



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 101259 0002 Rev. 02

Manufacturer:

aXcent medical GmbH

Josef-Görres-Platz 2
56068 Koblenz
GERMANY

**Product Category(ies): patient monitors, anesthesia devices,
ventilators, transport ventilators**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713172443

Valid from:

2020-03-03

Valid until:

2023-12-09

Date,

2020-03-03

Christoph Dicks

Head of Certification/Notified Body

Konformitätserklärung EC-Declaration of Conformity			
		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*:

Adresse / *address*:

Kenn-Nummer / *ID-number*:

Reg.-Nr. / *registration no*:

TÜV SÜD PRODUCT SERVICE GMBH
Ridlerstrasse 65
80339 München / Germany
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

Konformitätserklärung EC-Declaration of Conformity			
		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

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*:

Patienten- Monitor / Monitoring-System

Bezeichnung des Gerätes / *name of device*:

CETUS x15

Artikel-Nummer / *article-number*:

200-300

Zweckbestimmung /

Gerät zur Überwachung der Vitalfunktionen von Patienten

Intended Use:

Device for monitoring of patient's vital parameters

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*:

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 10 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



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.

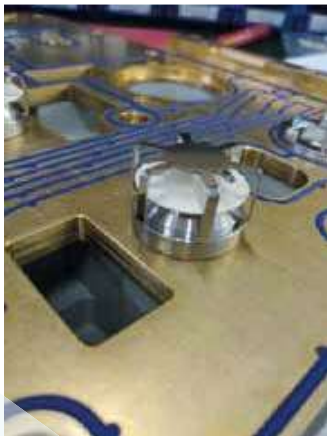
Featured with stable pressure tightness. Visual observation of bellows and valves. Breathing system with ascending or descending bellows.

Reliable CO₂ absorber

One-hand operation designed CO₂ 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 ₂ , N ₂ 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 ₂ O
Pressure support	(PEEP+5) – 50 cm H ₂ O
PEEP	Off, 3 – 30 cm H ₂ O
Trigger	Flow and pressure
Waveforms	Pressure-t, Volume-t, Flow-t, CO ₂ -t, user configurable
Spirometry loop	P-V, P-F, F-V, Reference Loop
Cylinder yoke	Optional (O ₂ N ₂)
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 ₂ , AA)
Breathing circuit heater	Standard
O ₂ cell	Chemical
Optional functions	BIS, NMT, Suction
Optional Patient Monitor	Integrated 15.6" monitor: ECG, SpO ₂ , 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 Ω

Electrode polarization voltage range: ± 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 Ω

Baseline impedance: 500-4000 Ω

Gain: 10 grades

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

TEMP

Accuracy: ± 0.1 or ± 0.2 °F (without probe)

Measurement range: 5~50 $^{\circ}\text{C}$ (41~122 °F)

Channel: Two channels

Resolution: 0.1 $^{\circ}\text{C}$

Parameters: T_1 , T_2 and T_D

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[®] 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: ± 2 bpm (non-motion)
 ± 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: ± 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 ± 1 mmHg, whichever is greater (without sensor)

Sensitivity: 5uV/mmHg/V

Impedance range: 300 to 3000 Ω

C.O. (Optional)

Method: Thermodilution

Range: C.O.: 0.2 to 20 L/min

TB: 23 to 45 $^{\circ}\text{C}$

T1: -1 to 27 $^{\circ}\text{C}$

Accuracy: C.O.: $\pm 5\%$ or ± 0.1 L/min, whichever is greater

TB, T1 ± 0.5 $^{\circ}\text{C}$ (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: ± 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 ± 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: ± 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: ± 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: ± 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: ± 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 M Ω

Noise (RTI) <2 μ V (0.25~50 Hz)

Input signal range: $\pm$ 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 $\pm$ 5% of full scale value)

Surface electrodes:

Constant current, 0-60 mA (0-12/18 μ C)
up to 5 K Ω m.

Monophasic, 200 μ s or 300 μ s pulse width

Needle electrodes:

Constant current, 0-6 mA (0-0.24 μ C)
up to 5 K Ω m.

Monophasic, 40 μ s pulse width

Acceleration transducer: Accuracy $\pm$ 5% of full scale value

Temperature sensor: Range 20.0-41.5°C
(accuracy $\pm$ 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)

