Patient Monitoring

Specification Sheet

Corometrics® 120 Series

Maternal/Fetal Monitors



Comprehensive maternal/fetal monitoring

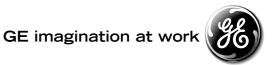
Every pregnancy is unique. So...the monitor you choose needs to help you manage the total pregnancy – from antepartum monitoring through labor, delivery and recovery. The compact and easy-to-use Corometrics 120 Series is a comprehensive maternal/fetal monitor, giving you the ability to address every monitoring need for both the mother and the foetus. You can begin by using the external monitoring modes and add non-invasive BP, FECG, IUP, maternal and/or fetal pulse oximetry, as the patient's needs change, without switching to another monitor or external device.

Corometrics 120 Series sets new standards for maternal/fetal care

- Our unique Spectra Alerts™ transforms the powerful 120 Series into a "Smart" monitor, complete with alert functions. This feature analyzes the fetal heart rate (FHR) and uterine activity (UA) patterns, as well as trend characteristics of variability, baseline, decelerations, and signal quality to assist the clinicians in evaluating the fetal strip.
- Smart BP™, a patented feature that works in conjunction with DINAMAP® non-invasive blood pressure technology, automatically delays a blood pressure measurement while a contraction is in progress thus assuring more clinically significant assessment and documentation of the maternal status.
- 3-Level-Heart Beat Coincidence (HBC) alerts the care provider with both visual and recorded messages when there is a possibility that you may be recording the same heart rate with two modes of monitoring. The monitor compares up to three heart rates and provides additional information for fetal assessment.
- Fetal Pulse Oximetry (FSpO₂) is an optional parameter that provides a real-time oxygen status of the fetus. In combination with other fetal parameters, FSpO₂ helps in the early detection of fetal hypoxia and provides additional information in the presence of non-reassuring fetal heart rate patterns.
- Integrated **Masimo SET or Nellcor** Maternal SpO₂ make it easy for the clinician to monitor, document or even view the waveform.

Other Features:

- Maternal ECG SpO, real-time 3-lead adult QRS waveform display and a snapshot printout.
- **Vital Signs History** at a glance. Documents 8 hours of maternal parameters in flowchart summary format... a time-saver during recovery.
- Software upgrade, via PC or laptop computer, allows easy flash reprogramming as new features become available.
- Expandability built in. System architecture allows for the addition of future parameters without purchasing a new unit.
- High/Low Fetal Alarms notify clinicians if the fetal heart rate is out of the user-configurable range.
- **Selectable Font Size** on the recording strip allows the font size to be adjusted quickly and easily (small, medium or large) for optimum viewing efficiency.
- Song Player serenades both mother and child to celebrate the new arrival. Three popular tunes are available with the turn of the Trim Knob®.
- Our ChartLight allows the clinician to easily read the fetal strip, while patients remain relaxed in their low light setting.



GE Healthcare offers two types of monitors Corometrics 170 Series, the 120 Series:

| | 171 | 172 | 173 | 174 | 126 | 128 | 129 | 128F | 129F |
|---------------------------|-----------|-----|-----|-----|--------------|-----|-----|------|------|
| LCD Display | numberics | | | | 5,5 in/14 cm | | | | |
| FHR | • | • | • | • | • | • | • | • | • |
| FHR Twins | | • | | • | • | • | • | • | • |
| Fetal ECG | | | • | • | • | • | • | • | • |
| Fetal SpO ₂ | | | | | | | | • | • |
| UA – Toco | • | • | • | • | • | • | • | • | • |
| UA – IUPC | | | • | • | • | • | • | • | • |
| Maternal NIBP | | | | | | • | • | • | • |
| Maternal SpO ₂ | | | | | | • | • | • | • |
| Maternal ECG | | | | | | | • | | • |

FHR = Fetal Heart Rate; UA = Uterine Activity; IUPC = Intrauterine Pressure Catheter

Performance Specifications

Ultrasound Mode

Technique: Pulsed Doppler with autocorrelation processing; Transducer Type: 9-crystal; Pulse Repetition Frequency: Single Ultrasound Mode: 4 kHz; Dual Ultrasound Mode: 2 kHz; Pulse Duration: 92 μ s; Transmitter Frequency: 1.151 MHz; Intensity: < 5 mW/cm² (Isata);

Heart Rate Counting Range: 50-210 BPM;

Leakage Current: < 10 μA at 120-240 VAC, isolated by transducer

FECG Mode

Technique: Peak detecting, beat-to-beat cardiotachometer;

Heart Rate Counting Range: 30-240 BPM; Heart Rate Resolution: ± 1 BPM;

Artifact Elimination: Switch selectable, $\pm\ 25$ BPM artifact rejection;

Countable Input Signal Range: 15 μV to 2 mV peak-to-peak;

Offset Voltage Tolerance (Differential): \pm 300 mVdc maximum;

Maximum Common Mode Voltage: 20 V peak-to-peak; Preamplifier Bandwidth: 1-100 Hz;

Common Mode Rejection:

Balanced: > 120 dB at mains frequency, with patient cable; Unbalanced: 5 k Ω RA or LA: > 110 dB at

mains frequency;

Input Equivalent Noise: < 10 μV peak-to-peak;

Input Impedance: Differential: 10 M Ω ; Common Mode: > 20 M Ω ;

Mains Frequency Rejection: > 40 dB; Leakage Current: < 60 μ A @ 254 VAC, electrically isolated; Isolation, Mains-to-Patient: > 4 kVAC; Leg Plate Tester Jack: Simulated R-Wave at 120 ± 1 BPM

Fetal Alarms (for ultrasound or FECG modes)

Audio: Alternating 1.5 second chimes (773 Hz and 523 Hz); Visual: Flashing heart rate numeric;

Limits: User-Selectable high and low fetal heart rate; Technical: Signal Quality;

Tachycardia Response Time: 5 minutes at 100 % limit violation; Bradycardia Response Time: 30 seconds at 100 % limit violation;

Signal Quality Response Time:

100 % Signal Loss: 1.25 minutes; 70 % Signal Loss: 5 minutes; 65 % Signal Loss: 10 minutes

Uterine Activity Mode

Range: IUPC: 0-100 mmHg, Tocotransducer: 0-100 relative units; Resolution: IUPC: 1 mmHg, Tocotransducer: 1 relative units; Bandwidth: IUPC: dc to 0.5 Hz, Tocotransducer: dc to 0.5 Hz;

Excitation Voltage: IUPC: + 4.0 Vdc;

Zero Set Temperature Drift: Strain Gouge: < 0.1 mmHg/°C (0.013 kPa/°C), excluding transducer

Leakage Current: Strain Gauge: < 60 μA at 254 VAC, electrically isolated

Fetal Pulse Oximetry Mode

Technique: Spectrophotometry and plethysmography

Sensor Type: Nellcor OxiFirst Foetal Oxygen Sensor (Series FS14C) only

Saturation Range: 10 – 100%

Saturation Accuracy: Reproducibility is one standard deviation = 4.7%. Nominally, 67 of the measurements

across the population will be within \pm standard deviation Wavelengths: Red: 735 μ M, nominal; Infrared: 890 μ M, nominal Response Time: User-selectable: slow and fast averaging modes

Transmitter Frequency: 1.151 mHz

Spatial-Peak Temporal Average Intensity: Ispta < 10 mQ/cm₂

Maternal Blood Pressure Mode with Smart Technology

Technique: Oscillometric; Blood Pressure Range: 20-255 mmHg (2.7-34.0 kPa);

Pulse Rate Range: 40-240 BPM;

Blood Pressure Accuracy: ± 5 mmHg (0.7 kPa) with a standard deviation no greater than 8 mmHg (1.1 kPa);

Pulse Rate Accuracy: \pm 2 BPM or \pm 2 % (whichever is greater);

Cuff Inflation: Initial inflation to 160 mmHg (21.3 kPa). Subsequent inflation approximately 30 mmHg (4.0 kPa)

greater than the previous systolic pressure.

Cuff Deflation: Automatic;

Safety Features: Automatic cuff deflation if: cuff pressure exceeds 280 mmHg (37.3 kPa); maximum

measurement time exceeded (not to exceed AAMI SP 10 limit of 180 s); or safety timer detects microprocessor failure. Auto mode minimum 30-second delay from the end of one determination to the beginning of another to

allow for venous return.;

Display/Record: Systolic, diastolic, and mean pressure; pulse rate;

Alarms (audible and visual): Audio: Alternating 1.5 seconds chimes (773 Hz and 523 Hz);

Visual: Flashing numeric or message;

Limits: User-selectable high and low systolic, diastolic, and mean pressures, user-selectable high and low pulse rate.

Technical: Cuff/hose errors, connection errors, insufficient signal, excessive inflation/motion or determination

times, overpressure, communication problem, or self-test failure.

The blood pressure module complies with the American National Standard for Electronic or Automated Sphygmomanometers (AAMI/ANSI SP 10-1992).

Maternal Pulse Oximetry Mode Nellcor

Sensor Type: Nellcor adult finger sensors DS 100-A (reusable) or Max-A (disposable);

Saturation Range: 0-100 %; Pulse Rate Range: 30-250 BPM;

Saturation Accuracy: % SpO_a ± 1 standard deviation*: (w/Nellcor Puritan Bennett™ D-25 Sensor)

70-100 % \pm 2 digits; 50-69 % \pm 3 digits; 0-49 % (unspecified);

Pulse Rate Accuracy: ± 3 BPM;

Alarms (audible and visual): Audio: Alternating 1.5 seconds chimes

Visual: Flashing % SpO₂ numeric or message;

Limits: User-selectable high and low SpO₂ and high and low pulse rate.;

Technical: Sensor errors, connection errors, insufficient signal, excessive motion, communication problem,

internal calibration error, or self-test failure.

Maternal Pulse Oximetry Mode Masimo

Sensor Type: Masimo Oximetry Sensors for SpO₂ measurements (LNOP recommended)

Saturation Range: 1-100%

Saturation Accuracy: $70-100\% \pm 2$ digits; 0-69% (unspecified)

Pulse Rate Range: 25-240 BPM

Pulse Rate Accuracy: ± 3 digits (no motion); ±5 digits (motion)

Alarms: Audio: Alternating 1,5 second chimes; Visual: Flashing % SpO₂ numeric or message

Limits: User-selectable high and low SpO₂ and high and low pulse rate

Technical: Sensor errors, connection errors, insufficient signal, excessive motion, communication problem,

internal calibration error, or self-test failure

MEGG Mode

Maternal ECG Electrode Type: Medtronic™ 1700-003 or equivalent;

Leads Available: I, II, and III;

Heart Rate Counting Range: 30-240 BPM; Heart Rate Resolution: ± 1 bPM; Heart Rate Averaging: 1 second average;

Countable Input Signal Range: < 0.5 mV to 5 mV peak-to-peak;

Tall T-wave Rejection: > 0.8 x QRS amplitude; Offset Voltage Tolerance (Differential): ± 300 mVdc maximum;

Maximum Common Mode Voltage: 30 V peak-to-peak; Preamplifier Bandwidth: 0.6 to 40 Hz;

 $\label{eq:common Mode Rejection: Balanced: > 80 dB at mains frequency, with patient cable; \\$

Unbalanced: 5 K RA or LA: > 50 dB at mains frequency;

Input Equivalent Noise: < 30 μV peak-to-peak;

Input Impedance: Differential: > 2.5 M Ω , Common Mode: > 10 M Ω ;

Mains Frequency Rejection: > 40 dB;

Leakage Current: < 60 μA at 254 VAC, with cable, electrically isolated;

Isolation, Mains-to-Patient: > 4 kVAC; Leads Off Detection: dc current < 0.1 μA

Alarms: Audio: Alternating 1.5 seconds chimes; Visual: Flashing heart rate numeric or message;

Limits: User selectable high and low maternal heart rate;

Technical: Leads off;

Tachycardia Response Time: < 8 seconds;

Pacemaker Detection/Rejection: Input Voltage Range: ± 2.5 mV to ± 700 mV; Input Pulse Width: 0.1 to 2 ms;

Pulse Rise/Fall Time: < 10 % of pulse width; not greater than $100 \mu s$;

Over-, Under-shoot: 2 mV

Baseline Drift: < 0.5 V with a $\pm 700 \text{ mV}$, 2 ms

pacemaker pulse applied. Excessive over shoot time of pacemaker pulse may cause false QRS detection.

Maternal Vital Signs History: Storage/Recall (8 hrs maximum)

Physical Specifications

Height x Width x Depth: 17,0 x 41,9 x 43,9 cm; Weight: 10,9 kg approx.

Strip Chart Recorder

Heart Rate ScaleUS-FormatInternationalChart Width:7 cm8 cmScaling:30 BPM/cm20 BPM/cmRange:30-240 BPM50-120 BPMResolution:1 BPM1 BPM

Uterine Activity Scale IUPC Tocotransducer

Chart Width: 4 cm 4 cm

Scaling: 25 mmHg/cm 25 relatives units/cm
Range: 0-100 mmHg 0-100 relative units
Resolution: 1 mmHg 1 relative unit

Pulse Oximetry

SpO2 ScaleUS-FormatInternationalChart Width:4 cm4 cm

Scaling: 10 %/cm or 25 %/cm 2.5 %/cm or 25 %/cm Range: 60-100 % or 0-100 % 50-100 % or 0-100 %

Resolution: 1 % 1 %

Recorder Drive: Speeds: 1, 2, and 3 cm/min; Speed Accuracy: \pm 1 %

Power Requirements

Line Voltage: 100, 120, 220, 230, 240 VAC; Line Frequency: 50/60 Hz; Power Consumption: 100 VA/0.4 A Maximum

Physical Characters

Height x Width x Depth: 17 cm x 41.9 cm x 43.9 cm; Weight: approx. 10.9 kg

Environmental Characteristics

Monitor:

Ambient Temperature: Operating: 10 °C to 40 °C, Storage: -10 °C to 55 °C

Relative Humidity: Operating: 10 % to 95 %, non-condensing, Storage: 0 % to 95 %, non condensing

Atmospheric Pressure: Operating: 700-1060 mbar (525-795 mmHg), Storage: 700-1060 mbar (525-795 mmHg)

Strip Chart Paper**:

Ambient Temperature: Operating: 10 °C to 40 °C, Storage: < 26.5 °C

Relative Humidity: Operating: 30 % to 70 %, non-condensing, Storage: 45 % to 65 %, non-condensing

Atmospheric Pressure: Operating: 700-1060 mbar (525-795 mmHg), Storage: 700-1060 mbar (525-795 mmHg)

Certification

ANSI/AAMI EC 13-1992:

Complies with all areas except those listed below:

3.1.3.1e: Heart Rate Meter Accuracy and Response to Irregular Rhythm (not tested)

3.2.6.1: Range of CRS wave amplitude and duration

3.2.8.1: Lower Alarm Limit (The lowest alarm limit on the 120 Series is 35 BPM.)

AAMI/ANSI Sp 10-1992: The blood pressure module complies with the American National Standard for

Electronic or Automated Sphygmomanometers (AAMI/ANSI SP10-1992).

UL-260-1: Designed to meet UL-2601-1 Medical electrical equipment classified by Underwriter's Laboratories, Inc.,

with respect to fire, shock and mechanical hazards in accordance with UL-2601-1

CE: CE marking indicating compliance with the Medical Device Directive 93/42/EEC

- * Accuracy of given oxygen range is valid for only 68 % of the data points taken and the remaining 32 % of the data points are not counted in the specification.
- ** Paper operating environmental conditions are for a period of less than one month. Paper storage environmental conditions are for extended storage.



GE Healthcare

European Headquarters

GE Medical Systems Information Technologies GmbH P.O. Box 60 02 65 • 79032 Freiburg, Germany Tel. +49 761 45 43 - 0 • Fax +49 761 45 43 - 233

World Headquarters

GE Medical Systems Information Technologies, Inc. 8200 West Tower Avenue • Milwaukee, WI 53223, USA Tel. +1 414 355 5000 • Fax +1 414 355 3790

Asia Pacific

GE Medical Systems Information Technologies Asia 24F Floor, Shanghai MAXDO Center, No. 8 Xing Yi Road, Hong Qiao Development Zone • Shanghai 200336, P.R. China Tel. +86 21 5257 4650 • Fax +86 21 5208 2008

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