

breathdirect

quicker access to life-saving devices



The BDR-19™ Ventilator

When All Care is Critical

The BDR-19™ is a first-of-its-kind, ICU-ready ventilator that's affordable, portable and simple enough so all acute-care clinicians can confidently administer lifesaving ventilatory support in any facility setting.

RETHINKING READINESS.

Overwhelmed by a lack of specialized clinicians, equipment and facilities, COVID-19 has taught us all the importance of being prepared.

Few would now question the need to be ready for the future. Unfortunately the research tells us that we are not. Of the 140,000 ventilators now in the Strategic National Stockpile (SNS), almost half are basic breathing devices that don't meet the minimum requirements needed to treat Acute Respiratory Distress Syndrome (ARDS) – and only 10% are suitable for ICU use.

While vaccines bring some assurances that this current challenge is under control, government and medical leadership need to re-evaluate the efficacy of stockpiled ventilators and readiness for future demands.

Respiratory specialists recommend that ventilators, including those in the SNS, should be suitable for severely ill patients such as those in the pandemic, and be easy to set up and initiate with user-friendly, intuitive interfaces that are quickly understood.

And, with many hospitals experiencing financial pressures – particularly considering the pandemic's effects on curtailing elective procedures – they also need to be cost-effective.

The BDR-19™ answers all of the above.





The BDR-19™ is a breakthrough device for medical facilities needing to resource critical-care ventilators for times of increased demand.

Adept, Adaptable and Affordable.

Compact, cost-effective and configured for a full continuum of ventilatory support, the BDR-19™ fills the void between minimally capable ventilators and expensive, overly complex machines.

Designed primarily for the ICU, it's a first-of-its-kind, flexible and multi-faceted ventilator for use by acute-care clinicians with critically-ill patients in all acute-care settings – including intra-facility transport.

Easy to Master, Mobilize and Maintain.

Medical staff can be confident the BDR-19™ can be mobilized quickly and operated confidently by specialty and non-specialty clinicians after only brief training – vital in times of increased demand.

With a simple, intuitive user interface and three main operating functions, the BDR-19™ is easy to set up and learn. Utilizing tactile rotary knobs ensures the operator can see all settings at a glance – reducing the confusion and complexity of expensive touchscreen interfaces with multiple levels and settings.



The BDR-19™ allows administrators to flex their critical care capacity without overwhelming staff.

Comprehensive Capabilities

- Full Function, Affordable Ventilator
- Designed for Long Term Critical Care
- Provides Full Continuum of Ventilatory Support
- Invasive and Non-Invasive Operation
- Mandatory and Assisted Ventilation
- BPAP, PRVC, and PC-CMV modes
- Can be used for intra-facility transport (4hrs)
- Simple and Intuitive User Interface
- Dependable, Safe and Easy to Learn and Operate
- Easy maintenance and long-term stockpiling
- Designed and Built to Stringent FDA Standards
- Engineered and Manufactured in the U.S.



Delivers the three most frequently used modes of ventilation, sufficient for even ARDS patients:

- Bilevel Positive Airway Pressure (BPAP) – which includes a back-up rate – conforming to the highest critical care ventilator standards
- Pressure Regulated Volume Controlled Ventilation (PRVC) – utilized to wean a patient from dependency on the ventilator.
- Continuous Mechanical Ventilation (CMV)

The BDR-19™ Ventilator has an **Internal Oxygen Blender** so oxygen concentration can be set on the machine without an external device.

The FIO2 control can be set at 21%, and from 30-100% in 10% increments.

The FIO2 control is independent of other controls – which facilitates convenient, safe and effective use in the ICU critical care setting.



A full complement of Alarms include:

Operator, Adjustable, High and Low Tidal, Volume, Fixed Alarm, Low and High PEEP, Low and High Inspiratory Pressure, Rate, Mandatory Ventilation in BPAP-S/T mode

Special Alarms:

Mains Power Lost, Battery Low, Battery Critically Low, Loss of Internal Voltage, Loss of Gas Supply, Hardware Failure, Power Off While Ventilating, Power On Self-Test, Fault, Loss of Flowrate Signal During Ventilation, Speaker, Multitonal, High, Medium and Low Priority, Backup Buzzer, Single Tone, Hardware Fault

External Exhalation Valve:

- The BDR-19 uses commonly available, universal, dual limb patient circuits - No proprietary vent circuit is required.
- The expiratory limb attaches to a built-in exhalation valve which accurately and reliably helps regulate pressure throughout the breathing cycle and controls the PEEP pressure during the expiratory phase.
- Uses simple exhalation valve and paper-filter PM kit.



Cost Effective

The BDR-19™ offers a price point below full-featured ICU vents with low per-patient maintenance costs.



- Low acquisition cost
- Low per-patient cost
- Low cost for consumables

The BDR-19™ provides a viable alternative to expensive short-term ventilator rentals

Intuitive

The BDR-19™ has comprehensive capabilities but is easy to learn and operate.



- User interface consists of only eight dials and a single segmented LED display.
- All controls are immediately visible and adjustable on one tactile surface with no multi-level touch screen menus to navigate
- Settings are clearly marked and set with tactile dials
- Color-coded LEDs indicate the key settings for adjustment relevant to each selected mode of ventilation.

Ergonomic

The BDR-19™ is Compact and Lightweight with a Small Footprint.



- Size: 415mm W x 368mm D x 243mm H. Weight: 11.2Kg**
- Can be easily carried, placed beside a bed, in a transport vehicle or on a cart.
 - Can be deployed to any acute-care setting, even when bedside space is limited.
 - Facilitates ergonomic intra-facility transport
 - Operates for 2 hours w/o wall power.
 - Optional roll-cart is available for counter-less use.

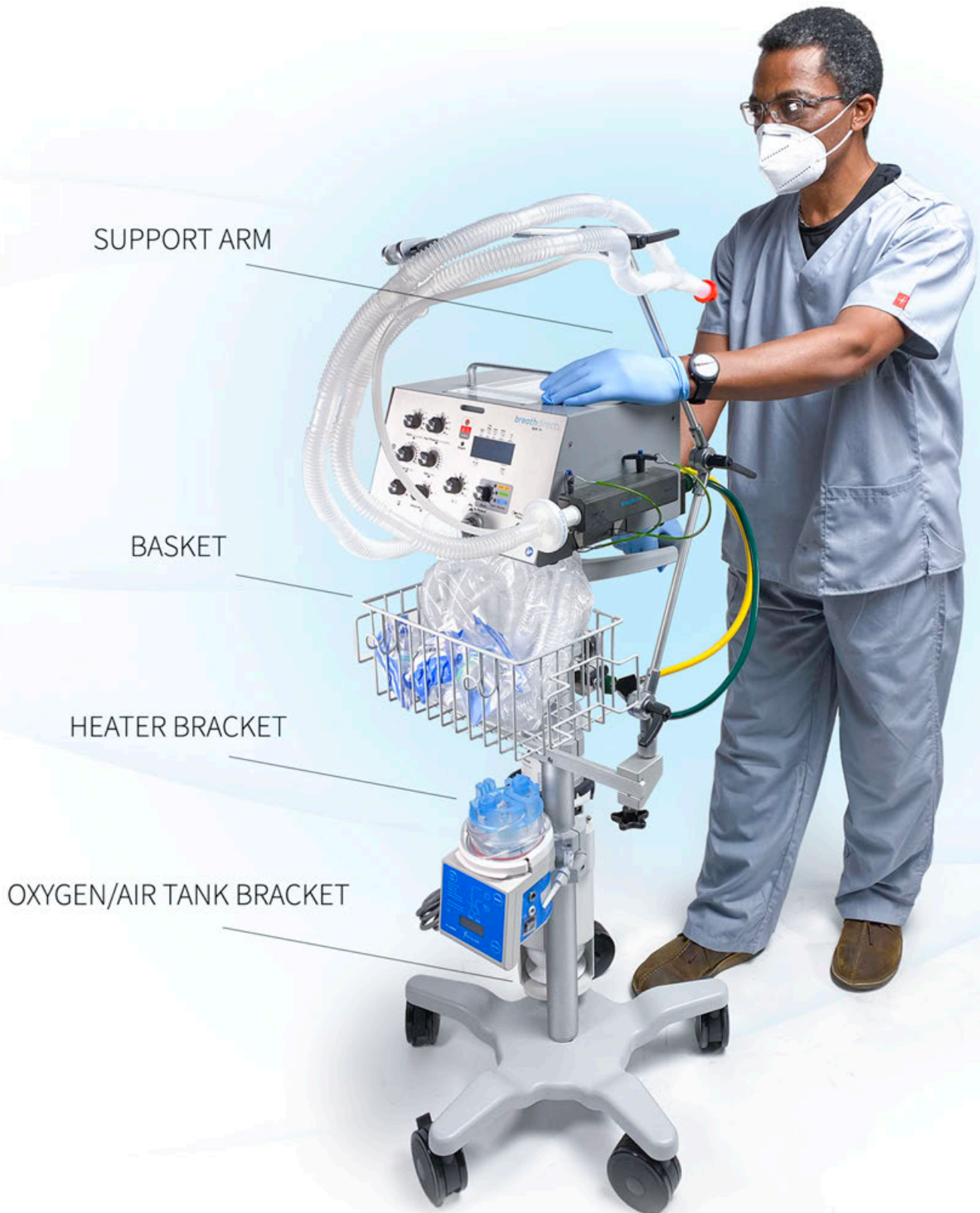
Easy to Maintain

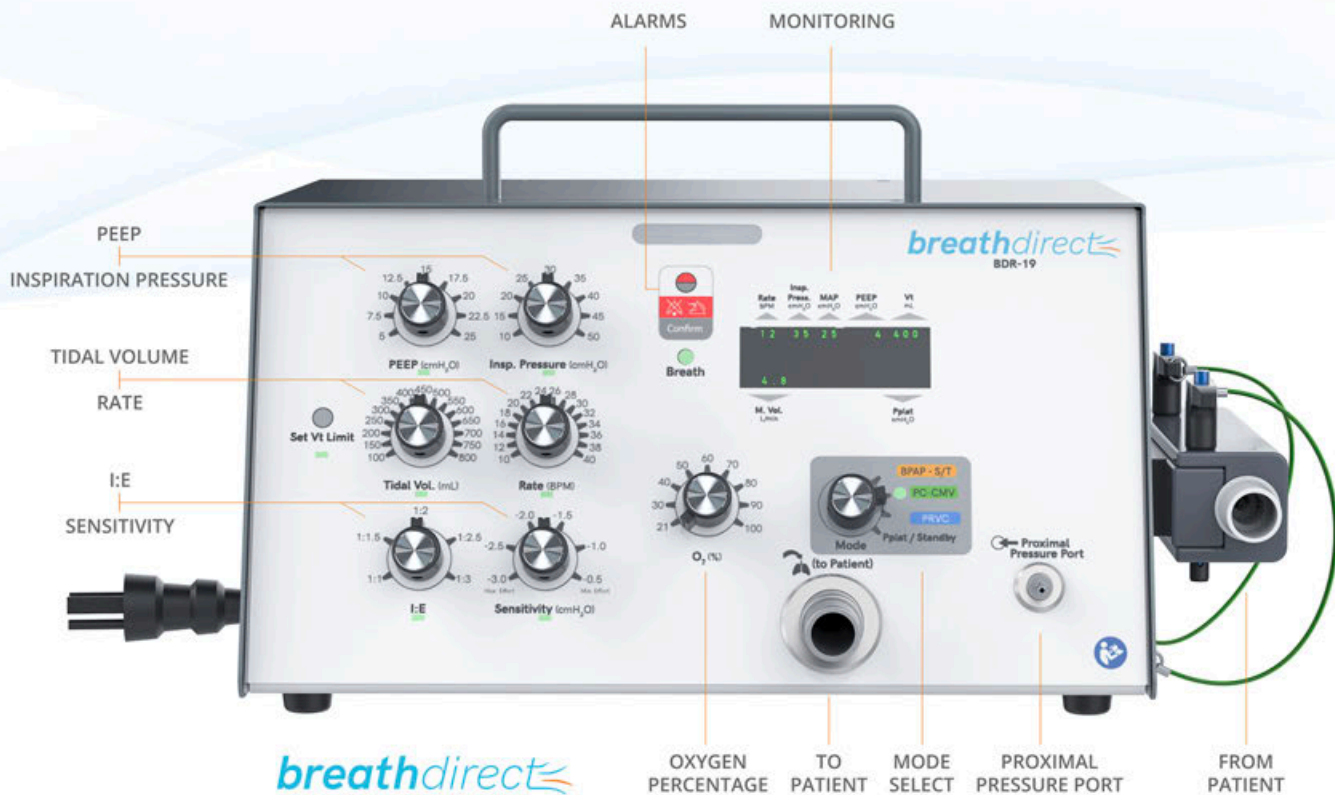
The BDR-19™ is reliable, durable and easy to service with stress-free disposables procurement.



- Can be cleaned with a wipe down between patients.
- All connections are compatible with standard bacterial filters.
- Exhalation valve is the only proprietary disposable and is easy to replace between patients
- All subsystems are easily accessible to make it easy to maintain..
- Maintains positive pressure and valves to prevent entrainment of contaminated room air.
- Is durable during heavy use and while in extended storage.

Optional Rolling Cart & Accessories





BDR-19™ Technical Specifications

PRVC	Pressure-Regulated Volume Control. Also called a pressure-controlled mode with adaptive targeting.
PC-CMV	Pressure-Controlled Continuous Mandatory Ventilation
BPAP-S/T	Bilevel Positive Airway Pressure with Spontaneous/Timed Mode

Technical Specifications

Monitoring	Display with 6 monitoring parameters Rate, Inspiratory Pressure, MAP, PEEP, Tidal Volume, Minute Volume, Plateau Pressure
Other Display	Breath delivered indicator Alarm indication Mode selection

Alarms

Operator-adjustable	High and Low Tidal Volume
Fixed Alarms	Low and High PEEP, Low and High Inspiratory Pressure, Rate, Mandatory ventilation in BPAP-S/T mode
Special Alarms	Mains power lost, battery low, battery critically low, loss of internal voltage, loss of gas supply, hardware failure, power off while ventilating, Power On Self-Test, fault, loss of flowrate signal during ventilation
Speaker	Multitonal, High, Medium and Low Priority
Backup Buzzer	Single tone, Hardware fault

Ventilation Modes

Type	Mode	Description
Pressure/Volume	PRVC	PRVC targets a set tidal volume at a set respiratory rate, but also responds to a patient's inspiratory effort
Pressure	PC-CMV	PC-CMV is a mandatory ventilation mode that delivers a set constant pressure at a constant rate to the patient
Invasive and noninvasive	BPAP-S/T	BPAP-S/T is a bilevel pressure support mode that supports spontaneous breathing of the patient, and defaults to mandatory ventilation if the patient does not initiate a breath

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Standards

Designed to these Standards,
Certifications Pending

IEC 60601-1:2005/A1:2012, IEC 60601-1-2:2007,
ISO 80601-2-12:2011 + Cor.:2011, IEC 80601-2-80,
ISO 5356, ISO 80601-2-74:2017, ISO 10993:2018
ISO 18562-1:2017, ISO 18562-2:2017, ISO 18562-3:2017
ISO 18562-4:2017, ISO 62304:2015

Electrical and Pneumatic Specifications

Input Voltage	100 to 240 VAC, 50/60 Hz
Power Consumption (Charging)	34 VA typical, 50VA maximum
Backup Battery Time	2.5 hours
Oxygen Supply	40 to 72 psi (276 kPa to 496 kPa) up to 100 L/min max
Air Supply	40 to 72 psi (276 kPa to 496 kPa) up to 100 L/min max
Degree of Protection	IPX21

Environment

Temperature	Operating: 50°F to 95°F (10°C to 35°C) Storage: 32°F to 95°F (0 to 35°C)
Humidity	10% to 80% relative humidity non-condensing
Altitude	Operating/Storage/Shipping: 0 to 10,000 ft. (0 to 3,048 m) at Mean Sea Level (MSL) under 600 to 1,100hPa of atmospheric pressure

Control Settings and Adjustments

Setting	Range	Increments
PEEP	5 to 25 (cmH ₂ O)	2.5
Inspiratory Pressure	10 to 50 (cmH ₂ O)	5
Rate	10 to 40 (BPM)	2
I:E Ratio	1:1 to 1:3	0.5
Sensitivity (Pressure Trigger)	-3 to -0.5 (cmH ₂ O)	0.25
Tidal Volume	100 to 800 (ml)	50
Tidal Volume Alarm	N/A	±50% of setpoint or user adjustable in 50 ml increments
FiO ₂	21% to 100%	21, 30, 40, 50, 60, 70, 80, 90, 100%

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Controls

PRVC Mode (Blue LED Indicators for active controls)		PEEP Setpoint
		Inspiratory Pressure Setpoint
		Rate
		I:E Ratio
		Sensitivity (Pressure Trigger)
		Tidal Volume Target
PC-CMV (Green LED indicators for active controls)		PEEP Setpoint
		Inspiratory Pressure Setpoint
		Rate
		I:E Ratio
		Tidal Volume Alarm Limits (Default or User Set)
BPAP-S/T (Amber LED indicators for active controls)		PEEP Setpoint
		Inspiratory Pressure Setpoint
		Rate
		I:E Ratio
		Sensitivity (Pressure Trigger)
		Tidal Volume Alarm Limits (Default or User Set)
		15 second Apneic Window (Default setting only)
Physical Dimensions	Size	415mm W x 368mm D x 243mm H
	Weight	11.2Kg
	Display	4 lines, 20 characters per line
	Main patient outlet	22mm
	Oxygen inlet	DISS
	Air inlet	DISS

