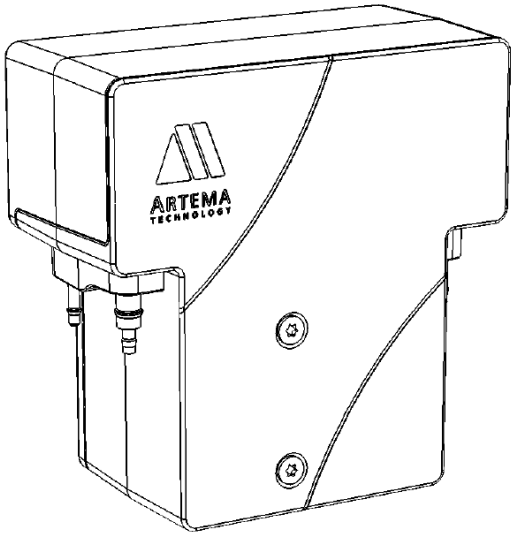
AION Rhodium® CO_2 Analyzer

Product Specification



Interfaces to optional

HUMMINGBIRD
SENSING TECHNOLOGY

INTRODUCTION

AION Rhodium® is a highly integrated CO_2 analyzer designed specifically for the OEM market. Even though it is not classified as a finished medical device it fulfils all relevant regulatory requirements. This, combined with a high degree of integrated parameters provides for an uncomplicated integration into host systems. The AION Rhodium® interfaces to optional oxygen sensors, paramagnetic or galvanic and can also be used together with the SPIRIT™ Respiratory Mechanics Analyzer for a full set of respiratory parameters.

INTENDED USE

AION Rhodium® is a highly integrated gas analyzer intended to continuously analyze CO_2 concentration and breath rate during intensive care and anesthesia. When used with an optional oxygen sensor, paramagnetic or galvanic, the analyzer also provides O_2 concentration data. All parameters are transmitted to a host instrument over a digital data interface. It is a compact, low-power and high-performance sub-unit intended to be integrated in other manufacturer's medical devices.

Indications:

- The respiratory gas measurement information provided by the analyzer is intended to be used by trained and authorized healthcare professionals only.
- The analyzer is only intended to be integrated into host devices by engineering professionals with relevant knowledge of medical device development and manufacturing. The host device manufacturer is responsible for the correct integration of the analyzer and handling of any risks that may arise.
- For accurate and safe function, the AION Rhodium® shall be used only together with Artema Technology® subsystems, accessories and disposables.
- The host instrument must fulfill applicable national requirements for Medical Devices.

Contraindications:

- The analyzer is not intended for use with flammable anesthetic agents.
- The analyzer is not intended to be used in outdoor transport applications such as cars or aircrafts.
- The analyzer is not intended to be used as the only means of monitoring a patient and it shall always be used in combination with other vital sign monitoring devices and/or professional human judgments of patient condition.
- **WARNING:** No modification of the analyzer is allowed.

NORMAL RANGE GENERAL SPECIFICATIONS			
Technology	NDIR type, diverting (side-stream) gas analyzer with optional external paramagnetic or galvanic oxygen sensor. Automatic ambient pressure and temperature compensation. Host supplied O_2[1)], N_20 and agent compensation input.		
Oxygen Sensor	• Optional external Hummingbird Paracube® Sprint Paramagnetic Oxygen sensor • Optional external OXIMA™ Galvanic Oxygen Sensor		
Operating modes	• Startup • ISO accuracy • Full accuracy		
Measured gases	CO_2, and O_2[2)]		
Measured parameters	• Momentary gas concentration • Inspired and expired concentrations of all measured gases • Breath rate		
Resolution	CO_2 : 0,01%; O_2[2)]: 0,1%		
CO_2 Zero threshold	Gas concentration set to zero if level below: • in full accuracy mode: 0.1 % • in ISO accuracy mode: 0.3% for more than 3 s		
Initialization time	Performs a self-test and enters standby mode within 10s where no data frames will be transmitted after hardware reset or a Reset command.		
System rise times ($t_{10-90\,\%}$) • 70 ml/min using DRYLINE™ II • 120 ml/min using DRYLINE™ II	**Gas component**	**@ 70 ml/min**	**@ 120 ml/min**
	CO_2	200 ms	200 ms
	O_2 Paramagnetic[2)] 15 to 21% (21 to 60%)	/	600 ms (800 ms)
	O_2 OXIMA™[2)] 15 to 21% (21 to 60%)	/	500 ms (600 ms)
System[3)] delay time ($t_{0-10\,\%}$)	<4 seconds		
Patient category	Adult, pediatric and neonatal		

Notes:

1. Automatic O_2 compensation if used with optional oxygen sensor
2. With optional oxygen sensor.
3. For a complete system with Artema Technology gas sampling accessories.

CO_2 MEASUREMENT SPECIFICATIONS[1)]	
Full accuracy	±0,263 $\%_{abs}$ (±2 mmHg)
ISO accuracy[2)]	±(0,43 $\%_{abs}$ + 8 $\%_{rel}$)

Notes:

1. Inaccuracy specifications include stability and drift.
2. Corresponding to requirements in ISO 80601-2-55:2011

CO_2 ACCURACY MODE APPLICATION

The AION® Rhodium provides full accuracy specification (white areas in the graphs below) in a majority of clinical cases and environmental conditions. During more extreme conditions, clinical or environmental, the AION Rhodium® provides ISO accuracy (light grey areas below).

Gas range	CO_2 level 0 – 6 %: Full	CO_2 level 6 – 20 %: ISO	
Time from startup	<10 s Startup	10 s – 5 min: ISO	> 5 min: Full
Ambient temperature	10 – 15 °C : ISO	15 – 30 °C: Full	30 – 55 °C: ISO
Ambient pressure	660 – 800 hPa: ISO	800 – 1100 hPa: Full	1100 – 1200 hPa ISO
End tidal value accuracy vs. respiration rate *For I:E ratio 1:1*	0 – 60 bpm: Full[1)]	60 – 150 bpm: ISO	

Notes:

1. For CO_2 range 0 to 6%

O_2 MEASUREMENT SPECIFICATIONS[1), 2)]				
Gas	**Gas level [%]**	**Inaccuracy [$\%_{ABS}$]**	**Interference [$\%_{ABS}$]**	**Resp. rate limit for accurately resolved EtO2[3)]**
O_2 Paracube® Sprint	0 – 25 25 – 80 80 – 100	±1 ±2 ±3	CO_2 0.2 N_2O 0.2 Any agent 1.0	30 bpm
O_2 OXIMA™	0 – 40 40 – 60 60 – 80 80 – 100	±(1%abs +1%rel) ±(1%abs +2%rel) ±(1%abs +3%rel) ±(1%abs +4%rel)	<0.3	60 bpm

Notes:

1. With optional oxygen sensor
2. Inaccuracy specifications include stability and drift.
3. At 120 ml/min using Artema Technology® neonate gas sampling accessories

GAS CONTAMINANTS INTERFERENCE			
Contaminant	**Interference [$\%_{ABS}$]**		
	CO_2	**O_2 Paracube® Sprint (optional)**	**O_2 OXIMA™ (optional)**
< 100 % Xenon	0.1	0.5	0.3
< 50 % He	0.1	0.5	0.3
Metered dose inhaler propellants	Unspec.	0.5	Unspecified
< 0.1 % Ethanol	0	0.5	0.3
Saturated Isopropanol vapour	0.1	0.5	Unspecified
< 1 % Acetone	0.1	0.5	0.3
< 1 % Methane	0.1	0.5	0.3

PNEUMATIC SPECIFICATIONS	
Technology	Side-stream gas sampling
Pneumatic modes	• Room air reference measurement: Automatic • Sampling system purge: Automatic
Pump	Flow controlled membrane type
Gas flow	Gas sample and purge flows
Gas sampling accessories:	DRYLINE™ range of airway adapters, gas sampling lines and water traps
Gas sampling rate[1)]	CO_2 only mode: 70 ml/min CO_2 + O_2 mode: 120 ml/min Flow accuracy ±10 ml/min or 10%, whichever is greatest.
Gas system leakage	<0.1% of set sampling flow
Occlusion alarm	Actual flow <40 ml/min
Reference measurement interval in full accuracy mode[2)]	Automatic when gas measurement bench temperature change is > 1°C or time since last ref. measurement is > 4 hours.
Reference measurement gas requirement	Air (room or other) < 800 ppm CO_2
Reference measurement duration	Typical: 4 s Maximum: 9 s[3)] Synchronized with inspiratory section of breathing cycle[4)].
Room air gas valve check	Automatic, once every 24 h
Purge cycle	Automatic when occlusion detected
Change water trap alarm	Actual flow <75% of set flow
Pressure difference [5)]	Pressure highest at gas sampling point: $P_{SAMPLING\ POINT}$ - P_{EVAC} : <30 hPa Pressure highest at gas return point: P_{EVAC} - $P_{SAMPLING\ POINT}$ (normal operation): <40 hPa P_{EVAC} - $P_{SAMPLING\ POINT}$ (reference measurement): <120 hPa

Notes:

1. AION™ measures volumetric flow at actual barometric pressure, normalized to room air at 21 °C and 0% RH. The use of gas mixtures other than room air for flow calibration may cause flow measurement errors.
2. Reference measurement interval in ISO Accuracy Mode > 30 seconds.
3. Longer at high O_2 concentrations when using OXIMA™ galvanic oxygen sensor.
4. Synchronized with expiratory plateau of capnogram when reference valve function test performed.
5. For a complete system with Artema Technology gas sampling accessories.

GAS DATA OUTPUT	
Breath detection	Adaptive threshold (>1%$_{ABS}$ change in CO_2 concentration)
Respiration rate	2 – 60 bpm, accuracy ±1 bpm 60 – 150 bpm, accuracy ±2 bpm
Fi and ET values	CO_2 and O_2[1)]
Waveforms	Up to five simultaneously
Units for Measure[2)]	Gas data can be reported in [%], [hPa] or [Torr], separately selectable for CO_2 and O_2[1)].
Status	Atmospheric pressure, Sampling flow, Sensor head temperature and an extensive set of diagnostic parameters.
Flags	Apnea, No water trap, Water trap type, Change Water trap, Occlusion, Purge, Hardware errors.

Notes:

1 With optional oxygen sensor.

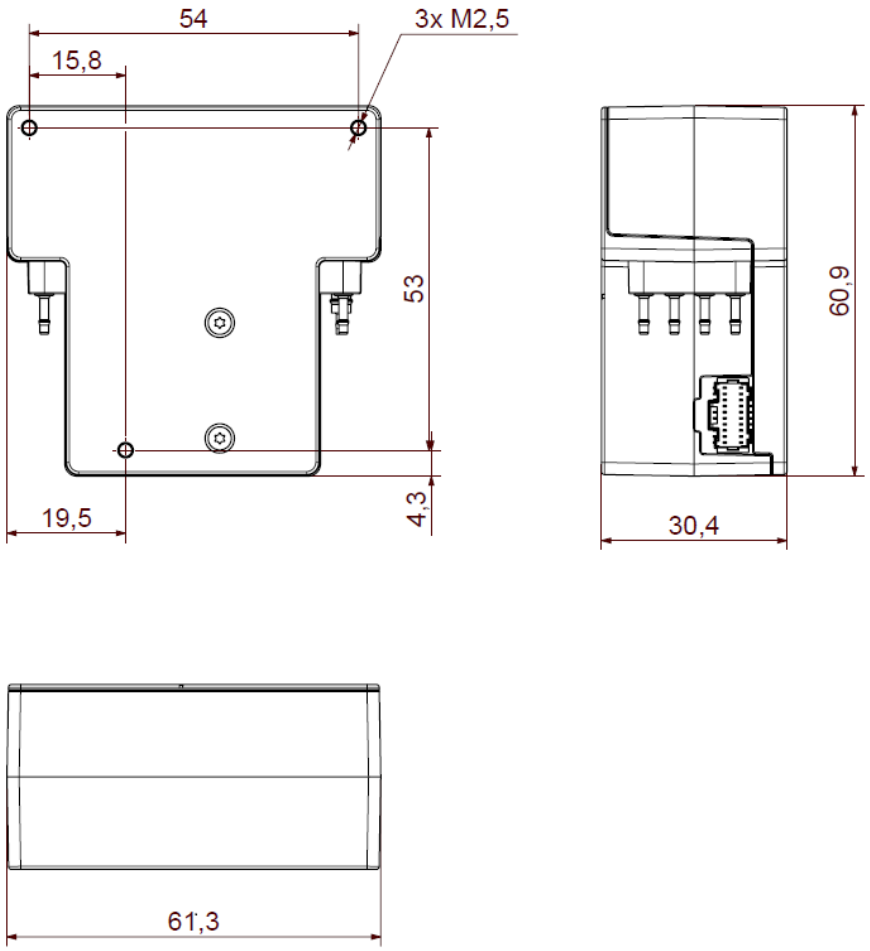
2 All gas readings are normally referenced to dry gas conditions, ambient room temperature and atmospheric pressure (ATPD). The gas readings may instead be referenced to saturated breathing gas at body temperature (BTPS) by sending a command to AION™ via the communication interface.

ELECTRICAL SPECIFICATIONS	
Supply voltage	11 – 30 V_{DC} (max ripple 500 mV_{p-p})
Power consumption[1)]	1.0 W Typical 1.8 W Maximum
Electrical interface	One polarized 15-pin connector for all electrical interfaces.
Communications interface	AION™ standard communications protocol; RS-232, 10ms data interval, 115.2 kBaud.
Data sample rate	50Hz. Data presentation is 100 Hz, every second data point is interpolated.

Notes:

1 When powered at 12 VDC. Add maximum 0.3 W when powered at higher voltage

MECHANICAL SPECIFICATIONS



Weight	265 g
Color	Silver
Mechanical interface	3 x threaded holes on one side for M2.5 bolts.
Pneumatic interface	6 x Stainless steel fittings: Secondary flow inlet from water trap Gas sample inlet from water trap Evacuation outlet External oxygen sensor outlet External oxygen sensor return inlet External reference gas inlet

ENVIRONMENTAL SPECIFICATIONS The device is not intended to be used outside of the specified environmental limits	
Storage temperature	-40 to 70 °C.
Storage humidity[1)]	5 – 100% RH, condensing
Storage pressure	50 – 120 kPa
Operating temperature[2)]	10 – 55 °C. Full accuracy within 15 – 30 °C
Operating ambient humidity	10 – 95% RH, non-condensing
Operating ambient pressure	660 – 1200 hPa. Full accuracy within 800 – 1100 hPa
Operating ambient CO_2 concentration	< 800 ppm
Maximum positive pressure in patient breathing circuit	120 hPa (during lung recruitment)
Maximum negative pressure in patient breathing circuit	-310 hPa (during closed suctioning)
EMC compatibility	Supports EMC requirements for life-supporting ME equipment as per IEC 60601-1-2:2007. Final EMC compliance is the responsibility of the host system integrator.
MR compatibility	The device is not intended for use in a MR environment without extra protective measures.

Notes:

1 After storage in a condensing atmosphere, the unit shall before use be kept for more than 24 h in an environment equivalent to the operating atmosphere.

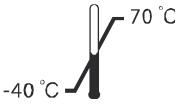
2 Refers to the temperature of the cover.

REGULATORY COMPLIANCE (APPLICABLE PARTS)	
ISO 80601-2-55:2011	Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors.
IEC 60601-1:2005	Medical electrical equipment – General requirements for basic safety and essential performance.
IEC 60601-1-2:2007	Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard Electromagnetic compatibility – Requirements and tests.
IEC 62304:2006	Medical device software – Software life cycle processes.
RoHS 2011/65/EU	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Notes:
The above standards refer to several sub-standards not listed in this document. It is the responsibility of the customer to ensure that the host instrument meets the requirements in the international standards and regulatory requirements relevant for the market where the host instrument is sold.

REGULATORY DESIGNATIONS	
Essential performance	*"Measurement accuracy"* only, *"Gas reading alarm conditions" and "Technical alarm conditions"* are handled by the host device.
Protection against electric shock	Non-electrical connection to patient. Protection against electrical shock is handled by host device.
Oxygen rich environments	The device is suitable for use in an oxygen rich environment.
Mode of operation	Continuous
Ingress of water and particulate matter	As the AION Rhodium® is a component and no classification according to IEC 60529 is made.
Protection against Hazards of Explosion	Not protected (ordinary)

PACKAGE INFORMATION	
Packaging	• Transparent Static Shielding Bag • Die cut dissipative foam fittings • White mini-well box
Package size	118 × 81 × 32 [mm]
Package weight	< 360 g including product.
Package durability	Meets "basic values" in ISO 4180: 2009: Storage, Road, Rail, Water and Air transport
Package labeling	Includes Product name, Part number, Firmware version, Serial number, Artema Technology logo, Mindray Medical Sweden AB name.

PACKAGE MARKING	
REF	Catalogue number
SN	Serial number
	Date of manufacture
	Manufacturer
	Storage humidity limitation
	Storage atmospheric pressure limitation
	Storage temperature limitation

ORDERING INFORMATION	
Designation	**Part no.**
AION Rhodium® CO_2 Analyzer *For use with external galvanic, or no oxygen sensor*	115-027548-00
AION Rhodium® CO_2 + O_2 Analyzer *AION Rhodium® and Hummingbird Paracube® SPRINT preassembled and calibrated.*	115-030104-00

mindray SWEDEN

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