



<h1>Konformitätserklärung</h1> <p><i>EC-Declaration of Conformity</i></p>			
		Dok.-Nr.:	F 711-004
		Date:	09.10.2019
Projekt-Nr.:	PM-01-001	Revision:	1.2
Projekt:	Anästhesieeinheit	Page	1 / 1

im Sinne der Richtlinie 93/42/EWG des Rates über Medizinprodukte  
*according to 93/42 EEC Medical Device Directive*

Wir, das Unternehmen  
*We as responsible manufacturer*

**aXcent medical GmbH**  
**Josef-Görres-Platz 2**  
**56068 Koblenz / Germany**

erklären hiermit in alleiniger Verantwortung die Konformität des Medizinproduktes / *declare that this product*  
Gerätetyp / *type of device:*

**Anästhesieeinheit / *anesthesia unit***

Bezeichnung des Gerätes / *name of device:*

**APUS x3**

Artikel-Nummer / *article-number:*

**100-300**

Zweckbestimmung /

**Gerät zur inhalativen Verabreichung von Anästhesiegasen unter maschineller  
Aufrechterhaltung der Atemfunktion während eines operativen Eingriffs  
*Device for application of inhalative anesthetic agents maintaining automatic  
ventilation of the patient during a surgical treatment***

*Intended Use:*

mit allen anwendbaren Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG Anhang II ohne (4).

*is developed, constructed and manufactured in conformity all applicable requirements of Medical Device Directive  
93/42 EEC, annex II without (4).*

Benannte Stelle / *notified body:*

**TÜV SÜD PRODUCT SERVICE GMBH**

Adresse / *address:*

**Ridlerstrasse 65**

Kenn-Nummer / *ID-number:*

**80339 München / Germany**

Reg.-Nr. / *registration no:*

**0123**

**G1 101259 0002**

Konformitätsbewertungsverfahren: nach Anhang II ohne (4) der Richtlinie 93/42/EWG  
*conformity-assessment method: acc. Annex II excluding (4) of guideline 93/42 EEC*

Klassifizierungsverfahren: Klasse IIb nach Anhang IX Regel 11 der Richtlinie 93/42/EWG  
*classification method: acc. annex IX rule 10 of guideline 93/42 EEC; this product is codified to class IIb.*

Koblenz, Oct-09th - 2019



Torsten Kullmann  
General Manager



Sascha Tietz  
Product Management

<h1>Konformitätserklärung</h1> <h2>EC-Declaration of Conformity</h2>			
		Dok.-Nr.:	F 711-004
		Date:	09.10.2019
Projekt-Nr.:	PM-02-002	Revision:	1.2
Projekt:	Patientenmonitoringsystem	Page	1 / 1

im Sinne der Richtlinie 93/42/EWG des Rates über Medizinprodukte  
according to 93/42 EEC Medical Device Directive

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erklären hiermit in alleiniger Verantwortung die Konformität des Medizinproduktes / *declare that this product*  
Gerätetyp / *type of device:*

**Patienten- Monitor / Monitoring-System**  
**CETUS x15**  
**200-300**

Bezeichnung des Gerätes / *name of device:*

Artikel-Nummer / *article-number:*

Zweckbestimmung /

**Gerät zur Überwachung der Vitalfunktionen von Patienten**  
**Device for monitoring of patient's vital parameters**

*Intended Use:*

mit allen anwendbaren Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG Anhang II ohne (4).

*is developed, constructed and manufactured in conformity all applicable requirements of Medical Device Directive 93/42 EEC, annex II.*

Benannte Stelle / *notified body:*

Adresse / *address:*

Kenn-Nummer / *ID-number:*

Reg.-Nr. / *registration no:*

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Koblenz, Oct -09th - 2019



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Product Management



## APUS x3 Anesthesia Machine

### Features

- 15.6" TFT touch screen display, integrated patient monitor as option.
- User friendly interface design and easy to operate.
- Rotatable and adjustable supporting arm.
- Full-electronic flowmeter with precise control and accurate data monitoring.
- All ventilation modes to suit neonatal, pediatric and adult patients.
- Highly integrated breathing circuit with built-in heater





### **Breathing circuit applicable for complete range**

Autoclavable metal and plastic materials. Suitable for adult, pediatric and neonatal patients.

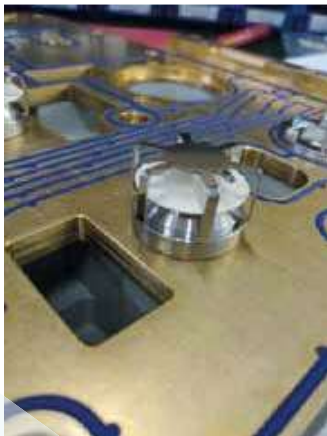
Featured with stable pressure tightness. Visual observation of bellows and valves. Breathing system with ascending or descending bellows.

### **Reliable CO<sub>2</sub> absorber**

One-hand operation designed CO<sub>2</sub> absorber. By-Pass function to ensure smooth operation. Canister detection feature. Autoclavable PPSU material (up to 134°C)

### **Superior ventilator**

Fresh gas, compliance and leakage compensation. VCV, PCV, PSV, SIMV, PRVC and Manual ventilation modes. Integrated ACGO feature to connect open circuit.



### **Comfortable structure**

Two-sided guide rails for patient monitor, support arm and injection pump. Stainless steel material can withstand any chemical sterilization agent. Equipped with LED light to provide lighting for the large workbench.

# APUS x3 Anesthesia Machine



## Specifications

Screen	15.6/17/19 inch TFT LED screen, 1366 x 768 pixels
Gas supply	O <sub>2</sub> , N <sub>2</sub> O, AIR
Vaporizer mount	Selectatec® type for two vaporizer
ACGO	Standard
Flowmeter	Electronic type – numerical and graphical
Absorber bypass	Standard
Ventilator modes	VCV, PCV, PSV, SIMV, PRVC, HLM, Manual/Spont
Tidal volume	5 – 1.500 ml
Frequency	4 – 100 bpm
I:E ratio	4:1 – 1:10
Pressure control	(PEEP+5) – 70 cm H <sub>2</sub> O
Pressure support	(PEEP+5) – 50 cm H <sub>2</sub> O
PEEP	Off, 3 – 30 cm H <sub>2</sub> O
Trigger	Flow and pressure
Waveforms	Pressure-t, Volume-t, Flow-t, CO <sub>2</sub> -t, user configurable
Spirometry loop	P-V, P-F, F-V, Reference Loop
Cylinder yoke	Optional (O <sub>2</sub> N <sub>2</sub> )
Battery	Standard 120 min (1 Li-Ion battery, 4800 mAh), optional 240 min (2 batteries, 9600 mAh)
AGSS	Optional
Auxiliary power outlets	3
Drawers	2
Reading lamp	LED lighting included
Gas monitor module	Optional (CO <sub>2</sub> , AA)
Breathing circuit heater	Standard
O <sub>2</sub> cell	Chemical
Optional functions	BIS, NMT, Suction
Optional Patient Monitor	Integrated 15.6" monitor: ECG, SpO <sub>2</sub> , NIBP, TEMP, RESP, 2-IBP)



## CETUS x15

### Critical Care Patient Monitor

#### Features

- 15.6" High resolution TFT LCD Touch screen
- 10 waveform display, up to 12-lead ECG analysis
- Useful calculation (Hemodynamic, Drug Dose, Oxygenation, Ventilation)
- Pacemaker detection
- ST & arrhythmia analysis
- SpO2 support PVI and PI, low perfusion 0.2%
- Aspect BISx module, NMT module optional
- Wired/Wireless CMS, support HL7 protocol to HIS
- SpO2 pulse-tone modulation (Pitch Tone)
- VGA support external display
- Graphical & tabular trend review (120 hours)
- 48 hours full disclosure wave review for each patient



# CETUS x15 Critical Care Patient Monitor

## Multiple parameter options satisfy the need for ICU, CCU, NICU.

Configuration: ECG, SpO2, NIBP, TEMP, Resp, PR; Li-ion battery

Optional: Touch-Screen, 12-lead ECG, Masimo SpO2, 2/4/6 IBP, C.O., EtCO2, Multi-Gas, BIS, NMT, VGA, Thermal Recorder, Wired/Wireless CMS



### Masimo SET® SpO2

Provides anti-motion and anti-low perfusion SpO2 measurement.



### Bispectral Index™ by Aspect

Monitor the level of consciousness of the patient under general anesthesia or sedation. provides BIS, SQI, EMG, SR, SEF, TP, PC value and EEG wave.



### Masimo Phasein IRMA™/ISA

Sidestream/Mainstream EtCO2  
Allows selection of the modality best suited to the application, monitoring with infrared absorption technique.



### NMT

Intergrade Organon TOF-Watch® SX



### IBP

2-4 Channel, support IBP waveform overlapping display



### C.O.

Cardiac Output

## Technical Specifications

### Display

15.6" TFT (touch screen optional)

Resolution: 1366 x 768

Number of traces: 10 waveforms

### I/O

LAN: 1 standard RJ45 port

WLAN: IEEE 802.11b/g/n

USB: 2 USB connectors

VGA: 1 VGA monitor connector (option)

Output: 1 connector for Nurse call,

Defib Sync Analog Output (options)

### ECG

Lead type: 3-lead, 5-lead, 12-lead

ECG waveform: 2 channels, 7 channels, 12 channels

Display sensitivity: 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1.0), 20 mm/mV (×2.0)

Wave sweep speed: 6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s

Bandwidth

Diagnostic mode: 0.05 Hz~100 Hz

Monitor mode: 0.5 Hz~40 Hz

Surgery mode: 1 Hz~20 Hz

Strong filter mode: 5Hz~20 Hz

CMRR>100 dB



## Technical Specifications

Notch: 50/60 Hz notch filter can be set to on or off

Differential input impedance >5M $\Omega$

Electrode polarization voltage range:  $\pm 400$ mV

Baseline recovery time <3s after defibrillation (in monitor and surgery mode)

Calibration signal: 1 mV (peak - peak), accuracy  $\pm 3\%$

### RESP

Measurement method: Thoracic electrical bioimpedance

Rate: 0 – 150 bpm

Measuring lead: Lead I, II

Wave gain:  $\times 0.25$ ,  $\times 0.5$ ,  $\times 1$ ,  $\times 2$

Respiratory impedance range: 0.5-5  $\Omega$

Baseline impedance: 500-4000  $\Omega$

Gain: 10 grades

Scan speed: 6.25 mm/s, 12.5 mm/s, 25 mm/s

### TEMP

Accuracy:  $\pm 0.1$  or  $\pm 0.2$  °F (without probe)

Measurement range: 5~50 $\times$  (41~122 °F)

Channel: Two channels

Resolution: 0.1 $\times$

Parameters:  $\times$ T1, T2 and TD

### SpO2

Measurement range: 0-100%

Resolution: 1%

Accuracy:  $\pm 2\%$  (70-100%, Adult/Pediatric);  
 $\pm 3\%$  (70-100%, Neonate);  
0-69%, unspecified

Refreshing Rate: 1s

### Masimo SET<sup>®</sup> SpO2(Optional)

Measurement range: 0-100%

Resolution: 1%

Accuracy:  $\pm 2\%$  (70-100%, Adult/Pediatric, non-motion, low perfusion);  
 $\pm 3\%$  (70-100%, Neonate, non-motion);  
 $\pm 3\%$  (70-100%, motion); 0-69%, unspecified

Refreshing Rate: 1s

### Pulse Rate

Range: 30~254 bpm

Resolution: 1 bpm

Accuracy:  $\pm 2$ bpm (non-motion)  
 $\pm 5$ bpm (motion)

Refreshing rate: 1s

### NIBP

Measurement method: Automatic oscillometric method

Operating mode: Manual, automatic, continuous

Measurement unit: mmHg/kPa selectable

Typical measurement time: 20~40 s

Measurement type: Systolic, Diastolic, Mean Measurement range (mmHg)

Range of Systolic pressure:	Adult	40-270
	Pediatric	40-200
	Neonatal	40-135

Range of Diastolic pressure:	Adult	10-210
	Pediatric	10-150
	Neonatal	10-95

# CETUS x15 Critical Care Patient Monitor

## Technical Specifications

Range of Mean pressure:   Adult       20-230  
                                  Pediatric  20-165  
                                  Neonatal  20-105

Measurement accuracy  
Maximum average error:  $\pm 5$  mmHg  
Maximum standard deviation: 8 mmHg  
Resolution: 1 mmHg  
Interval: 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240, 480 minutes  
Overpressure protection: Software and hardware, double safety protection  
Cuff pressure range: 0-280 mmHg

### IBP (Optional)

Channel: 2, 4 or 6-channel  
ART: 0 to 300 mmHg  
PA: -6 to 120 mmHg  
CVP/RAP/LAP/ICP: -10 to 40 mmHg  
Measurement range: P1/P2 -50 to 300 mmHg  
Resolution: 1mmHg  
Accuracy:  $\pm 2\%$  or  $\pm 1$ mmHg, whichever is greater (without sensor)  
Sensitivity: 5uV/mmHg/V  
Impedance range: 300 to 3000  $\Omega$

### C.O. (Optional)

Method: Thermodilution  
Range: C.O.: 0.2 to 20 L/min  
          TB: 23 to 45  $\mu$   
          T1: -1 to 27  $\mu$   
Accuracy: C.O.:  $\pm 5\%$  or  $\pm 0.1$ L/min, whichever is greater  
TB, T1  $\pm 0.5$   $\mu$  (without sensor)

### Standard Mainstream CO2 (Optional)

Measurement range: 0-19.7%, 150 mmHg, or 0-20 kPa  
Resolution: 0.1 mmHg  
Measurement accuracy  
          0-40 mmHg:  $\pm 2$  mmHg  
          41-70 mmHg:  $\pm 5\%$  of reading  
          71-100 mmHg:  $\pm 8\%$  of reading  
          101-150 mmHg:  $\pm 10\%$  of reading  
Respiration rate: 3-150 bpm  
Respiration rate accuracy:  $1 \pm 1$ bpm  
Warm-up time: 97% within 8 s, full accuracy within 20 s

### Standard Sidestream CO2 (Optional)

Measurement range: 0-20% (0-150 mmHg)  
Accuracy: < 5.0% CO 2:  $\pm 2$  mmHg  
          > 5.0% CO 2: < 6% of reading  
Respiration rate: 2~150 BPM  
Respiration rate accuracy: 1%  $\pm 1$ BPM  
Warm-up time: 97% within 45 s, full accuracy within 10 min.  
Rise times (t 10-90%): About 100 ms, when flow is 100 ml/min, adult water trap, 1.5 m sampling tube  
Delay time: <3 sec when flow is 100 ml/min, adult water trap, 1.5 m sampling tube

### Recorder (Optional)

Built-in, Thermal dot array  
Horizontal resolution: 16 dots/mm (25 mm/s paper speed)  
Vertical resolution: 8 dots/mm  
Paper speed: 25 mm/s, 50 mm/s  
Number of waveform channels: 3



12-lead ECG



4 channel IBP



OxyCRG screen



Dynamic trends

### Phasein ISA Sidestream CO2 (Optional)

Warm-up time: Full accuracy within 10 seconds  
 Sampling flow rate: 50ml/min(+/-10/min)  
 Measurement Range: 0-25%  
 Accuracy: 0~15% ( $\pm 0.2\%$  of the reading)  
 15~25%, unspecified  
 Rise time: 200 ms, typical at 50 ml/min flow rate  
 Total response time: within 3 seconds (with 2 m Nomoline sampling line)  
 AWRR Range: 0-150 bpm  
 AWRR Accuracy:  $\pm 1$  breath

### Phasein IRMA™ Mainstream CO2 (Optional)

Measurement Range: 0-25%  
 Accuracy: 0~15% ( $\pm 0.2\%$  of the reading)  
 15~25%, unspecified  
 Warm-up time: Full accuracy within , 10 seconds  
 AWRR Range: 0-150 bpm  
 AWRR Accuracy:  $\pm 1$  breath

### Phasein IRMA™ AX+ Mainstream Multi-gas (Optional)

Gas: CO2, N2O, HAL, ISO, ENF, SEV, DES with automatic identification  
 Warm-up time: Full accuracy within 20 seconds for IRMA  
 AX+ CO2 Accuracy:  
 0-10%:  $\pm (0.2\%+2\%$  of the reading)  
 0-15%:  $\pm (0.3\%+2\%$  of the reading)  
 N2O Accuracy:  
 0-100%:  $\pm (2\%+2\%$  of the reading)  
 HAL, ISO, ENF:  
 0-8%:  $\pm (0.15\%+5\%$  of the reading)  
 SEV:0-10%:  $\pm (0.15\%+5\%$  of the reading)  
 DES:0-22%:  $\pm (0.15\%+5\%$  of the reading)  
 Agent identification time: <20 s (typical <10 s)  
 AWRR range: 0-150 bpm  
 AWRR accuracy:  $\pm 1$  bpm  
 Apnea time: 20~60 s

# CETUS x15 Critical Care Patient Monitor

## Technical Specifications

### Aspect BISx module (Optional)

Parameter Measurement:

BC: 0~30 (Only limited to the combined use of an external sensor with a BIS module)

EMG: 30~55 dB (bar chart) with intensity between 30 dB and 80 dB (tendency chart)

BIS: 0~100

SQI: 0%~100%

SR: 0%~100%

SEF: 0.5 Hz~30 Hz

TP: 40~100 Db

EEG Measurement:

Input impedance >5 MΩ

Noise (RTI) <2 μV (0.25~50 Hz)

Input signal range: ±1 Mv

EEG bandwidth between: 0.25 Hz~110 Hz

### NMT Tof-Watch® SX (Optional)

Microprocessor-controlled

Stimulation Mode: TOF, TOFS, PTC,  
1 Hz Twitch, 0.1 Hz Twitch, DBS DBS3.3 and  
3.2 (Double Burst), Tetanic Stimulation (Burst),  
5s – 50 Hz or 100 Hz

Output (accuracy ±5% of full scale value)

Surface electrodes:

Constant current, 0-60 mA (0-12/18μC)  
up to 5 KOhm.

Monophasic, 200 μs or 300 μs pulse width

Needle electrodes:

Constant current, 0-6 mA (0-0.24 μC)  
up to 5 KOhm.

Monophasic, 40 μs pulse width

Acceleration transducer: Accuracy ±5% of full scale value

Temperature sensor: Range 20.0-41.5°C (accuracy ±5 °C)

### Operation Environment

Power: AC 100-250 V, 50/60 Hz

Temperature: 5-40 °C

Humidity: <80%

Patient Range: Adult, Pediatric, Neonate

Battery backup: Standard 2-3 hrs (2.600 mAh), optional 3-5 hrs (4.800 mAh)

