture	
GAS	Concentration
CO2	4%-11%

Figure 3

Accuracy of mixture  $\pm 0.03$  vol% or  $\pm (0.02$  vol% + 0.1% of reading), whichever is greater.

Gas readings shall be within the following ranges:

Capnography Reading Measurement Values	
GAS	Accuracy
CO2	+/- (0.3 kPa + 4% of reading)

Figure 4

\*See service manuals P/N 070-2475-02 (92517) and 070-2458-03 (92516) for instructions in addition to gas data considerations for further information about effects of humidity and interfering gas and vapor effects.

\*See CSN P/N 077-0505-00 regarding capnography effects of O2 on CO2 readings.