CLV-213

Introduction

High Frequency Percussive Ventilation using the VDR-4 Percussionaire Ventilator was conceived and clinically designed to recruit and ventilate lungs with major airway obstructions and interstitial pulmonary compromises in all patient populations. The continuous ventilation Breathing Circuit CLV-213 constitutes an exclusive and unique feature of this mode of ventilation, dedicated to be applied in the treatment of patients with Acute Respiratory Failure.

Intended use

The CLV-213 Breathing Circuit (CLV-213) is an accessory to the VDR-4; and is intended to be used with the VDR-4 Percussionaire Ventilator only, which, mechanically controls or assists patient breathing and enhances the mobilization and raising of endobronchial secretions, enhances bronchodilation, and reduces mucosal edema and the resolution of diffuse patchy atelectasis in all patient populations. The CLV-213 is indicated for ICU hospital use.

Contraindication

No contraindications exist for the use of the CLV-213 with the exception of the contraindications for use of the VDR-4 as follows: unvented pneumothoracies, maintenance of a high mean intrathoracic pressure with low vascular volumes, and maintenance of a sustained intrathoracic pressure sufficient to block normal venous return

Training

The CLV-213 is intended to be used by clinical staff who have been authorized to independently assemble and utilize the VDR-4 and its accessories in ICU settings. The predominant users within the US include Respiratory Care Practitioners (RCPs). Outside the US other clinical staff includes licensed professionals such as Respiratory Therapists (RTs), Registered Nurses (RNs) with a clinical specialty, Nurse Practitioners (NPs), or MDs. All new users of the CLV-213 must have training and clinical experience with the VDR-4.

All users must be trained on the use of the CLV-213 before using the product to ventilate a patient.

Description of Device and Operating Principle

The CLV-213 is a VDR-4 accessory used to treat patients suffering from respiratory illnesses. When used together with the VDR-4 Percussionaire Ventilator and an external heater/humidifier, the CLV-213 delivers high frequency subtidal volumes of heated and humidified gas to the lungs.

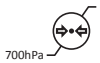
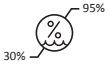
When in use, the VDR-4 is connected to the CLV-213 using four colored tubes (**Fig D**). The CLV-213 receives high pressure pulsatile flow from the ventilator. It also receives low pressure constant flow (bias flow) from the ventilator which first travels through the external heater/humidifier chamber. The gas is delivered to the patient through the CLV-213's Patient Interface Delivery Port.

During normal use exhaled gas is directed outside the CLV-213. If the moisturizer pressure line stops working, exhaled gas is partially reused within the breathing circuit to ensure that temperature, humidity, and levels of oxygen concentration remain stable.

Two safety valves are present in the CLV-213, the exhalation safety valve and the inhalation safety valve. The inhalation safety valve allows the patient to breathe in air from the ambient as needed to reduce the work of breathing. The exhalation safety valve allows the bias flow to escape each time that gas entrainment decreases.

Specifications

The breathing circuit shall be fully operational when used in the following environmental conditions:

	• a temperature range of +15°C to +40°C
	• an atmospheric pressure range of 700 hPa to 1060 hPa
	• a relative humidity range of 30% to 95%, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa

- Supported Flow, Pressure and Pulsatile Frequency: as dictated by the VDR-4
- Patient Interface Delivery Port: the inner diameter (ID) is 15mm and the outer diameter (OD) is 22mm; and the port meets the universal use requirements for breathing systems
- Storage Temperature Range: 15°C to + 30°C, up to 95% humidity

Symbol Definition

To indicate that caution is necessary when operating the device or control, close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

To signify a mandatory action.

Indicates important information.

SN Serial number

REF Catalogue number

LOT Batch number

EC REP Authorized representative in the European Community.

CE Systems with this mark agree with the European Council Directive (93/42/EEC) for Medical Devices when they are used as specified in their User's Reference manuals.

Manufacturer

Date of manufacture

Use by date

Refer to Instructions For Use

Single patient use

Temperature limitation

Atmospheric pressure limitation

Humidity limitation

℞ Only Prescription only

Warnings and Precautions

Device to use sterile water only. Do not use tap water or other liquids with the device

Do not block the exhalation safety valve (see **Fig D**)

Do not block the inhalation safety valve (see **Fig D**)

The device has a life expectancy of 7 days - If used beyond the verified 7 days life expectancy, the device could be compromised leading to patient harm or death

This device is single patient use only - If used on more than one patient, cross-contamination could occur leading to patient harm or death

Do not modify the device

Adding attachments beyond those listed herein can change the intended pressure gradient and adversely affect ventilator performance

Ensure the moisturizer bowl is not allowed to overfill or spill during operation

In the event of a drop, inspect the circuit for damage. If damage is found, or you are unsure if damage has occurred, replace the breathing circuit with a new one

Assemble the device as directed by following the set-up instruction

Before use, check all connections for a secure fit

Prescription use only - use only as directed by a physician

This device is intended for use in hospital and ICU environments only

For single use only

To be used only in conjunction with the VDR-4 and only by users who have been trained on the use and application of the VDR-4 Ventilator

Following use on a single patient, the CLV-213 should be disposed of according to the healthcare facility's protocols and in accordance with local, state, federal, and international laws to avoid contamination from potentially infectious substances of human origin

This Circuit should only be used with the VDR-4 and compatible external heaters/humidifiers such as the Fisher&Paykel Humidifier MR850 or MR730

The healthcare facility is responsible for use and prior to use must ensure that the CLV-213 Breathing Circuit is compatible

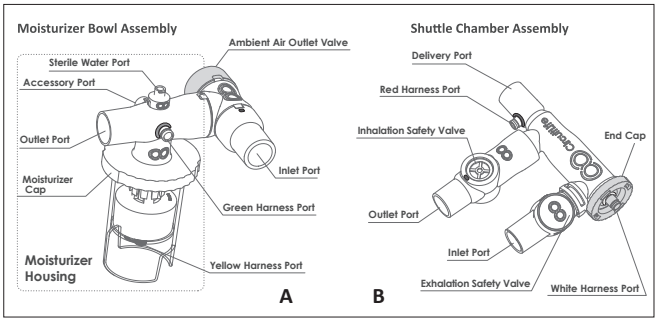
with the ventilator, respiratory equipment, and respiratory supplies used to connect any part of the circuit to the patient

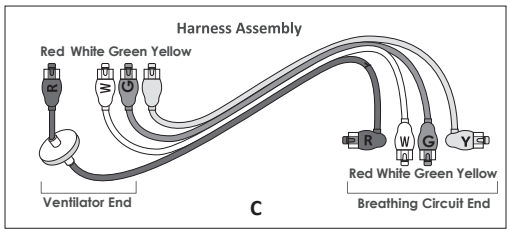
- Do not use the CLV-213 Breathing Circuit if the manufacturer's original packaging is open, punctured, or damaged
- Open directly prior to assembly/use
- This device is non-sterile
- Not made with natural rubber latex
- The design of the Volume Regulator does not require a balloon.

Contents of CLV-213 Packaging

The CLV-213 packaging contains the following assemblies:

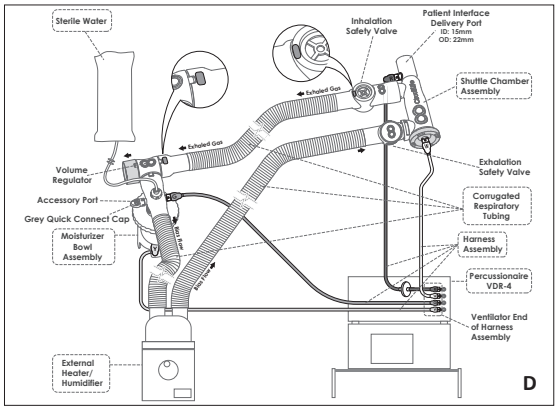
- Moisturizer Bowl Assembly (**Fig A**)
- Shuttle Chamber Assembly (**Fig B**)
- Harness Assembly (**Fig C**)





Overview and Set Up

The CLV-213 shall be set-up using the outlined steps. Once assembled, the system should resemble the assembled view, illustrated in (**Fig E**)



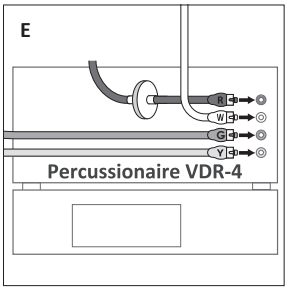
Open the Packaging and remove the CLV-213 breathing Circuit

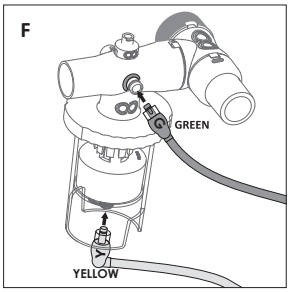
To prevent contamination, place the breathing circuit on a clean surface. When setting up the device, always follow your standard contamination prevention procedure as per your standard ICU protocol.

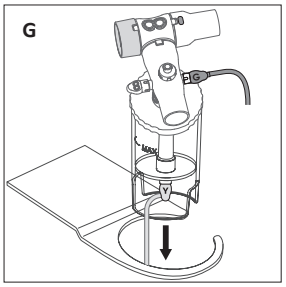
Connect the Harness Assembly

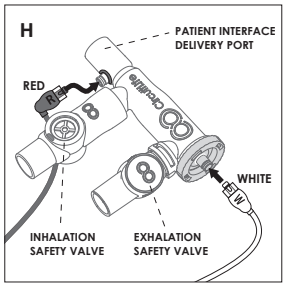
1. Locate the Ventilator End of the Harness Assembly. Push and click in to connect each of the Harness Assembly tubes into the matching color-coded service sockets of the VDR-4 (**Fig E**)
2. Connect the **Yellow** tube of the harness (with 90^{o} connection) to the service socket located at the bottom of the **Moisturizer Bowl Assembly,** Connect the **Green** tube of the harness to the service socket located on the cap of the **Moisturizer Bowl Assembly (Fig F**)
3. Place the **Moisturizer Bowl Assembly** into the VDR-4 Percussionaire Ventilator Bowl Holder (**Fig G**) Connect the **Red** tube of the harness to the Proximal Pressure Port service socket. Connect the **White** tube of the harness to the service socket located on the End Cap of the Shuttle Chamber Assembly (**Fig H**)

Ensure that the **Exhalation Safety Valve** is facing downward, and the **Inhalation Safety Valve** is facing upward when attached to the patient (**Fig H**).



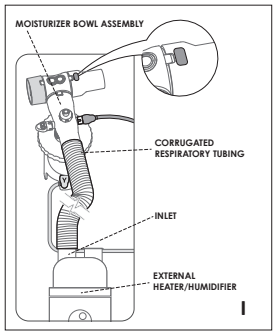


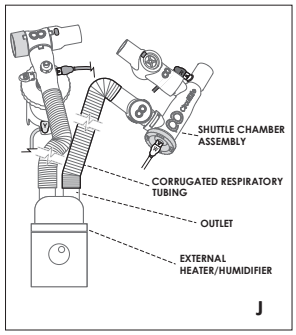


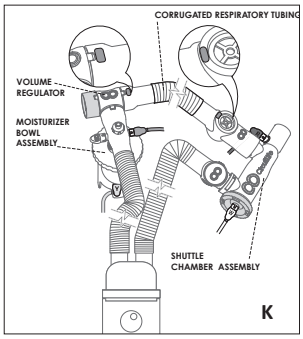


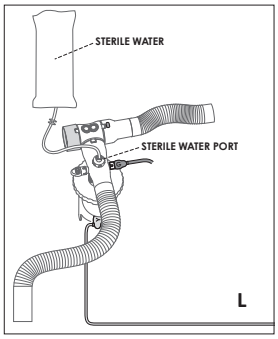
Connect the Respiratory limb/tubing

1. Connect appropriate corrugated respiratory tubing to the outlet port of the **Moisturizer Bowl Assembly** (the end/port **without** the purple sticker), and to the inlet port of the **External Heater/Humidifier** chamber on the other side (**Fig I**)
2. Connect approved corrugated respiratory tubing between the outlet port of the **External Heater/Humidifier** chamber and the inlet port of the exhalation safety valve of the **Shuttle Chamber Assembly (Fig J**)
   Note: The External Heater/Humidifier must always be kept below the Patient Interface Delivery Port on the shuttle chamber assembly side of the circuit. This prevents any chance of water flowing from the moisturizer bowl to the breathing airway of the patient.
3. Connect the approved corrugated respiratory tubing to the outlet port of inhalation safety valve on the **Shuttle Chamber Assembly**, on one side, and to the inlet port of the **Volume Regulator** on the other side. These are identified by the **purple markings (Fig K**)
4. Connect the **Sterile Water Source** to the **Sterile Water Port** on the **Moisturizer Bowl Assembly (Fig L**)
   Note:
   -Ensure that the Moisturizer Bowl is not allowed to run dry
   -During normal operation liquid should not reach the cap of the bowl. In the unlikely event of the liquid reaching the white cap of the bowl, stop the procedure and replace with a new breathing circuit.





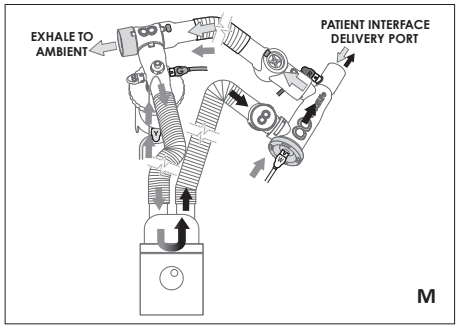




Once assembled the normal direction of flow through the circuit is as depicted (**Fig M**)

Should a decrease in airflow be detected, straighten any kinks in the small-bore tubing (**Harness Assembly**) and the 22mm corrugated respiratory tubing.

Do not stand close to the exhaled gases exit.



Pre-use Check

1. Verify that all ports have been securely connected to the corresponding respiratory tubing and ports.
2. Verify that the exhalation safety valve is facing downward. The CircuitLife logo at the rear of the exhalation safety valve should be facing up (**Fig D**).
3. Verify that the inhalation safety valve is facing upwards. The purple dot and word CircuitLife should be facing up when attached to the patient (**Fig D**).
4. Ensure that the accessory port has its gray quick connect cap attached (**Fig D**) and is not open to ambient air.

Start-Up

1. Start the external heater/humidifier per the external heater/humidifier IFU and manufacturer's directions.
2. Start the VDR-4 Ventilator and enter or confirm settings in accordance with physician orders.

Ventilation

- The Clinician (MD, ICU Nurse, RCP) connects the CLV-213 to the patient by securing the Patient Interface Accessory to the Patient Delivery Port of the shuttle chamber. Endotracheal tube, tracheostomy tube or facemask is to be used as per the facility's standard procedure.
- The Clinician (MD, ICU Nurse, RCP) operates, adjusts, and monitors ventilation of the patient using the VDR-4 Percussionaire Ventilator in accordance with physician orders.
- CircuitLife CLV-213 Breathing Circuit may have a lowered noise level compared to similar breathing circuits, which is acceptable.

Disassemble and Dispose after Use

Once the procedure has been terminated, the CLV-213 can be disconnected and disposed of. The following steps must be followed:

1. Remove the CLV-213 from the Patient Interface Accessory
2. Disconnect the Harness Assembly from the VDR-4 (**Fig D**).
3. Disconnect the Heater/Humidifier chamber (with the corrugated respiratory tubing still attached) from the Heater/Humidifier unit (**Fig D**).
4. Unmount the Moisturizer Bowl Assembly from the ventilator bowl holder as applicable (**Fig D**).
5. Dispose of the CLV-213, Sterile Water Source, and Heater/Humidifier chamber as per the facility's standard protocol.

Service Instruction

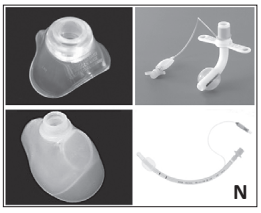
CLV-213 is a single use device. No service is required.

Device Use Life

The CLV-213 is to be used for a maximum of 7 days of continuous ventilation for a single patient.

Patient Interface Accessories

- The CLV-213 will interface with the patient's airways either via endotracheal tube, tracheostomy tube or facemask. The Patient Interface Accessories are to be connected to the Patient Delivery Port of the Shuttle Chamber. It is the responsibility of the physician to prescribe the appropriate patient interface accessory.
- Only approved respiratory Patient Interface Accessories should be used, and, as such will be compatible with the CLV-213 Delivery Port, which, is compatible with 15mm/22mm connections. (**Fig N**) illustrates accepted examples of patient interface accessories:



Troubleshooting

Troubleshooting for the CLV-213 is not required. In the unlikely event of an unexpected issue, please replace with a new device. Contact the manufacturer or your local reseller to report any unexpected operations or events.

Ventilator Compatibility

The CLV-213 is an accessory to be used with the VDR-4 Percussionaire Ventilator only. The small-bore tubing (Harness Assembly) is compatible with the connection ports of the VDR-4. The use of incompatible parts can result in degraded performance.

Limited Warranty

CircuitLife LLC warrants that your CLV-213 Breathing Circuit will be free from defects in material and workmanship during the shelf life indicated; and the CLV-213 can be used on a single patient for up to seven (7) days as indicated in the IFU. This warranty applies only to the initial consumer. It is not transferable. If the product fails to perform in accordance with product specifications under conditions of normal use, CircuitLife or its authorized distributor will repair or replace, at CircuitLife's or appointee's option, the defective product or any of its components. This limited warranty does not cover: (a) any damage caused as a result of improper use, abuse, neglect, negligence, modification or alteration of the Breathing Circuit; (b) repairs carried out by any service organization not authorized by CircuitLife to perform such repairs; or (c) any damage or contamination due to non-compliance with the applicable Instructions for Use (e.g., use of sterile water). Warranty is void on any Breathing Circuits sold or resold outside the region of original purchase.

EXCEPT FOR THE WARRANTY SET FORTH ABOVE, CIRCUITLIFE MAKES NO WARRANTY WHATSOEVER WITH RESPECT TO THE GOODS, INCLUDING ANY (A) WARRANTY OF MERCHANTABILITY; (B) WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE; OR (C) WARRANTY AGAINST INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF A THIRD PARTY; WHETHER EXPRESS OR IMPLIED BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE.

CIRCUITLIFE IS NOT LIABLE FOR CONSEQUENTIAL, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR ENHANCED DAMAGES ARISING OUT OF OR RELATING TO THE SALE, INSTALLATION OR USE OF ANY BREATHING CIRCUIT, REGARDLESS OF (A) WHETHER SUCH DAMAGES WERE FORESEEABLE, (B) WHETHER OR NOT CIRCUITLIFE WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, AND (C) THE LEGAL OR EQUITABLE THEORY (CONTRACT, TORT, OR OTHERWISE) UPON WHICH THE CLAIM IS BASED, AND NOTWITHSTANDING THE FAILURE OF ANY AGREED OR OTHER REMEDY OF ITS ESSENTIAL PURPOSE.

For further information on your warranty rights, contact CircuitLife or its authorized distributer from whom you made your purchase.