Operating Manual for the Im*pact*-III Veterinary MultiMonitor from Vetronic Services

This manual contains important information for your Im*pact*-III
Please keep it in a safe place.

- Impact-III Operators Manual -

Scope: This document covers the user features of the Impact-III only. For technical information see the Specification Sheets.

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Introduction

The Impact-III multi-parameter monitor is a hand-held, battery-powered unit designed for use in monitoring vital signs of animals. The Impact-III unit is capable of measuring 2 channels of temperature data, 1 channel of Pulse-Oximetry data and 1 channel of sidestream CO2 breath data. The unit has a set of internal rechargeable NimH batteries with an operating time of approximately 6 hours. The unit may be charged and used at the same time. The unit is charged by connecting the supplied charger to the DC input jack on the right hand side of the unit. Please note that the charger has very specific requirements and only the charger supplied with the unit should be used as irreparable damage may otherwise occur to the unit.

Impact-III Connections

Figure 1

Power Connection & Charging Indicator

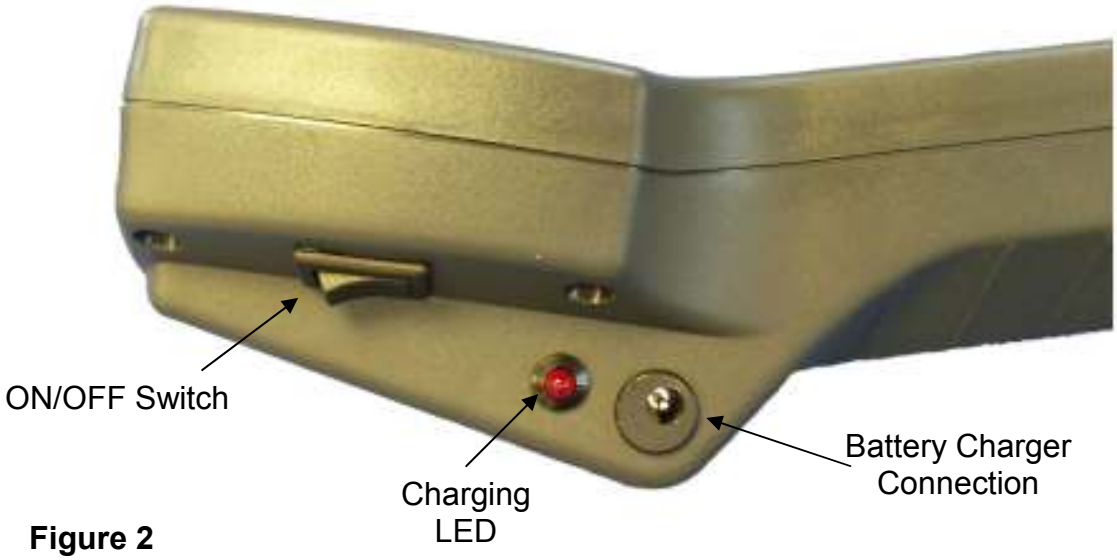

Figure 2

Temperature Sensor & Power Connections

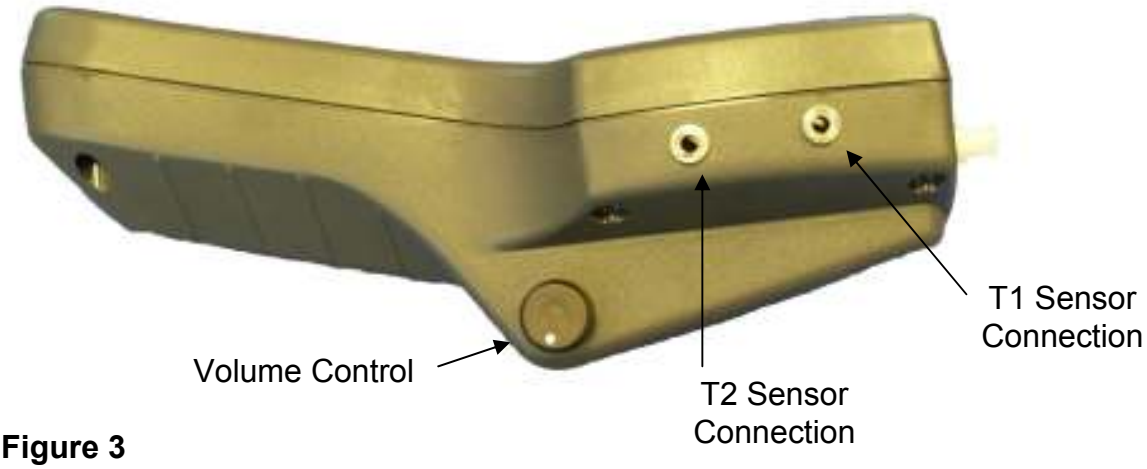

Figure 3

Button functions

There are just three buttons to control all of the functions of the Impact-III.
To move between options, press the NEXT button. To select an option or accept a change, press the CHANGE/OK button.

SETUP button
Use this button to access the first level of option menus. This button can be pressed at any time and will reveal a SETUP OPTIONS menu. From here the options for PULSE-OX, SIDESTREAM, TEMPERATURE and GENERAL are available. The individual options have the following functions:

PULSE-OX
Enter this menu option to set all Pulse-Ox trace parameters (e.g. gain, sweep speed) and all Pulse-Ox alarms.

SIDESTREAM
Enter this menu option to set all Sidestream Gas Analyser trace parameters (e.g. Sweep speed. Line or Fill) and all Sidestream alarms.

TEMPERATURE
Enter this menu option to set the temperature readings in Fahrenheit or Centigrade and to access all the Temperature alarm options.

NEXT button
Use the NEXT button to move between menu items.

CHANGE/OK button
Use the CHANGE/OK button to accept a menu option or to enter a sub-menu.
In alarm settings this button changes the value of the alarm parameter.

NEXT and **CHANGE** buttons
Pressing the NEXT and the CHANGE button simultaneously will either temporarily (60 seconds) or permanently silence any alarm conditions.

Initial Use

Turn the unit ON using the rocker switch on the left-hand side of the unit. The main screen will illuminate and 3 short beeps will be heard indicating that the unit is ready for use.

The unit is capable of displaying information for three separate systems. Which ones are displayed will depend on the actual modules fitted to the unit. The possible options are Pulse-Oximetry, Capnography and Dual temperature. With all three options fitted, the Pulse-Oximetry data will be displayed on the top half of the screen, Capnography data on the lower half of the screen and Temperature data to the left hand side on the lowest line of the screen. Status information, such as causes of Alarms and battery status are shown on the right hand side on the lowest line of the screen. For more information on Status and Alarm information see the section on Status Information.

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When using the Sidestream CO2 analyser (ISA Module) the sample gas must be returned to either the patient anaesthetic circuit or to the scavenging circuit as it will contain anaesthetic gases. Use the luer connector at the back of the unit to connect a waste gas line for gas removal.

Beeps and Alarms

Beeps and Alarms are indicated by a small loudspeaker located on the bottom of the unit. The volume control for these sounds is located on the right hand side of the unit. Turning the control clock-wise increases the loudness of the beeps.
Beeps can be associated with either Pulse-Oximetry or Capnography to indicate a pulse or a breath respectively. To control which monitored parameter produces a beep use the SETUP button to access the GENERAL OPTIONS menu. From here use OK to select the BEEPS menu. Then use the OK button to move between NONE, RESP (ISA CO2) or PULSE (Pulse-Oximetry)

Alarm Silencing

Alarms can be silenced for 60 seconds or permanently.
To silence alarms for 60 seconds press the OK and NEXT buttons simultaneously until the message “PAUSE:59” appears in the status window.
To silence alarms permanently, press the OK and NEXT buttons simultaneously until the message “SILENCED” appears in the status window.

Low Battery Indication
When the battery voltage is low and recharging is required a message will appear in the lower status line. This will alternate with any other message that may be displayed.

Two battery-related messages may appear:

LOW BATT! at which point all functions of the unit will remain normal but charging is necessary.

!! BATT!! if this message appears then the functions of the monitors may be affected and the unit will soon turn off unless the mains charger is plugged in.

Removing and Adding Traces
The Pulse-Ox or Sidestream traces can be removed if they are not needed during a monitoring session. This leaves more room for the remaining trace which will then use the screen to draw two traces, one above the other effectively lengthening the trace viewing region. Enable or disable a module using the ENABLED/DISABLED feature in the appropriate module’s OPTION menu. Access the module’s OPTION menu from the SETUP button.

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Capnography

Important Note:

The ISA sidestream multi-gas probe is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases of patients in intensive care, anaesthesia and emergency care. It is not intended to be used as the only means of monitoring a patient. It shall always be used in combination with other vital signs monitoring devices and/or professional human judgements of patient condition. The ISA multi-gas analyser is intended to be used by trained and authorised veterinary professionals only. It is not intended to be used in outdoor transport applications such as in cars or in aircrafts.

To monitor an animal's inspired and expired CO2 levels, connect a Nomoline sampling line to the Capnograph Port. On insertion of the Nomoline the clear plastic around the connector will be lit by a green LED indicating that all is well and that the unit is ready to use. If for any reason this LED is red then an error has occurred and the fault will be reported on the main screen.
As with all Sidestream sampling systems, the working life of the Nomoline can be greatly extended if sampling connection takes gas from the upper side of the airway connection. This prevents water vapour that condenses, running into the Nomoline. The sampled gas from the ISA unit must be returned to the patient circuit or scavenged so that anaesthetic gases are not allowed to escape into the room.

Best results will be obtained if the sampling line can connect to a point in the patient's breathing circuit that is as close to the end of the ET tube as possible and with as little dead space as possible. For this purpose a set of ET Tube connectors with side-port connections are provided. It is advised that these be used with patients requiring ET tube sizes of 5.0mm or less. For patients using ET tubes of greater than 5.0mm the standard 15mm (or larger) T-piece connector should be used. There is no upper weight or upper animal size limitation using the Nomoline sidestream unit. The lower size limitation is governed by animal tidal volume and effective dead space. If dead space can be effectively removed then the system is capable of monitoring animals as small as 100g accurately.

Waste Gas

The sampled gas taken from the patient's breathing circuit is expelled from the Impact-III via the Waste Gas Connector on the rear of the unit (see Figure 1). It is important that this waste gas is scavenged or returned to the patient circuit on the expiratory side. A waste line and 22mm airway adaptor are provided for this purpose. The Waste Gas output must not be left open to the atmosphere as this will result in anaesthetic agents being discharged into the room.

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ISA Usage and Information

- The ISA Sidestream gas analyser is intended for use by authorized and trained medical personnel only.
- Use only approved Nomoline sensors with the ISA analyser
- Replace the Sampling line if the sampling line input connector starts flashing red or a Nomoline occlusion message appears on the screen.
- The ISA Sidestream analyser must not be used with flammable anaesthetic agents
- Do not use the ISA Sidestream gas analyser with metered-dose inhalers or nebulised medications as this may clog the bacterial filter
- Do not autoclave any part of the Nomoline sampling line
- Never sterilise or immerse the ISA Sidestream gas analyser in liquid
- ISA Sidestream gas analysers are not designed for MRI environments
- Exhaust gases should be returned to the patient circuit or a scavenging system

Pre-use Check

Before connecting the Nomoline to the patient circuit, perform the following pre-use check:

- Connect the sampling line to the ISA gas inlet connector (LEGI)
- Check that the LEGI shows a steady green light, indicating that the system is OK
- Breathe into the sampling line and check that valid waveforms and values are displayed on the VitalStore main screen.
- Occlude the sampling line and wait 10 seconds, until the occlusion alarm is displayed and the LEGI shows a flashing red light

Calibration

The ISA modules are all self-calibrating. At turn-on, or insertion of a Nomoline sampling line, the unit will perform a self-calibration. For modules that have been running continuously during any monitoring session then an internal automatic calibration occurs at approximately 3 hour intervals.
There is no need or indeed any procedure that the user can perform for module calibration. During calibration, the input to the analyser is switched from the sampling line to room air. This means there is no need to disconnect the sampling line from the patient circuit during the automatic calibration period.

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LED's and Alarms

The status of the module is indicated by the colour and format of the LED on the LEGI

Indication	**Status**
Steady green light	System OK
Blinking green light	Zeroing in progress
Steady red light	Sensor error
Blinking red light	Check Sampling line

Trace and Alarm options for the Sidestream Gas Analyser

Trace Options

All Trace and Alarm options for the Sidestream Gas Analyser can be accessed through the SETUP menu. Press the SETUP button to display the SETUP OPTIONS menu. Use the NEXT button to position the cursor next to the SIDESTREAM option and then press the OK button. A sub-menu of SIDESTREAM OPTIONS appears. The following options are available:

ENABLED – use OK button to switch the trace between ENABLED/DISABLED.
When the trace is DISABLED no waveform or monitoring values are displayed on the screen

SWEEP SPEED – use the OK button to change the speed through the 4 options
V. SLOW
SLOW
MEDIUM
FAST

GAIN – use the OK button to change the height of the CO2 waveform. There are 5 options
SMALLEST
SMALL
MEDIUM
LARGE
LARGEST

TRACE – use the OK button to switch between a line trace and a solid/filled trace

CO2 – use the OK button to change the CO2 units from mmHg to vol%

ALARM OPTIONS – use the OK button to enter the ISA ALARM OPTIONS menu

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ISA ALARM OPTIONS Menu

All Alarm options for the ISA unit and other parameters in the IMPACT-III use the same basic format. There is an option to increase the alarm threshold value, an option to decrease the Alarm threshold value and an option to Enable or Disable the Alarm feature.
Select an option by using the NEXT button to place the selection arrow next to the option. Then use the OK button to change the value.
Use the EXIT option to exit each menu or submenu.
All Trace and Alarm options are saved to memory as soon as they are made and will be remembered when the machine is turned off.

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Pulse-Oximetry

The impact-III Pulse-Oximetry module uses Nonin veterinary Pulse-Oximeter technology and can be used with Nonin sensors or Nonin-compatible sensors. Two sensors are commonly used: a Transmission sensor and a Reflectance sensor. Transmission sensors are typically placed on the tongue or ear, whilst Reflectance sensors can be placed under the base of the tail, in the ear against the medial wall or against gingivae/nasal septum.

Sensors connect to the unit via a 9-Way Male D-Type connector at the rear of the unit (see Figure 1). Extension cables are available to enable further spacing between the monitor and the patient. Only Nonin-compatible extension cables should be used. The Pulse-Oximeter module will monitor the pulse rate and oxygen saturation levels of patients with heart rates in the range of 10 - 300 bpm. Sensors may be connected or disconnected while the unit is powered ON without any problems.

Obtaining a Plethysmogram or Pulse Trace

Patient Connection
Connect the probe to the unit either directly or through the extension cable. The red LED should become lit on the probe when connected. When using a Transmission probe, place the probe across a bed of vascular tissue such as the tongue, ear, vulval or prepucial folds. The probe should hold itself in place and should not be held fully open once in position. With a Reflectance probe, place the probe so that it lies over vascular tissue with some dense material such as bone or cartilage beneath the vessels. The dense material improves the amount of signal returned through the vessels, thereby improving the signal quality. Suitable sites are the medial wall of the ear canal, the ventral aspect of the proximal tail, or in larger animals the nasal septum. Hold the probe in place with a swab or cotton wool ball.

Validation of the Trace Information
The Pulse-Oximeter module evaluates the information obtained from the sensor and assigns a level of credibility to it. This level is displayed as the characters **A**, **B** or **C** below the % sign in the numerical region. These codes have the following meaning.
A - Good pulse strength, reliable signal and values
B - Moderate pulse strength, interpret signal and values with caution
C- Pulse strength too weak for signal and values to be reliable

In addition, the pulse waveform or plethysmogram is not displayed until a valid pulse and saturation has been detected. This means that there is a slight delay between placing the probe and obtaining a trace and value. During this time the trace will be a flat line and the saturation and pulse rate values will be shown as "--".

Scaling of the Plethysmogram
There is no automatic scaling of the plethysmogram. This means that if the trace height falls by 50% then the signal strength has fallen by 50%. This also means that for very strong signals the top of the waveform may be flattened, indicating the signal has reached maximum size.

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Viewing the Plethysmogram

Make sure the Pulse-Ox trace is visible in the monitor window. If the trace is absent then the Pulse-Oximetry option may be Disabled. To re-enable the Pulse-Oximeter trace, press the SETUP button. With PULSE-OX selected, press the OK button to enter the PULSE-OX Options menu. The first option is Enabling/Disabling of the trace. Press the OK button until the option ENABLED is shown. Then press the NEXT button to move down to the EXIT option and press OK. A line will be seen moving from left to right across the screen and the numerical region will display --% until a valid pulse is detected.
Once a pulse is detected the saturation and pulse rate values, together with the confidence level will appear in the numerical data region. This typically takes between 10 and 15 seconds.

Trace and Alarm options
The Trace options can be viewed by entering the SETUP menu and selecting PULSE-OX at any time. In the PULSE-OX OPTIONS menu use the NEXT button to move between menu options.

In the PULSE-OX OPTIONS menu the following is displayed:

ENABLED – use OK button to switch between ENABLED/DISABLED

SWEEP SPEED – use the OK button to change the speed through the 4 options
- V. SLOW
- SLOW
- MEDIUM
- FAST

GAIN – use the OK button to change the height of the Pulse-Ox signals. There are 5 options
- SMALLEST
- SMALL
- MEDIUM
- LARGE
- LARGEST

TRACE – use the OK button to switch between a line trace and a solid/filled trace

ALARMS – use the OK button to enter the PULSE OX ALARMS menu

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PULSE-OX ALARMS Menu

It is possible to set alarms for the following parameters:
Upper Heart Rate
Lower Heart Rate
Saturation Limit

All Alarm options for Pulse-Oximetry and other parameters in the IMPACT-III use the same basic format. There is an option to increase the alarm threshold value, an option to decrease the Alarm threshold value and a option to Enable or Disable the Alarm feature.
Select an option by using the NEXT button to place the selection arrow next to the option. Then use the OK button to change the value.
Use the EXIT option to exit each menu or submenu.

All Trace and Alarm options are saved to memory as soon as they are made and will be remembered when the machine is turned off.

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Status Information

The Impact-III displays status information on the right hand side of the screen on the lowest line of the screen. If there are no active alarms then this area will remain clear. Note that after turning on the unit, no alarms are active for the first 60 seconds regardless of cause. The possible alarm messages seen in the Alarm Status window are listed below. An alarm will only be announced if the alarm feature is ENABLED.

Alarm Message	Associated With	Reason for Alarm
HIGH HR	Pulse-Oximetry	The measured heart rate is above the maximum alarm threshold
LOW HR	Pulse-Oximetry	The measured heart rate is below the maximum alarm threshold
LOW SAT	Pulse-Oximetry	The measured oxygen saturation is below the alarm threshold
NO PROBE	Pulse-Oximetry	There is no Pulse-Ox probe fitted or the fitted probe is faulty
HIGH ET	Sidestream CO2	The measured End Tidal CO2 value is above the alarm threshold
LOW ET	Sidestream CO2	The measured End Tidal CO2 value is below the alarm threshold
INSP CO2	Sidestream CO2	The measured Inspired level of CO2 is above the alarm threshold
APNOEA	Sidestream CO2	The time since the last breath has exceeded the alarm setting
HIGH RR	Sidestream CO2	The measured Respiratory rate is above the alarm threshold
LOW RR	Sidestream CO2	The measured Respiratory rate is below the alarm threshold
NO S/L	Sidestream CO2	There is no Nomoline sampling line connected to the LEGI connector
HIGH T1	Temperature	The measure temperature on T1 is above the alarm threshold
LOW T1	Temperature	The measure temperature on T1 is below the alarm threshold
HIGH T2	Temperature	The measure temperature on T2 is above the alarm threshold
LOW T2	Temperature	The measure temperature on T2 is below the alarm threshold
HI DELTA	Temperature	The difference between t1 and T2 exceeds the alarm threshold
LOW BATT	Battery	The internal battery is low connect the mains charger
!! BATT !!	Battery	The internal battery is critically low. The unit may stop function at anytime if not connected to a mains supply. Readings are unreliable.

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Temperature Module

General

The Temperature module is a dual-temperature module suitable for monitoring internal and external body temperatures simultaneously. Each Temperature is shown on the lower left hand side of the display in turn along with the Delta Value.

Sensor Options

The temperature module may be supplied to be compatible with YSI 400 series temperature sensors or with type B8415 glass bead thermistors.
Type B8415 sensors are very small and form a measuring head of less than 1.2mm diameter and also have a fast response time.

Setup and Use

Connect the temperature sensor(s) to either of the temperature sensor sockets located on the right hand side of the unit – see Figure 3.
A 1m extension cable is provided to enable easier placement of the sensors, although the sensors can be directly connected to the unit without the extension cables if required.

Without any sensors connected the lower left hand corner of the screen will show:
T1: --, T2:--, DELTA:-- repeatedly in turn

Once a sensor is connected the temperature value will be displayed after the appropriate sensor. The values for T1, T2 and the Delta value are shown in turn. If there is no text shown in the lower left hand corner of the screen, the unit does not have the temperature module option fitted.
Note that a Delta value will only be shown if both temperature sensors are connected.

Changing Units

The temperature values and alarms can be viewed in either Celsius or Fahrenheit. To change the units, enter the TEMPERATURE OPTIONS menu by pressing SETUP and then selecting TEMPERATURE. The selection arrow will then lie next to the UNITS option. Press the CHANGE button to alter the units. To leave the menu press NEXT to move down to the EXIT option and then press CHANGE.

Setting Alarms

It is possible to set alarms for the following parameters:

Upper T1 Limit
Lower T1 Limit
Upper T2 Limit
Lower T2 Limit
Max Delta

All Alarm options for Temperature and other parameters in the IMPACT-III use the same basic format. There is an option to increase the alarm threshold value, an option to decrease the Alarm threshold value and an option to Enable or Disable the Alarm feature.

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Select an option by using the NEXT button to place the selection arrow next to the option. Then use the OK button to change the value.
Use the EXIT option to exit each menu or submenu.

All Trace and Alarm options are saved to memory as soon as they are made and will be remembered when the machine is turned off.

Alarm Behaviour
When an Alarm value is reached during normal use the Alarm will sound. This is heard as three consecutive beeps with a rising tone to each beep. This is repeated every 3 seconds until the alarm condition is cleared or the Alarms are paused or silenced.
If an Alarm condition relates to either Pulse-Oximetry or to the Sidestream Gas Analyser then the numerical values on the right of the screen will flash to indicate the module responsible for the alarm

DECLARATION OF CONFORMITY

For: Impact-III Veterinary Monitor

Date: September 25th 2012

It is hereby declared that the following equipment conforms with the essential protection requirements of Council Directive 89/336/EEC relating to Electromagnetic Compatibility. It is further declared that the following equipment conforms to the Low Voltage Directive EN60950

Such equipment is intended for use on animal patients only.

Equipment Description:
Hand-held Multi-parameter Monitor including Sidestream Gas Analyser, Pulse-Oximetry and Dual Temperature modules.
Model Prefix: Impact-III
Input Voltage: DC only. 9v, 2A
Rated power: 20W maximum
Intended use: For use in Veterinary practice or animal research establishments for the purpose of monitoring vital signs in anaesthetised or conscious patients.

Description:
A Class II appliance designed to run from an internal battery source. The Appliance may be additionally powered by a CE-compliant power source providing 9v, 2A DC

Standards Applied:

Safety	EN60950
EMC	EN50081-1 Emissions
	EN50082-1 Immunity

Authorised signatory to this declaration, on behalf of the manufacturer is identified below:

Name: Keith Simpson
Title: Managing Director
Vetronic Services LTD
12 Henleys Business Park
Manor Road, Abbotskerswell
Newton Abbot
Devon, TQ12 5NF

Signed……..
Keith Simpson, Managing Director, Vetronic Services LTD

Appendix 1
Specifications **ISA Gas Analyser**

Specifications

Intended use

The ISA product family consists of different types of sidestream gas analyzers, intended to be connected to other medical devices for display of real time and derived monitoring data of a selection of CO_2, N_2O, O_2 and the anesthetic agents Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane.

The ISA product family is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room and for applicable versions emergency medicine/emergency transport settings for adult, pediatric and infant patients.

The ISA product family is not intended to be used as the only means of monitoring a patient. They shall always be used in combination with other vital signs monitoring devices and/or professional human judgments of patient condition. Products in the ISA product family are intended to be used by trained and authorized health care professionals only.

They are only intended to be connected to medical devices approved by PHASEIN AB.

General specifications

Description	Ultra-compact, low-flow sidestream gas analyzers with integrated pump, zeroing valve and flow controller.	
Dimensions (W×D×H)[1]	ISA CO_2/AX+: ISA OR+: ISA CO_2/AX+ Module:	33 x 78 x 49 mm (1.3" x 3.1" x 1.9") 49 x 90 x 100 mm (1.9" x 3.5" x 3.9") 23 x 64 x 39 mm (0.9" x 2.5" x 1.5")
Weight	ISA CO_2/AX+: ISA OR+: ISA CO_2/AX+ Module:	130 g including cable 400 g including cable 70 g
Operating temperature	ISA CO_2: ISA OR+/AX+:	0 to 50 °C (32 to 122 °F) 5 to 50 °C (41 to 122 °F)
Storage temperature	−40 to 70 °C (−40 to 158 °F)	
Operating humidity	< 4 kPa H_2O (non-condensing) (95 %RH at 30 °C)	
Storage humidity	5 to 100 %RH (condensing)[2] (100 %RH at 40 °C)	
Operating atmospheric pressure	52.5 to 120 kPa (corresponding to a max altitude of 4572 m / 15 000 feet)	
Storage atmospheric	20 to 120 kPa	

[1] Excluding cable, tubing and Nomoline.
[2] The unit shall after condensation be stored for more than 24h in an environment with relative moisture content below 95 %RH (non-condensing).

pressure	(corresponding to a max altitude of 11760 m / 38 600 feet)
Ambient CO_2	≤ 800 ppm
Mechanical robustness	ISA CO2: Meets the shock and vibration requirements for transport of SS-EN ISO 21647:2004 clause 21.102 and SS-EN 1789:2007 clause 6.3.4.2. ISA OR+/AX+: Meets the shock and vibration requirements of SS-EN ISO 21647:2004 clause 21.101
Power supply	ISA CO2: < 1.4 W (normal op.), < 1.8 W (peak @ 5 VDC) ISA AX+: < 1.6 W (normal op.), < 2.0 W (peak @ 5 VDC) ISA OR+: < 2.0 W (normal op.), < 2.4 W (peak @ 5 VDC)
Interface	USB or RS-232 serial interface. Software upgrade possible using the RS-232 serial interface.
Water handling	Sampling line with proprietary water removal tubing.
Sampling lines	2 ± 0.1 m and 3 ± 0.1 m versions
Sampling flow rate	50 ± 10 ml/min

Data output

Breath detection	Adaptive threshold, minimum 1 vol% change in CO_2 concentration.
Respiration rate	0 to 150 ± 1 breaths/min
Fi and ET	ISA CO_2: CO_2 ISA OR+/AX+: CO_2, N_2O, O_2, primary and secondary agents (HAL, ENF, ISO, SEV, DES)
Automatic agent identification	ISA OR+/AX+: Primary and secondary agent.
Waveforms	Up to five simultaneous gas concentration waveforms.
Diagnostic parameters	Atmospheric pressure Cuvette pressure Serial number Software revision Hardware revision
Flags	Breath detected No breaths detected Replace O_2 sensor Check sampling line Unspecified accuracy Sensor error

Gas analyzer

Sensor head	2 to 9 channel NDIR type gas analyzer measuring at 4 to 10 µm.	
Compensations	ISA CO2:	Automatic compensation for pressure and temperature. Manual compensation for broadening effects on CO_2.
	ISA OR+/AX+:	Automatic compensation for pressure, temperature and broadening effects on CO_2.
Calibration	No span calibration is required for the IR bench. An automatic zero reference calibration is performed at startup and then every 24 hours[1].	
Warm-up time	ISA CO2:	< 10 seconds (Concentrations reported and full accuracy)
	ISA OR+/AX+:	< 20 seconds (Concentrations reported, automatic agent identification enabled and full accuracy)
Typical rise time at 50 ml/min sample flow	CO_2	≤ 200 ms (≤ 250 ms for ISA OR+/AX+)
	N_2O	≤ 350 ms
	Agents	≤ 350 ms
	O_2	≤ 450 ms[2]
Primary agent threshold (ISA OR+/AX+)	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol%	
Secondary agent threshold (ISA OR+/AX+)	0.2 vol% + 10% of total agent concentration	
Agent identification time (ISA OR+/AX+)	< 20 seconds (typically < 10 seconds)	
Total system response time	< 3 seconds (with 2 m sampling line)	

Accuracy – standard conditions

The following accuracy specifications are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa:

Gas	Range[3]	Accuracy
CO_2	0 to 15 vol% 15 to 25 vol%	±(0.2 vol% + 2% of reading) Unspecified
N_2O	0 to 100 vol%	±(2 vol% + 2% of reading)
HAL, ENF, ISO	0 to 8 vol% 8 to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified
SEV	0 to 10 vol% 10 to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified
DES	0 to 22 vol% 22 to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified

[1] Every 8 hours for ISA OR+/AX+.
[2] For a 5 vol% O_2 step.
[3] All gas concentrations are reported in units of volume percent and may be translated into mmHg or kPa by using the reported atmospheric pressure.

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O_2	0 to 100 vol%	±(1 vol% + 2% of reading)

Accuracy – all conditions

The following accuracy specifications are valid for all specified environmental conditions:

Gas	Accuracy
CO_2	±(0.3 kPa + 4% of reading)
N_2O	±(2 kPa + 5% of reading)
Agents [1]	±(0.2 kPa + 10% of reading)
O_2	±(2 kPa + 2% of reading)

Note 1: The accuracy specification is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set.

Interfering gas and vapor effects

Gas or vapor	Gas level	CO_2		Agents	N_2O
		ISA CO_2	ISA AX+		
N_2O [4]	60 vol%	– [2]	– [1]	– [1]	– [1]
HAL [4]	4 vol%	– [1]	– [1]	– [1]	– [1]
ENF, ISO, SEV [4]	5 vol%	+8% of reading [3]	– [1]	– [1]	– [1]
DES [4]	15 vol%	+12% of reading [3]	– [1]	– [1]	– [1]
Xe (Xenon) [4]	80 vol%	−10% of reading [3]		– [1]	– [1]
He (Helium) [4]	50 vol%	−6% of reading [3]		– [1]	– [1]
Metered dose inhaler propellants [4]	Not for use with metered dose inhaler propellants				
C_2H_5OH (Ethanol) [4]	0.3 vol%	– [1]	– [1]	– [1]	– [1]
C_3H_7OH (Isopropanol) [4]	0.5 vol%	– [1]	– [1]	– [1]	– [1]
CH_3COCH_3 (Acetone) [4]	1 vol%	– [1]	– [1]	– [1]	– [1]
CH_4 (Methane) [4]	3 vol%	– [1]	– [1]	– [1]	– [1]
CO (Carbon monoxide) [5]	1 vol%	– [1]	– [1]	– [1]	– [1]
NO (Nitrogen monoxide) [5]	0.02 vol%	– [1]	– [1]	– [1]	– [1]
O_2 [5]	100 vol%	– [2]	– [2]	– [1]	– [1]

Note 1: Negligible interference, effect included in the specification "Accuracy, all conditions" above.

Note 2: Negligible interference with N_2O / O_2 concentrations correctly set, effect included in the specification "Accuracy, all conditions" above.

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO_2 and 50 vol% Helium, the actual measured CO_2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO_2.

Note 4: According to the EN ISO 21647:2004 standard.

Electromagnetic compatibility (EMC)

Electromagnetic emissions

This section constitutes the guidance and PHASEIN's declaration regarding electromagnetic emissions for the ISA gas analyzers.

ISA gas analyzers are intended for use in the electromagnetic environment specified in the table below. Customers and end users of ISA gas analyzers should assure that they are used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The ISA sensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ISA sensor is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Electromagnetic immunity

This section constitutes the guidance and PHASEIN's declaration regarding electromagnetic immunity for the ISA gas analyzers.

ISA gas analyzers are intended for use in the electromagnetic environment specified below. Customers or end users of ISA gas analyzers should assure that they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	AC power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s)	N/A	AC power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
	to earth		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T[1] (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	N/A	The AC power quality should be the same as in a typical commercial or hospital environment. If the user of the ISA sensor requires continued operation during power outages, the ISA sensor should be powered by an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Portable and mobile RF communications equipment should be used no closer to any part of the ISA sensor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms	$d = 0.35\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	20 V/m	$d = 0.18\sqrt{P}$ 80 MHz to 800 MHz $d = 0.35\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which ISA is used exceeds the applicable RF compliance level above, ISA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating ISA.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

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