WATO EX-35

Anesthesia Machine

Physical Specifications

Dimensions and Weight

Height 1410 mm

Width 780 mm (not including breathing system)

945 mm (including breathing system)

Depth 690 mm Weight <145 kg

(without vaporizers and cylinders)

Top Shelf

Weight limit 30 kg Width 630 mm Depth 315 mm

Work Surface

Height 850 mm Width 545 mm Depth 310 mm

Drawer (Internal Dimension)

 Height
 130 mm

 Width
 415 mm

 Depth
 325 mm

Bag Arm

Height 1150 mm Length 312 mm

Connection ISO 22mm OD, 15mm ID

Casters

Diameter 125 mm

Brakes All four casters with brakes

Ventilator Specifications

Modes of Ventilation

Manual/Spontaneous Ventilation/Bypass

 $\label{thm:control} \mbox{Volume Control Ventilation (VCV) with PLV function}$

Pressure Control Ventilation (PCV)

Synchronized Intermittent Mandatory Ventilation (SIMV-Volume Controlled and SIMV-Pressure Controlled) Pressure Support Ventilation (PS) with apnea backup

Compensation

Circuit gas leakage compensation and automatic compliance compensation

Ventilation Parameters Range

Patient Size Adult, Pediatric, Infant
Tidal volume 20~1500 mL ((Volume Mode)

(increments of 1 mL)

5~1500 mL (Pressure Mode)

Pinsp $5\sim60~cmH_2O$ (increments of $1~cmH_2O$)
Plimit $10\sim100~cmH_2O$ (increments of $1~cmH_2O$) $\Delta Psupp$ $3\sim60~cmH_2O$ (increments of $1~cmH_2O$)
Rate $4\sim100~bpm$ (increments of 1~bpm)

l:E 4:1 - 1:8 (increments of 0.5) Inspiratory pause (Tip:Ti) OFF, 5% - 60% (increments of 1%) Inspiratory time (Tinsp) 0.2 - 5.0 s (increments of 0.1 s)



Trigger window 5% - 90% (increments of 5%)

Flow trigger 0.5 \sim 15 L/min (increments of 0.5L/min) Pressure trigger -20 \sim -1 cmH₂O (increments of 1 cmH₂O) Expiration termination level 5% - 60% (increments of 5%) Min Rate 2 - 60 bpm (increments of 1 bpm) Tslope 0.0 - 2.0 s (increments of 0.1 s) Apnea l: E 4:1 \sim 1:8 (increments of 0.5)

 Δ Papnea 3 - 30 cmH₂O (increments of 1 cmH₂O)

Positive End Expiratory Pressure (PEEP)

Type Integrated, electronic controlled

Range OFF, 3~30 cmH₂O (increments of 1 cm H₂O)

Ventilator Performance

Driving pressure 280 kPa to 600 kPa Peak gas flow 120 L/min + Fresh Gas Flow

Monitoring Parameters

0 ~ 100 L/min Minute volume 0~2500 ml Tidal volume 18% ~ 100% Inspired oxygen (FiO₂) Peak airway pressure -20 ~ 120 cmH₂O Mean pressure -20 ~ 120 cmH₂O -20 ~ 120 cmH₂O Plateau pressure I:E 8:1 ~ 1:10 Rate 0~120 bpm PFFP $0 \sim 70 \text{ cmH}_2\text{O}$ Resistance (R) $0 \sim 600 \text{ cmH}_2\text{O}/(\text{L/s})$ Compliance (C) 0 ~ 300 ml/ cmH₂O

Control Accuracy

Volume delivery $< 75 \text{ ml:} \pm 15 \text{ ml}$

 \geq 75 ml: \pm 15 ml or \pm 10% of the set value,

whichever is greater

Pressure delivery $\pm 3.0 \text{ cmH}_2\text{O} \text{ or } \pm 8\% \text{ of the set value,}$

whichever is greater

PEEP delivery OFF: \leq 4.0 cmH₂O

3 to 30 cmH2O: \pm 2.0 cmH2O or $\pm 8\%$ of the set

value, whichever is greater

Monitoring Accuracy

Volume monitoring < 75 ml: ± 15 ml

 \geq 75 ml: \pm 15 ml or \pm 10% of the reading,

whichever is greater

 $Pressure \ monitoring \qquad \pm \ 2.0 \ cmH_2O$

PEEP monitoring $\pm 2.0 \text{ cmH}_2\text{O} \text{ or } \pm 10\% \text{ of the reading,}$

whichever is greater

MV monitoring $\pm 15\%$ of the reading

Trend Graph

Continuous trend information with time discrete events for the latest 48 hours

Trend Table

Continuous trend information together with time discrete events for

the latest 48 hours

Alarm Log Book

500 events storage, first in first out

Alarm Setting

Tidal volume Low: 0 ~ 1595 ml

High: 5 ~ 1600 ml

Low: 0 ~ 99 L/min Minute volume

High: 0.2 ~ 100 L/min

Inspired oxygen Low: 18% ~ 98%

High: OFF, 20% ~ 100%

Apnea alarm VTe < 10ml measured in 20s

Paw < (PEEP + 3) cmH₂O in 20s

0~98 cmH₂O Airway pressure low Airway pressure high 2~100 cmH₂O Sustained airway pressure alarm: 15s

Subatmospheric pressure alarm: Paw < -10 cmH₂O Alarm silence countdown timer: 120 to 0 seconds

Ventilator Components

Flow Sensor Variable orifice flow sensor Type

Location Inspiratory and expiratory port

Oxygen Sensor

Type Galvanic fuel cell FiO₂ displayed 18% to 100%

Accuracy ± (volume fraction of 2.5 % +2.5 % gas level)

Response Time ≤20 seconds

Ventilator Screen

Color active matrix TFT touch screen Display type

Display size 10.4 in diagonal 1024 x 768 Pixel format Adjustable Brightness Screen display configurable

Display parameters All setting and alarm parameters (including

Breath rate, I/E ratio, Tidal volume, Minute volume, PEEP, MEAN, PEAK, PLAT, and O2 concentration, EtCO₂, N₂O, Aesthesia gas

concentration)

Display waveforms P-T, F-T, V-T, CO_2 , O_2 , Anesthetic gas, N_2O

Spirometry loops P-V, F-V and F-P Timer On screen timer

Communication Ports

One RS-232C connector and one DB9 connector

Ethernet (RJ-45)

USB

Vaporizers

Mindray V60 Anesthetic Vaporizer or Penlon Vaporizer

Sigma Delta Anesthetic Vaporizer

Support agents Halothane, Enflurane, Isoflurane,

Sevoflurane

Position MAX 2

Mounting mode Selectatec®, with interlocking function

Plug-in®, with interlocking function

Modules

Anesthesia Gas (AG) Module

Measurement mode Side-stream

Monitor gases CO₂, N₂O, Halothane, Enflurane, Isoflurane, Sevoflurane, Desflurane, MAC, Paramagnetic

O₂ (optional)

Warm-up time 45 s (ISO accuracy mode)

10min (full accuracy mode)

Adu/Ped: 150, 180, 200 ml/min Sample rate

Neo: 100, 110, 120 ml/min

Accuracy \pm 10 mL/min or \pm 10% of the set value,

whichever is greater

Range CO₂: 0% ~ 10%

> Des: 0% ~ 18 % Sev: 0% ~ 8% Enf, Iso, Hal: 0% ~ 5% O₂/N₂O: 0% ~ 100%

AwRR range 2~100 bpm

AwRR accuracy 2 bpm \sim 60 bpm: \pm 1 bpm

61 bpm \sim 100 bpm: \pm 2 bpm

Carbon Dioxide (CO₂) Modules

Method Infrared absorption

Module type Mindray side-stream

Capnostat mainstream Oridion micro-stream

(optional)

Work mode Standby or measurement

Displayed numerics EtCO₂, FiCO₂ Waveform Capnography

Side-Stream Carbon Dioxide (CO₂) Module

Measurement range 0 ~ 99 mmHg

Accuracy $\pm 2 \text{ mmHg} (0 \sim 40 \text{ mmHg})$

> \pm 5% of the reading (41 ~ 76 mmHg) \pm 10% of the reading (77 ~ 99 mmHg)

Resolution 1 mmHg

Sampling rate Neonatal: 100 mL/min and 120 mL/min

optional

Adult/children: 120 mL/min and 150 mL/min

optional

 \pm 15% of the set value or \pm 15 mL/min, Sampling rate accuracy

whichever is greater

Warming-up time <1 min, enter the ISO accuracy mode

After 1 min, enters the full accuracy mode

Response time <4.5 s@100 mL/min

<4.5 s@120 mL/min

Measured by using neonatal watertrap and

2.5 m neonatal sampling line

<5.5 s@120 mL/min <5 s@150 mL/min

Measured by using adult watertrap and 2.5 m

adult sampling line

Capnostat Mainstream CO₂ Module

Measurement range 0 ~ 150 mmHg

Accuracy $\pm 2 \text{ mmHg} (0 \sim 40 \text{ mmHg})$ \pm 5% of the reading (41 ~ 70 mmHg)

 \pm 8% of the reading (71 ~ 100 mmHg) \pm 10% of the reading (101 ~ 150 mmHg)

Resolution 1 mmHg Rise time <60 ms Response time <2 s

Alarm limit EtCO₂ High: OFF, 2 ~ 150 mmHg

EtCO₂ Low: OFF, 0 ~ 148 mmHg FiCO₂ High: OFF, 1 ~ 150 mmHg

Micro-stream CO₂ Module

Measurement range 0 ~ 99 mmHg

Accuracy $0 \sim 38 \text{ mmHg: } \pm 2 \text{ mmHg}$ $39 \sim 99$ mmHg: \pm (5 % of the reading + 0.08 %

of (the reading minus 38 mmHg))

Sampling rate 50 ml/min

Sampling accuracy -7.5 ml/min ~ + 15 ml/min

Initialization time 30s
Response time 2.9s
Rising time < 190 ms
Delay time 2.7s

Alarm range EtCO₂ High: OFF, 2 ~ 99 mmHg

EtCO₂ Low: OFF, 0 ~ 97 mmHg FiCO₂ High: OFF, 1 ~ 99 mmHg

Electrical Specifications

Current Leakage

 $100 \sim 240V$ < 500 μA

Power And Battery Backup

Power input 220-240 Vac, 50/60 Hz, 6A

100-120 Vac, 50/60 Hz, 7A 100-240 Vac, 50/60 Hz, 7A

Auxiliary electrical outlets

Up to 4 outlets (3A for each, total 5A)

Battery backup 90 min for 1 piece battery

(powered by new fully-charged batteries with 25°C ambient temperature) 240 min for 2 pieces battery

(powered by new fully-charged batteries

with 25°C ambient temperature)

Battery type Build-in Li-ion battery, 11.1 VDC, 4500 mAh
Safety feature In case of electricity and battery failure,

manual ventilation, gas delivery and agent

delivery are possible

Pneumatic Specifications

ACGO (Auxiliary Common Gas Outlet)

Connector ISO 22 mm OD and 15 mm ID

Pipeline Supply

 $\begin{array}{ll} \text{Gas type} & \text{O}_2\text{, N}_2\text{O} \text{ and Air} \\ \text{Pipeline input range} & 280 \text{ to } 600 \text{ kPa} \\ \text{Pipeline connections} & \text{DISS or NIST} \end{array}$

Pipeline Supply Pressure Gauges

Display type Mechanical Ranges 0 to 1000kPa

Accuracy \pm (4% of the full scale reading + 8% of the

actual reading)

Cylinder Supply

Cylinder Supply E Cylinder (American style or UK style)

 $\begin{array}{ll} O_2 \ Input \ Range & 6.9 \ to \ 20 \ MPa \\ N_2O \ Input \ Range & 4.2 \ to \ 6 \ MPa \\ Air \ Input \ Range & 6.9 \ to \ 20 \ MPa \end{array}$

Cylinder Connections Pin-Index Safety System (PISS)

Yoke Configuration O_2 , N_2O , Air

Cylinder Supply Pressure Gauges

 $\begin{array}{lll} \mbox{Display type} & \mbox{Mechanical} \\ \mbox{Air Range} & \mbox{0 to 25 MPa} \\ \mbox{O}_2 \mbox{ Range} & \mbox{0 to 25 MPa} \\ \mbox{N}_2 \mbox{O Range} & \mbox{0 to 10 MPa} \\ \end{array}$

Accuracy \pm (4% of the full scale reading+8% of the

actual reading)

O₂ Controls

Method N₂O shut off with loss of O₂ pressure

Supply failure alarm \leq 220.6 kPa O_2 Flush $25 \sim 75$ L/min

O₂-N₂O Link system

Type Mechanical

Range O₂ concentration not lower than 25%

Auxiliary O₂ Flowmeter (optional)

Range $0 \sim 15 \text{ L/min}$ Indicator Flow tube

Mechanical Control Flow Meters

 O_2 flow range Two flow tubes with the ranges of $0 \sim 1$ L/Min

and 1 ~ 15 L/min

Air flow range Two flow tubes with the ranges of 0 \sim 1 L/Min

and 1 ~ 15 L/min

and $1 \sim 10 L/min$

Accuracy between -10% and +10% of the indicated

value (under 20°C and 101.3 kPa, for flow between 10% and 100% of full scale)

Environmental Specifications

Operating

Temperature $10 \sim 40^{\circ}$ C

Relative humidity 15% ~ 95% (noncondensing)

Barometric (Kpa) 70 ~ 106 kPa

Storage

Temperature $-20 \sim 60^{\circ}$ C for main unit,

 $-20 \sim 50^{\circ}\text{C}$ for O_2 sensor

Relative humidity 10% ~ 95% (noncondensing)

Barometric 50 ~ 106 kPa

Electromagnetic Compatibility

Immunity Complies with all requirements of IEC 60601-

1-2

Emissions Complies with all requirements of IEC 60601-

1-2

Breathing System Specification

Breathing system volume (Pre-pak)

Automatic ventilation 2850 ml Manual ventilation 1800 ml

Breathing system volume (Non Pre-pak)

Automatic ventilation 2600 ml Manual ventilation 1800 ml

Carbon dioxide absorbent canister

Absorbent capacity 1500 mL Integrated expiratory limb water trap Capacity: 6 mL

Breathing Circuit Parameters

Compliance ≤4 mL/100Pa (bag mode)

Automatically compensates for compression losses within the breathing circuit in

mechanical mode

 $\begin{array}{ll} \text{Expiration resistance} & < 6.0 \text{ cm H}_2\text{O @60 L/min} \\ \text{Inspiration resistance} & < 6.0 \text{ cm H}_2\text{O @60 L/min} \\ \end{array}$

System Pressure Gauge

 $Range \hspace{1cm} -20 \sim 100 \hspace{1cm} cm H_2 O$

Accuracy \pm (2% of the full scale reading + 4% of the

actual reading)

Ports And Connectors

Exhalation 22 mm OD / 15 mm ID conical Inhalation 22 mm OD /15 mm ID conical Manual bag port 22 mm OD /15 mm ID conical

Please contact your local Mindray sales representative for the most current information.

Bag-to-Ventilator Switch

Type Bi-stable

Control Switch between manual and mechanical

ventilation

Integrated Adjustable Pressure Limiting (APL) Valve

Range $1 \sim 75 \text{ cmH}_2\text{O}$ Tactile knob indication at above $30 \text{ cmH}_2\text{O}$

Accuracy \pm 10 cmH₂O or \pm 15% of the setting value,

which is greater

Anesthetic Gas Scavenging System (AGSS)

Size (H x W x D) 430 x 132 x 114 mm

Type of disposal system

Active: High-flow or Low-flow

Passive

Applicable standard ISO 80601-2-13

Pump rate 75 ~ 105 L/min (High-flow)

25 ~ 50 L/min (Low-flow)

Pressure relief device: Pressure compensation opening to the air State indication of the disposal system: The float falls below the "MIN" mark on the sight glass when the disposal system does not work or the pump rate is lower than 25 L/min (Low-flow) or 75 L/min (high-flow).

Filter Stainless screen with hole diameter of

 $140\sim150~\mu m$

Connector of the disposal system: ISO 9170-2

Materials

All materials in contact with exhaled patient gases are autoclavable, except flow sensors (being not capable of being autoclaved), O_2 sensor, and mechanical pressure Gauge.

All materials in contact with patient gas are latex free.

Suction Device

Venturi Suction Regulator

Gas source Air, from system gas source

Minimum flow 20 L/min

Maximum vacuum ≥72 kPa at supply gas pressure of 280 kPa;

≥73 kPa at supply gas pressure of 600 kPa

Continuous Suction Regulator

Supply Negative Pressure Suction

Maximum vacuum 517.5 mmHg to 540 mmHg (69 kPa to 72 kPa)

with external vacuum applied of 540 mmHg $\,$

and 40 L/min free flow

Maximum flow 39 L/min to 40 L/min with external vacuum

applied of 540mmHg and 40 L/min free flow

Minimum flow 20 L/min

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