Instrumentation Laboratory

A Werfen Company

GEM PREMIER

SERIES

Test assured in *Critical Care diagnostics.*

Biosite

MEDICAL INSTRUMENTS

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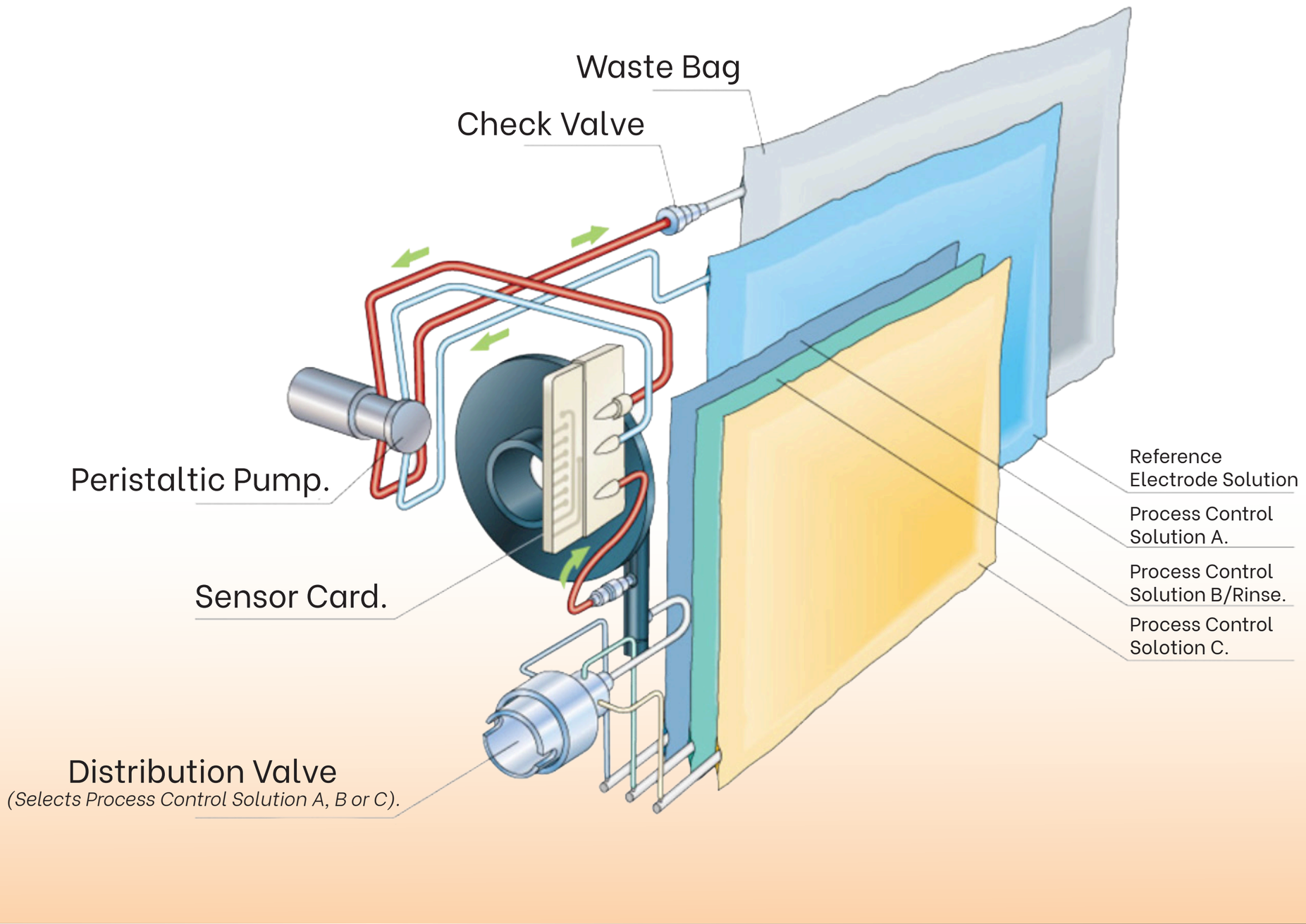
Intended Use

A portable critical care system for use by health care professionals to rapidly analyze heparinized whole blood samples at the point of health care delivery in a clinical setting and in a central laboratory. The instrument provides quantitative measurements of pH, pCO2, pO2, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin and CO-Oximetry (tHb, O2Hb, COHb, MetHb, HHb, sO2*) parameters from arterial, venous or capillary heparinized whole blood. These parameters, along with derived parameters, aid in the diagnosis of a patient's acid/basestatus, electrolyte and metabolite balance and oxygen delivery capacity.

Instruction for Use

1. Press the power switch to turn it ON.The system will automatically begin the power-up cycle. The analyzer has a momentary power switch (button). Press the button and immediately release it to turn the analyzer on. If the button is pressed and held for 5 seconds or longer, the power is turned off.
2. The analyzer will enter a selfdiagnostic mode.
3. When self-diagnostic mode is completed the Insert Cartridge screen is displayed.
4. Press "Open Door".
5. Remove the shipping cartridge by grasping it on both sides and pulling it straight out of the analyzer. Save this cartridge in case the analyzer must be shipped back to IL.
6. If barcode gun has been connected previously, skip to configuring the GEM Premier Series Analyzer section below. Select the Menu button, and press Shut Down. Remove the power cord.
7. Connect the barcode gun to the appropriate custom peripheral port on the back of the analyzer.
8. Reconnect the power cord to the power module. Then connect the plug to a grounded electrical supply.
9. Press the power switch to turn it ON. The system will automatically begin the power-up cycle.

Major Parts and Components



TECHNICAL SPECIFICATIONS

Dimensions and Weight

Analyzer

H: 17.5 in, W: 13 in, D: 11.8 in, Wt: 31.2 lbs

PAK

H: 6 in, W: 8.5 in, D: 3 in, Wt: 4.2 lbs

Sample Volume

135µLB	G*, Hct cartridges
135µL	BG, Lytes**, Hct cartridges
145µL	BG, Lytes, Glu, Lac, Hct cartridges (capillary mode)
150µL	BG, Lytes, Glu, Lac, Hct cartridges

*BG = pH, $pC0_{22}$, p0

**Lytes = Na^{+}, $K^{++}$and Ca^{+}

Sample Type

Heparinized whole blood

Sample Volume

All tests: 85 seconds from sample introduction

Measurement Methodology

Amperometric:	$p0_2$, Glu, Lac
Potentiometric:	pH, $pC0_2$, Na^{+}, K^{+}, Ca^{++}
Conductivity:	Hct

Power Requirements

Universal power input, 100-240 VAG, 50/60 Hz. 60 minute power interrupt allows transport without power.

Temperature Control

Electrode chamber maintained at 37û Cnominal.

Data Output Port

3 RS-232 Serial I/O Ports, 1 Parallel Printer Port, 1 Ethernet Port,4 USB Ports.

Product Safety

Complies with IEC 610101, IEC 61326, ISTA, and ASTM 999.

Time to Results

ASTM or HL7 enables data transmission to a Laboratory,Hospital or third-party Information System.

Measured Analytes

Analyte	Displayed Ranges	Resolution
pH	6.80 to 7.80	0.01
$pC0_2$	5 to 115 mmHg	1 mmHg
$p0_2$	0 to 760 mmHg	1 mmHg
Na^{+}	100 to 200 mmol/L	1 mmol/L
K^{+}	0.1 to 20.0 mmol/L	0.1 mmol/L
Ca^{++}	0.10 to 5.00 mmol/L	0.01 mmol/L
Glu	5 to 500 mg/dL	1 mg/dL
Lac	0.2 to 15.0 mmol/L	0.1 mmol/L
Hct	15 to 65%	1%

†See Operator's Manual for complete validated ranges, specifications and performance characteristics. pCO2 trending to 150 mmHg available.

Derived(calculated) Parameters

Derived Analyte	Displayed Ranges	Resolution
HC0	3.0 to 60.0 mmol/L	0.01
$HC0_3^{-}$ std	3.0 to 60.0 mmol/L	1 mmHg
$TC0_2$	3.0 to 60.0 mmol/L	1 mmHg
BE(B) (*in vitro*)-	30.0 to 30.0 mmol/L	1 mmol/L
BE(ecf) (*in vivo*)	-30.0 to 30.0 mmol/L	0.1 mmol/L
SO_2c	0 to 100%0	.01 mmol/L
Ca^{++}(7.4)	0.10 to 5.00 mmol/L	1 mg/dL

PAK Configurations

Analyte Menu	Test/PAKO	nboard Life (weeks)
BG, Hct	35	4
	75	4
	150	3
	300	3
	450	3
	600	2
BG, Lytes, Hct	75	4
	150	3
	300	3
	450	3
	600	2
BG, Lytes, Glu, Lac, Hct	75	3
	150	3
	300	3
	450	3
	600	2

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