TENDE VAVE





Built-In Color TFT Touch Screen Display

Tende VAV NICU incubator comes with an integrated 7-inch color TFT Touch Screen Display. This feature makes monitoring and control of the device easier for clinicians and increases the productivity and effectiveness of the treatment as all other features are easy to control and the device is responsive to the commands in a fast manner.

Color TFT Touch Screen Side Display (Optional)

If a bigger display is needed, we can offer the 10.1-inch display as a perfect solution. This display allows the user to easily monitor the parameters measured by the Masimo Rainbow Set feature. On this display, the alarm can be silenced by hand movement in front of the sensor.

Temperature Control Modes

Tende VAV comes with two temperature control modes. Thanks to this feature clinicians can easily control and monitor the skin temperature of the neonate and air temperature inside the canopy. The temperature range can be defined as per the clinician's needs. In case the measured value is higher or lower than the determined range the system automatically sets on the audible and visual alarm.

Patented Servo Humidity System

Humidity has vital importance for neonates. Having this in mind Tende has developed a patented servo humidity system. This sophisticated system can be completely removed from the device for cleaning purposes, and this feature combined with hot steam technology provides a whole new level of hygiene and safety. Using its 2000ml reservoir Tende humidity system can maintain a humidity range for a long time.

Electronic Mattress Tilt System (Trendelenburg)

Mattress tilt can be easily controlled and adjusted electronically using the options featured on the display. Thanks to its powerful motor Tende VAV allows the user to adjust the mattress tilt angle in two directions to the needed level without using mechanical force. The tilt angle of the mattress can be seen on the screen. The process itself is silent and vibrationless, which is highly important for the health of the newborn. This system has an "Emergency Down" button which can put the mattress into a neutral position with one click.

Trend Observation

This feature allows clinicians to monitor skin and air temperature, humidity and oxygen levels, the weight of the neonate, and the heater power of the incubator on both displays for 2, 4, 8 hours, 1 day, and 7 days period. It is possible to follow 1 day and 7 days trends at 1-minute intervals.

Servo Oxygen System (Optional)

Safety and accuracy are the important characteristics of the Tende VAV Oxygen System therefore it comes with two oxygen sensors. This system operates silently and monitors continuously the oxygen circulation to prevent oxygen leakage, even when the rates are not set. If there are other oxygen sources the clinician can stop the oxygen alarm by activating the manual mode. Even in this case, the monitoring continues and the clinician can see the oxygen percentage.

Integrated Digital Scale (Optional)

Monitoring the weight is very important for the newborn's health, as each gram of weight matters in the early stage of life. Having this in mind Tende team has developed an integrated digital scale that can measure the weight of a neonate fast and accurately. Using this feature is simplified by the integrated guide animation with sound.



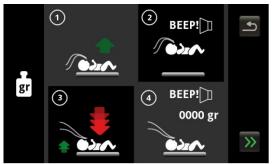




Mattress Tilt



Trend



Digital Scale Instructions

Electronic Height Adjustment (Optional)

The height of the incubator can be adjusted easily by using the foot pedals. Lifting and lowering the incubator is done silently, without vibration as it is powered by the unique motor specially produced for Tende VAV.

Pulse-Oximeter (Optional)

Tende VAV is the first incubator in the world with the integrated Masimo Rainbow SET technology. Thanks to this feature it is possible to measure oxygen saturation (SpO2), perfusion index (PI), pleth variability index (PVI), total hemoglobin (SpHb), methemoglobin (SpMet), carboxyhemoglobin (SpCO) values without taking blood samples from the newborn (Non-Invasive method).

NIBP (Non-Invasive Blood Pressure Measurement) (Optional)

Blood pressure and pulse values can be measured within determined time intervals. Clinicians can determine and set values as per their assessment. In case the measured values are not in the predetermined range the audible and visual alarms are activated.

Mom's Bosom Mode & Air Curtain

"Mom's Bosom Mode" allows monitoring skin temperature when the newborn is out of the incubator for breastfeeding. During this process, the Air Curtain can be activated to maintain the temperature inside of the incubator.

Automation / Suggestion

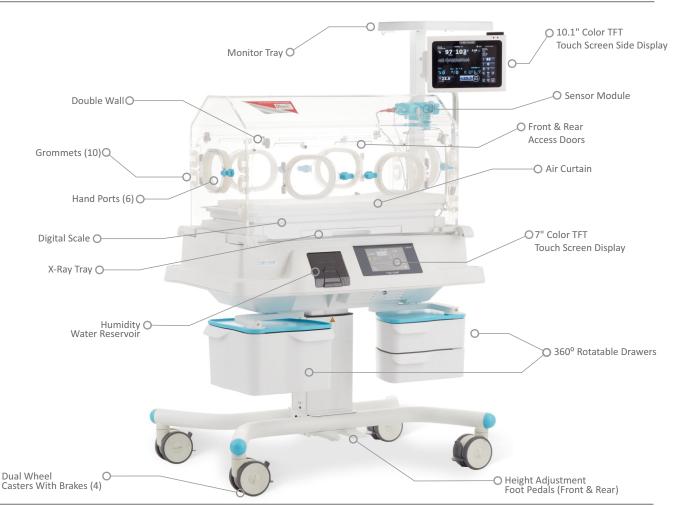
The incubator suggests the degree of ambient temperature and the level of humidity according to the baby's gestational age and weight. If the clinician approves the suggested temperature and humidity values, these values will automatically be adjusted accordingly.



Sensor Module



Tende VAV Side Display



TECHNICAL SPECIFICATIONS

rendi

GENERAL SPECIFICATIONS

7 inches Color TFT Touch Screen Display **Built-in Display**

10.1 inches Color TFT Touch Screen Side Display Side Display (Optional)

Height (Standard): 137.5 cm, Width: 108.5 cm, Depth: 73.5 cm Electronic Height Adjustment (E-Base) (Optional) Min. 134 cm Max. 153 cm

Standard; 107.5 Kg, with Height Adjustment (E-Base) Option; 111.5 Kg Weight Wheels 4 Dual Wheel Casters with Friction Brakes (Diameter: 125 mm)

Monitorization Backup Alarm Sound Level

Power Requirement

Minimum 1 Hour Monitorization After Power Failure

Adjustable 4 Levels

230V $^{+}\pm$ %10, 50/60 Hz, Max 675W, 2.93A $^{+}\pm$ %10 115V $^{+}\pm$ %10, 50/60 Hz, Max 675W, 5.87A $^{+}\pm$ %10

OPERATING CONDITIONS

Temperature 18°C to 30°C

Humidity 0% to 80% (Noncondensing Relative Humidity)

HOOD SPECIFICATIONS

Double Wall Yes Front and Rear Access Doors Width; 85.5 cm x Height; 35.3 cm (Each Doors)

Biocompatible, Cytotoxicity and Skin Irritation Free, Fire Retarded, Mattress Water Proof & Washable (ISO 10993-10 Sensitivity Reported, ISO 10993-5)

Mattress Size Length; 74 cm x Width; 38 cm x Height; 3 cm

Mattress Tilt (Electronic Control) ± 12 Degrees, Continuously Variable with 1 Degree Resolution

Hand Ports 6 Pcs **Tubing Ports (Grommets)** 10 Grommets Opening Angle of the Doors/Ports ~1800

Operating Noise Level < 45 dBA (When Servo Oxygen in Use Max 48 dBA)

Air Flow Velocity < 10 cm/s

Air Filter 0.1 Micron, 99.9% Efficiency, Antibacterial, Easy replaceable

Air Curtain CO₂ Concentration < 0.5%

TEMPERATURE

Temperature Control Modes Air & Skin

20°C to 39°C with 0.1°C Resolution (> 37° C with Approval) Air Temperature Control 34°C to 38°C with 0.1°C Resolution (> 37.5° C with Approval) Skin 1 Temperature Control

Air & Skin 1 - Skin 2 Temperature Display Range 20°C to 42°C with 0.1°C Resolution

< 35 Minutes Temperature Rise Time

0% to 100% (in 5 levels) **Heater Output Indication**

SERVO HUMIDITY Humidity Control Range 30% to 95% with 1% Resolution

Humidity Display Range 0% to 100% with 1% Resolution, Accuracy ±10%

Humidity Water Reservoir Capacity 2000 ml

Humidity Operating Time Without Refilling 24 Hours Max. 95% Humidity

SERVO OXYGEN (OPTIONAL)

Oxygen Control Range 21% to 65% with 1% Resolution Oxygen Display Range 15% to 100% with 1% Resolution

INTEGRATED DIGITAL SCALE (OPTIONAL

100 gr to 10 kg (10,000 gr) Weight Range

Weight Accuracy ±5gr Weight Display Resolution

SpO₂ & PULSE OPTION (Masimo Rainbow SET)

0-100% SpO₂ with 1% Resolution SpO₂ Display Range Pulse Rate Display Range 0 to 240 bpm with 1 bpm Resolution PI, Arterial Pulse Signal Strength Perfusion Index 0 to 20 Values

PVI, Pleth Variability Index 0 to 100 Values SpMet, Methemoglobin Saturation 0% to 100% SpCO, Carboxyhemoglobin Saturation 0% to 100%

SpHb, Total Hemoglobin Concentration in Arterial Blood 0% to 25% g/dL, 0% to 16% mmol/L

NIBP OPTION (Method of Measurement; Oscillometric)

Blood Pressure Range Systolic 40-130 mmHg, MAP 26-110 mmHg, Diastolic 20-100mmHg **Cuff Pressure** Measurement Range; 0-300 mmHg, Accuracy; ± 3 mmHg (0-50 °C) **Cuff Deflate Rate** Deflation Step Size Varies with Heart Rate, Cuff Pressure and Cuff Volume Initial Inflation Pressure 90 mmHg (Default), Variable from 60 to 140 mmHg

Previous Systolic + 20 mmHg Self-Adjusting Inflation Pressure

Clinical Accuracy (Meets accuracy requirements of...) ANSI/AAMI SP10:2002(R)2008, EN1060-4:2004 and ISO 81060-2:2009/2013

Startup Initialization Period 6 Seconds

Long Term Interval Periods 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 240 Minutes TREND PARAMETERS

2, 8, 24, 168 hours (7 Days) Trend Parameters for...

Air Temperature, Skin Temperature (Skin 1 and Skin 2), Relative Humidity

Oxygen Concentration, Weight, Heater Power, NIBP ALARMS (Audible & Visual)

High/Low Temp., Over Temp., Sensor Failure

Skin 1 (In Skin Mode) High/Low Temp., Over Temp., Skin 1 Read Fault, Skin 1 Disconnected Humidity High/Low Humidity, Low Water Level, Place Water Case, Humidity Sensor Fault

High/Low Oxygen, Oxygen System Fault, Oxygen Sensor Fault Oxvgen Oxygen Leakage

SpO₂, Pulse Rate High/Low Values, Related Security Alarms

Alarms Indicators (Audio & LED Lights) LED; Yellow & Red Lights, Audio; Different Sounds for Different Alarms

Others Motor Speed Fault, Heater Temp. Fault,

Power, Low Battery, Motor Speed Fault, Sensor Module, Excess Weight, etc.

1984

MDD 93/42/EEC ANNEX 2 / SEC 3

ISO 13485 ISO 9001

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