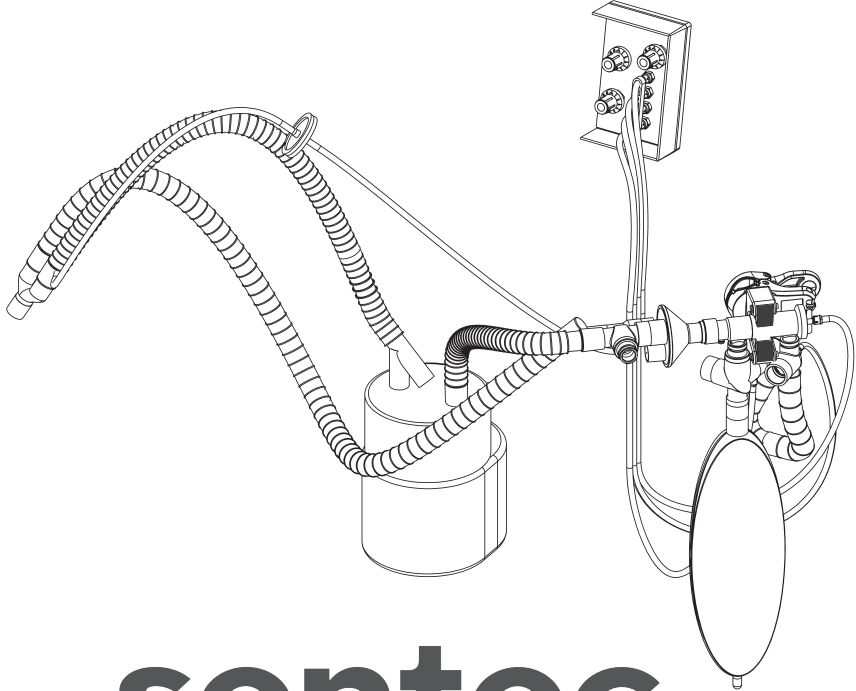




DISTAL PHASITRON®

Breathing Circuit for VDR®-4



sentec.

■ Percussionaire®, 130 McGhee Rd., Suite 109, Sandpoint, Idaho 83864

□ sentec.com ☎ +1.208.263.2549

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P20158
Rev B

EN

Distal Phasitron® Breathing Circuit Kit, Single Patient, Instructions for Use - English

Intended Purpose

The Distal Phasitron® breathing circuit is an active medical device, intended to be used with adults, pediatrics, and neonates. The Distal Phasitron® is part of a system to be used only with a Percussionaire® VDR®-4 control driver (or control unit) configured to deliver all flow through a single heated humidifier using a traditional, conventional ventilator breathing circuit. The Distal Phasitron® breathing circuit and VDR®-4 control driver are to be used within the hospital environment to provide Airway Clearance Therapy (ACT) by clinically trained professionals or respiratory technicians.

Contraindications

- History of pneumothorax
- Recent pneumectomy
- Pulmonary hemorrhage
- Myocardial infarction
- Vomiting
- Pulmonary air leak (without functioning chest tube)
- Lack of patient cooperation
- Untreated tension pneumothorax
- Untrained or unskilled operator

Document Symbols

WARNING	Single Patient Multiple Use
CAUTION	Only Prescription Only (USA)
Read manual before use	Catalog Number
Manufacturer	Lot Number
Manufacture Date	Disposal
Does Not Contain the Phthalate Plasticizers DEHP, DIBP, DBP, or BBP	Not Made with Natural Rubber Latex

Read and understand the instructions completely before setting up and using your Distal Phasitron® breathing circuit kit.

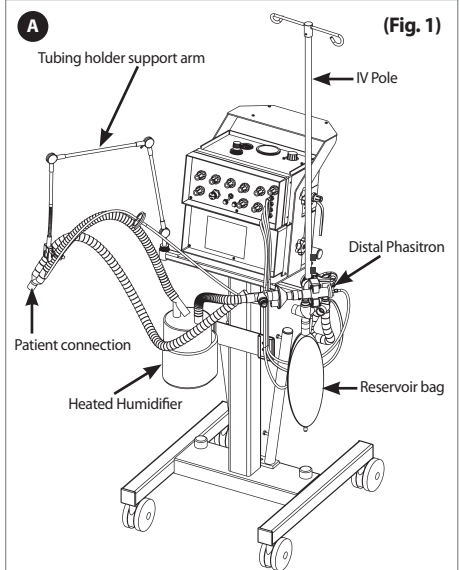
WARNING: This device should be used only with a low-compliance ventilator breathing circuit. Use of a high-compliance circuit may cause issues with carbon dioxide levels.

WARNING: Use of a non-approved ventilator circuit with the Distal Phasitron® may lead to unstable arterial carbon dioxide levels.

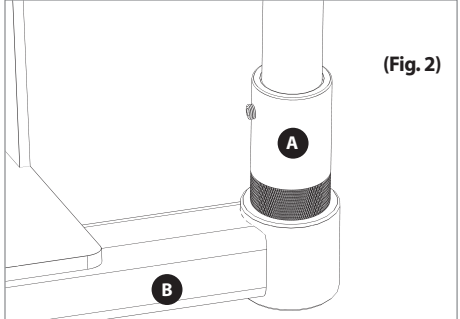
WARNING: The Distal Phasitron® and Percussionaire® VDR®-4 ventilator should only be used by physicians or clinicians specifically trained in mechanical ventilation and ventilation specifically with the VDR®-4 ventilator.

NOTE: Percussionaire® permits the use of the following systems with the Distal Phasitron®:
Fisher & Paykel 850 Evaqua™ circuits
Hamilton Medical H900 circuits

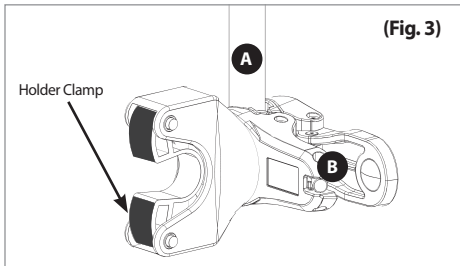
Complete Distal Phasitron® Breathing Circuit Setup with VDR®-4



1. Install heated tubing patient wye piece connection support arm (Fig. 1, A).
2. Install IV pole (Fig. 2, A) into right side of VDR®-4 stand (Fig. 2, B).

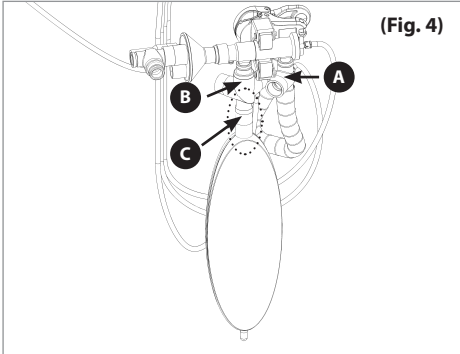


3. Permanently mount the Holder Clamp onto the IV pole (Fig. 3, B). Use adjusting screw nut on clamp to tighten to correct pole diameter (Fig. 3, A). Ensure the Holder Clamp is facing the front.



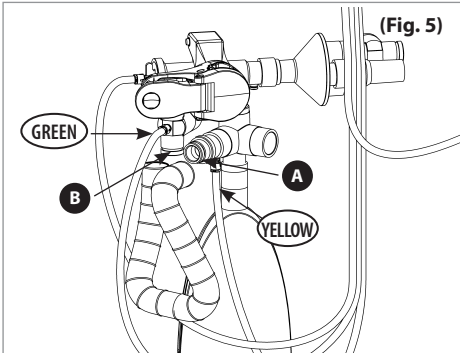
NOTE: The tubing is pre-connected on the Distal Phasitron® (Fig. 6), Clear, Green, and Yellow. The 22 mm corrugated tubing is also pre-connected to the balanced safety valve (Fig. 4, A) and the volume regulator with reservoir bag (Fig. 4, B).

4. If reservoir bag is disconnected, reconnect onto cross tee until fully seated onto the indicated port (Fig. 4, C).



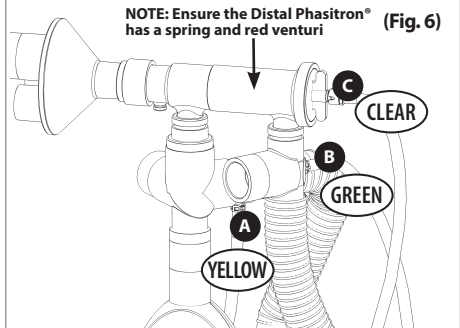
NOTE: The reservoir bag is integral to the safety system of the Distal Phasitron®. This will allow for a high minute volume demand from the patient instantaneously. High gas flow keeps the bag from accumulating any moisture. The yellow and green tubing delivers a bias flow of gas into the inspiratory safety valve on the Distal Phasitron®. If a patient has a high minute volume demand that exceeds the total flow from the green and yellow tubing, gas from the reservoir bag will be used and delivered to the entrainment side of the Distal Phasitron®.

5. If supplied 22 mm corrugated tubing is disconnected, connect to cross tee port near yellow tubing (Fig. 5, A). Connect opposite end of 22 mm corrugated tubing to port near green tubing (Fig. 5, B).

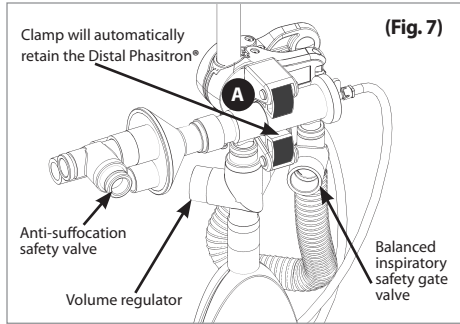


6. If not connected, connect tubing to the following locations: yellow

tubing to yellow fitting (Fig. 6, A), green tubing to green fitting (Fig. 6, B), and clear tubing to back of Distal Phasitron (Fig. 6, C).

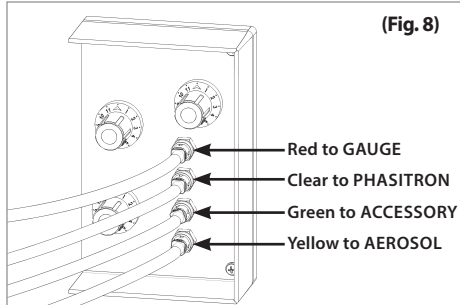


6. Press the Distal Phasitron® into Holder Clamp (Fig. 7, A).



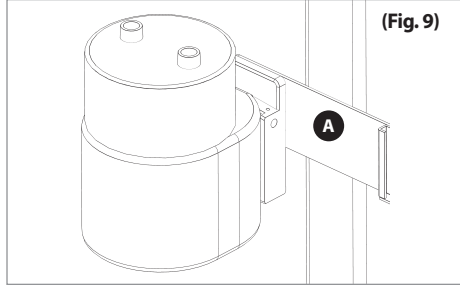
7. Connect red, white, green, and yellow tubing to the VDR®-4 Ventilator (Fig. 8).

Tubing Connections to the VDR®-4



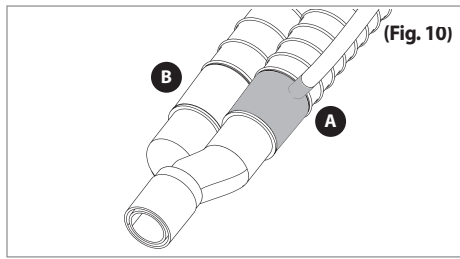
WARNING: The VDR®-4 device must be off before replacing any tubing.

8. Mount heater (Fig. 9) to VDR®-4 stand (Fig. 9 A). Percussionaire® universal mounting bracket for the most popular heaters is also available. Part number PRT-B13631.



Adult/Pediatric Wye Setup

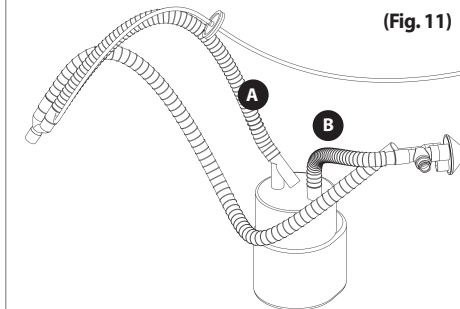
9. Press red tubing from VDR-4 GAUGE firmly on to the 22 mm/15 mm proximal pressure sampling adapter nipple and install onto the wye connector. Install the longer patient inspiratory (blue) side of corrugated tubing onto the adapter (Fig. 10, A). Install the exhalation (white/clear) side of corrugated tubing on to the other side of the wye (Fig. 10, B).



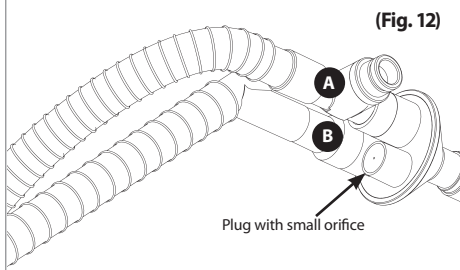
Adult/Pediatric Heater Setup

10. From the wye, connect other end of the inspiratory (blue) corrugated tubing to the fresh gas output side at the heater (Fig. 11, A). Install short blue corrugated tubing from the Distal Phasitron® into heater input side (Fig. 11, B).

CAUTION: Keep the red proximal line oriented in a straight up position at the patient wye to mitigate potential water accumulation in the line.



11. Connect exhalation (white/clear) corrugated tubing from patient wye to the Distal Phasitron® expiratory (Fig. 12, B).

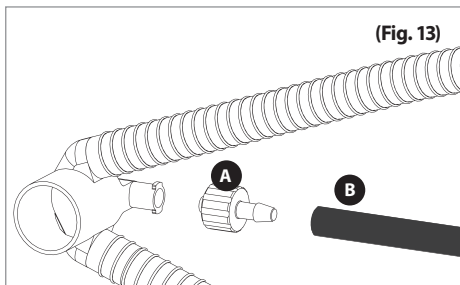


12. Check (A) short (blue) corrugated tubing from heater (Fig. 12). Check (B) (white/clear) corrugated tubing from expiratory side of the wye.

13. Set up and install heater wiring circuit normally.

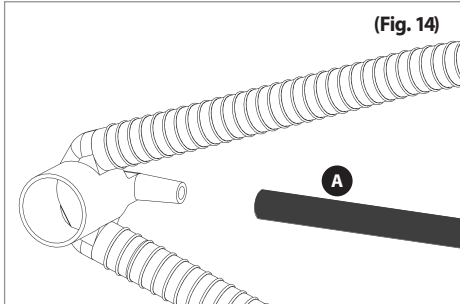
Neonatal Wye with Luer-Lock Setup

14. Add supplied luer connector onto wye (Fig. 13, A). Firmly press red tubing from VDR®-4 GAUGE onto luer connector nipple (Fig. 13, B).



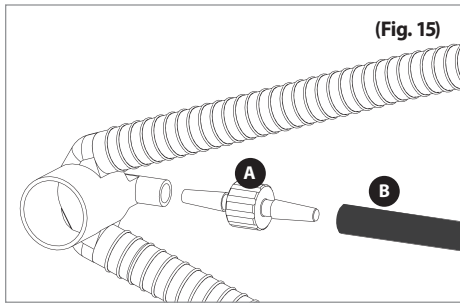
Neonatal Wye with Nipple Setup

15. Firmly press red tubing from VDR®-4 GAUGE directly onto wye (Fig. 14, A).



Neonatal Wye with 8 mm Port Setup

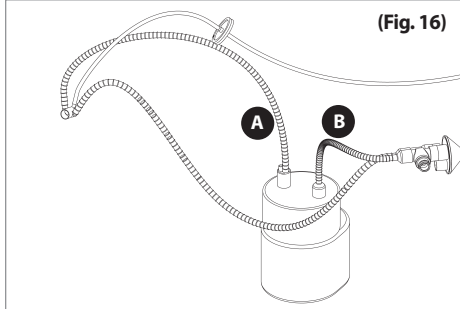
16. Firmly press two-sided connector onto wye (Fig. 15, A). Firmly press red tubing from VDR®-4 GAUGE onto other side of connector (Fig. 15, B).



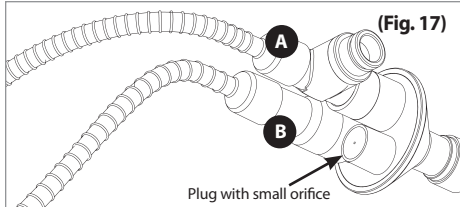
Neonatal Heater Setup

17. From the wye, connect other end of the inspiratory (blue) neonatal corrugated tubing to fresh gas output side at the heater (Fig. 16, A). Install short blue corrugated tubing from the Distal Phasitron® into heater input side (Fig. 16, B).

CAUTION: Keep the red proximal line oriented in a straight up position at the patient wye to mitigate potential water accumulation in the line.



18. Connect exhalation (white/clear) neonatal corrugated tubing from patient wye to the Distal Phasitron® expiratory (Fig. 17, B).



19. Check (Fig. 17, A) short (blue) corrugated tubing from heater.
20. Check (Fig. 17, B) (white/clear) corrugated tubing from expiratory side of the wye.

21. Set up and install heater wiring circuit normally.

Adapters supplied in the Distal Phasitron Kit



Cleaning of Distal Phasitron®

The Distal Phasitron is delivered clean, ready to be used on a patient.

Specifications

Red Line Filter	1-3 micron hydrophobic
Service Life	7 days
Shelf Life	2 years
	Used breathing circuits may be contaminated. Follow local applicable laws for disposal.

Limited Warranty

The manufacturer warrants to the initial purchaser that each new Phasitron® kit will be free from defects in workmanship and materials and will perform in accordance with the product specifications for a period of (7) days. The manufacturer's sole obligation under this warranty is to, at its own choice, repair or replace any component – for which the manufacturer acknowledges the warranty coverage – with a replacement component.

Warranty Exclusions and System Performance

Percussionaire® can neither guarantee nor verify product performance characteristics, nor accept warranty claims or product liability claims, if the recommended procedures are not carried out, if the product has been subject to misuse, neglect, or accident, if the product has been damaged by extraneous causes, or if accessories other than those recommended by Percussionaire® are used.

Any serious incident that has occurred in relation to the VDR®-4 system has to be reported to Sentec (Customerservice.us@sentec.com) and/or to the competent authority of the country where the incident occurred. If unsure whether an incident is a reportable event, contact Sentec.

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