CLT-210

Introduction

Intrapulmonary Percussive Ventilation was conceived as a method of mobilizing and raising retained endobronchial secretions as well as providing for the resolution of atelectasis while maintaining an adequate intrapulmonary gas exchange, in all patient populations. The Therapeutic Breathing Circuit is the most unique feature of Intrapulmonary Percussive Ventilation. Only used in conjunction with the IPV Percussionaire family of ventilators, this concept is dedicated to be applied in the treatment of patients with acute and or chronic respiratory illnesses.

Intended use

The CLT-210 Breathing Circuit (CLT-210) is an accessory to the IPV Percussionaire family of ventilators, and when used with the IPV devices,the CLT-210 is indicated to, mobilize and raise endobronchial secretions, reduce mucosal edema, and resolve diffuse patchy atelectasis in all patient populations. It is expected that either the patient, family member, or Healthcare Practitioner (HCP) may be the intended operator(s) of the CLT-210, following the therapy outlined by the prescribing physician. The operator must perform the manual cleaning and disinfection of the-CLT-210 as per described procedures.

Contraindication

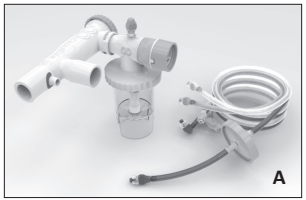
No contraindications exist for the use of the CLT-210 other than the ones relative to and indicated in the Instructions for Use (IFU) of the IPV Percussionaire family of ventilators: Untreated tension pneumothorax, lack of adequate and skilled supervision, availability of a simpler and more effective treatment, history of pneumothorax, pulmonary air leak, recent lobotomy/pneumonectomy, pulmonary hemorrhage, cardiovascular insufficiency/MI (decreased coronary perfusion), lack of patient cooperation, vomiting.

Training

The CLT-210 is intended to be used by both clinical staff and lay persons (home users) who have been authorized to independently assemble and utilize the IPV ventilator and its accessories (**Fig A**).The predominant users are home care nurses, home users, self-administering patients, licensed professionals such as Respiratory Care Practitioners (RCPs), Respiratory Therapists (RTs), Registered Nurses (RNs), Nurse Practitioners (NPs) or MDs. All new users of the CLT-210 must have training with the IPV Percussionaire Ventilator. All users shall have self-training on the use of the CLT-210 before using the product to ventilate themselves or a patient.

Description of Device and Operating Principle

The CLT-210 is only to be used with the IPV Percussionaire family of ventilators (IPV1C, IPV2C and Impulsator) except for the IPV-HC/black bag Ventilator. The CLT-210 is for use as an intermittent therapy for people suffering from acute or chronic cardio respiratory illness. The CLT-210 delivers rapid, high flow, mini-bursts (percussions) of moisturized gas into the lungs at rates of 60-600 percussions per minute when connected to an appropriate IPV ventilator.

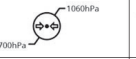


During operation, the IPV ventilator is connected to the CLT-210 using three colored tubes (Harness Assembly) at three different connection points located on the Shuttle Chamber and Moisturizer Assembly (**Fig A**). The Shuttle Chamber receives high pressure pulsatile gas flow from the ventilator, as well as a low-pressure bias flow, coming also from the ventilator and traveling through the Moisturizer Assembly. Gas is delivered to the patient via the proximal (to patient) open end of the Shuttle Chamber (Patient interface delivery port). A visualization of the assembly is available in **Fig B-C**.

Specifications

Environmental Operating Conditions

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

	• a temperature range of +5°C to +40°C
	• an atmospheric pressure range of 700 hPa to 1060 hPa
	• a relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa

Special Storage Conditions

The breathing circuit shall remain fully operational after being stored out of its package at the following conditions:

-25°C 5°C	• -25°C to +5°C
5°C 35°C with a RH of 90% non-condensing	• +5°C to +35°C at a relative humidity up to 90%, non-condensing
-35°C 70°C at a water vapor pressure up to 50 hPa	• +35°C to +70°C at a water vapor pressure up to 50 hPa

Technical Specifications

- Supported Flow, Pressure and Pulsatile Frequency: as dictated by the IPV Percussionaire family of ventilators
- 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

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

Warning and Precautions

Do not block Exhalation Port during use & Do not block Air Inlet Valve (**Fig B**).

Connecting a 20 cm length of 22 mm standard corrugated respiratory tubing to the exhalation port (**Fig S**) reduces the likelihood of Exhalation Port blockage occurring.

Device to use NaCl 0.9% Normal Saline Solution. NaCl 0.9% shall be present in the moisturizer bowl through the duration of the therapy session. Do not administer therapy if moisturizer bowl is dry.

Do not service or perform maintenance on the device.

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.

Do not store the CLT-210 outside its packaging.

Do not modify the CLT-210 or any of its components.

Before use, check all connections on the CLT-210 for a secure fit.

Assemble the device as directed in the present instruction.

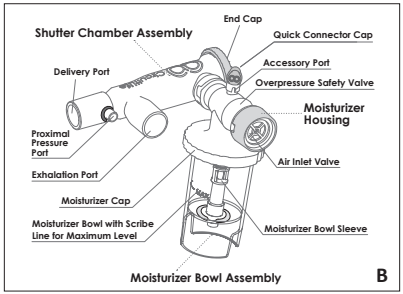
This device is single patient use only - If used on more than one patient, cross-contamination could occur leading to patient harm or death.

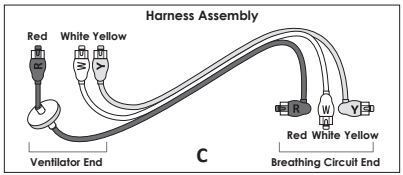
Do not use tap water to fill the Moisturizer Bowl. Only pre-packaged NaCl 0.9% must be used.

Do not overfill the Moisturizer Bowl past the scribe line for maximum fill level (**Fig E**).

- Do not use the CLT-210 beyond its service life – 6 months.
- Do not wash the CLT-210 or any of its components in a dishwasher.
- Hold the CLT-210 firmly during assembly and use to avoid injury caused by dropping on patient and/or operator.
- Use only approved cleaning agent to clean Breathing Circuit. Never use unapproved cleaning agents such as bleach.
- The device is not compatible with the Home Care IPV- HC.
- This device is non-sterile.
- Not made with natural rubber latex.
- To be used only by persons who have been trained in IPV ventilation, and in conjunction with the Percussionaire IPV family of ventilators, except for the IPV-HC/black bag Ventilator.
- Prescription use only - use only as directed by a physician.
- It is unsafe to use the CLT-210 in conjunction with unapproved ventilators or other unapproved devices.

CONTENTS OF PACKAGING

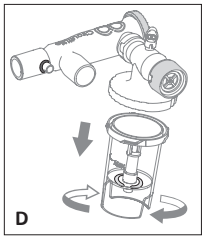


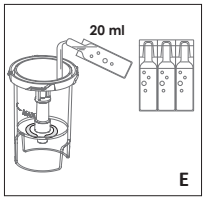


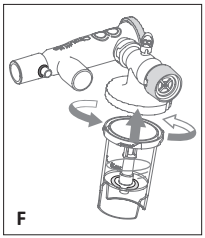
SET-UP INSTRUCTIONS

- ALWAYS CHECK THE EXPIRATION DATE ON THE PACKAGING, PRIOR TO SETTING UP THE CIRCUIT FOR USE
- ⚠ DO NOT REMOVE THE RUBBER BAND ON THE OVERPRESSURE SAFETY VALVE (**Fig B**)

Breathing Circuit Set-up – Direct From Package (or after cleaning and disinfection). Follow RE-ASSEMBLY instructions on page 6.

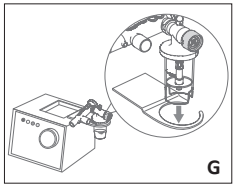


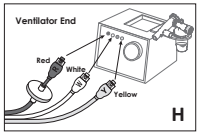


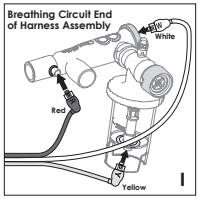


The breathing circuit assembly and component integrity check steps are required after cleaning and not directly from the package.
The CLT-210 is packaged preassembled.
- Disassemble the Moisturizer Bowl from the Moisturizer Housing by **twisting the Moisturizer Bowl clockwise, then pulling to detach**.(**Fig D**). If the Moisturizer Bowl is already detached from cleaning, continue to the next step.
- Inspect the Moisturizer Bowl Assembly for a **watertight connection** between the Moisturizer Bowl and the Moisturizer Bowl Sleeve. Place the Moisturizer Bowl **on a clean surface.**
Add up to **20 ml of NaCl 0.9%** to the bowl without exceeding the maximum level scribe line engraved into the Moisturizer Bowl. (**Fig E**)

⚠ DO NOT ADMINISTER THERAPY IF MOISTURIZER BOWL IS DRY OR FILLED ABOVE THE MAXIMUM LEVEL SCRIBE LINE.
- Reassemble the Moisturizer Bowl with the Moisturizer Housing by twisting the bowl counter-clockwise onto the Moisturizer Cap. (Fig **F**). **Keep the bowl upright to avoid spilling**.
- Place the Moisturizer Bowl Assembly into the dedicated Percussionaire bowl holder, if available. (**Fig G**)
- The Harness Assembly serves as the interface between the CLT-210 Breathing circuit and the Percussionaire IPV device.







Each individual tube is color coded, with a quick fitting on each end. The ventilator end of the Harness Assembly can be recognized as the closest end to the red line filter.

Note, the Harness Assembly, colored tubes are bonded together **but may be separated as required.**

Connect the Ventilator End of the Harness Assembly into the matching color-coded service sockets of the Percussionaire IPV ventilator. (**Fig H**)

- Connect the Breathing Circuit End of the Harness Assembly to the matching color-coded service sockets of the CLT-210.

The RED end of the harness assembly connects to the Proximal Pressure Port service socket.

WHITE end of the harness assembly connects to the service socket located at the End Cap of the Shuttle Chamber Assembly.

YELLOW end of the harness assembly connects to the service socket located at the bottom of the Moisturizer Bowl. (**Fig I**)

Pre-Use Check

Turn on the IPV ventilator and set it in accordance with physician orders and IPV ventilator user manual.

Before administering therapy, it is required to check the system as follows:

1. Check that colored tubes (Harness Assembly) have been accurately and securely connected to the corresponding service socket.
2. Ensure that the NaCl 0.9% level is at the maximum level scribe line on the Moisturizer Bowl.
3. Allow the system to run before patient hook up in order to allow any dust or particulates to exit the gas path. If any major debris exits the breathing circuit during the pre-use test, the user must cease use and contact CircuitLife or the distributor.
4. While the system is running, check that the air inlet valve is working correctly – Do so by checking that pulses of gas can be felt on your hand, and observe puffs of moisture/mist coming from the patient interface delivery port of the shuttle chamber.
5. Ensure the accessory port has its gray quick connect cap attached and is not open to ambient air (**Fig B**). This port is for measurement purposes only and not intended for use during normal operation.

VENTILATION

Connection to Patient

Attach the CLT-210 patient interface delivery port of the shuttle chamber to the appropriate standard patient interface accessory (**Fig B-S**).

Examples of such accessories include:

Endotracheal tube (ETT), tracheostomy tube, face mask, or mouthpiece. (**Fig T**)

Therapy Administration and Monitoring

- The user must administer therapy in accordance with physician pre-scription and direction, and in accordance to the Percussionaire IPV IFU. The Moisturizer Bowl should contains only enough NaCl 0.9%, do not administer therapy if moisturizer bowl is dry.
- The user can rotate the Shuttle Chamber Assembly just shy of 360° in order to accommodate user preferences related to positioning.
- Do not stand close to the exhaled gases exit.

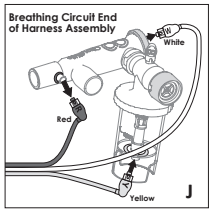
DEVICE USE LIFE

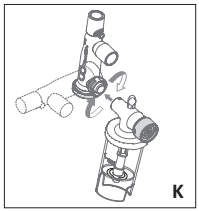
The CLT-210 is to be used for a maximum of 6 months service. The CLT-210 should not be used if components are found to be damaged during a visual inspection or pre-use check.

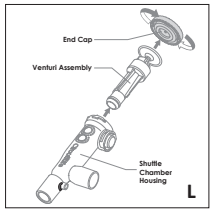
CLEANING AND DISINFECTION:

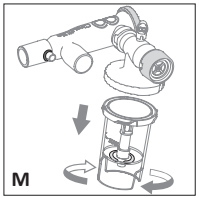
DISASSEMBLY

The CLT-210 should be cleaned after each use and disinfected weekly. Cleaning instructions are outlined in the steps below.





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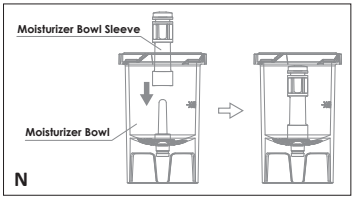


N

1. **Clean hands thoroughly** with soap and water prior to cleaning the Circuit.
   Detach all patient interface accessories on the CLT-210.
   Detach the Breathing Circuit End of the Harness Assembly from the service sockets of the CLT-210 by pulling the quick fittings. (**Fig J**)
   NOTE:
   Do NOT pull from the tubing when removing the harness assembly from the breathing circuit or ventilator.
   Remove the connections by holding the quick fitting connectors.
2. Twist the Shuttle Chamber Assembly so that the patient interface delivery port is pointed upwards.
   Pull to **detach the Shuttle Chamber Assembly from the Moisturizer Housing**. (**Fig K**)
3. Disassemble the **Shuttle Chamber Assembly** by rotating the **End Cap** counter-clockwise.
   Lightly tap the **Shuttle Chamber housing** into your hand to **dislodge the Venturi Assembly**. (**Fig L**)
4. Disassemble the **Moisturizer Bowl Assembly** by rotating the **Moisturizer Bowl** clockwise. (**Fig M)**
   The Moisturizer Bowl Sleeve and Quick Connector cap do not need to be removed. If the Moisturizer Bowl Sleeve is accidentally removed, reseat it – ensuring that the bottom face of the sleeve fully contacts the bottom face of the moisturizer bowl (**Fig N**)

CLEANING PROTOCOL **- After Each Use (does not apply to colored tubes)**
Note:

- All CircuitLife products are packaged clean. They **should not** be considered sterile or decontaminated
- The CLT-210 should be cleaned prior to use if it has been more than one (1) month since its last cleaning
- The harness assembly should be replaced with the device after 6 months of use, no cleaning is necessary prior to this replacement

The following steps **must be followed** to complete the manual cleaning protocol:

1. **Completely** disassemble the CLT-210 **Circuit except for the colored tubes.**
2. Rinse all separated parts **under warm, running, tap water.**
3. Prepare a dish soap solution **of Ultra Concentrated Liquid Dish Soap to a warm tap water.**
4. **Completely immerse the CLT-210 separated parts in the prepared dish soap solution and** brush each part with a soft bristled brush.
5. Remove all parts and **rinse them under running tap water** .
6. **Shake parts free of excess water** and allow them to air dry on an absorbent clean surface, such as a lint-free cloth. Allow them to air dry.
7. Visually inspect each part for visible mucus or contaminants - If anything is remaining, repeat the process beginning at Step 2.
8. Each time the CLT-210 is cleaned, perform a safety inspection of the components – including the following:
   - Inspect the parts for cracks or tears
   - Check that all components are present

DISINFECTION PROCEDURE, WEEKLY **- (Does not apply to colored tubes)**

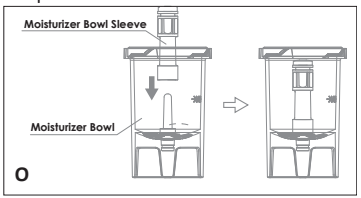
- ALWAYS WEAR PROTECTIVE RUBBER GLOVES WHEN USING 3% HYDROGEN PEROXIDE SOLUTION
- ALWAYS READ AND FOLLOW THE PERSONAL SAFETY PROTECTION PROCEDURES AS DESCRIBED ON THE LABEL OF THE 3% HYDROGEN PEROXIDE SOLUTION
- KEEP EYES AS FAR AS POSSIBLE FROM THE 3% HYDROGEN PEROXIDE SOLUTION WHILE PERFORMING THE DISINFECTION PROCEDURE.
- IN CASE OF EYE CONTACT, CHECK FOR AND REMOVE ANY CONTACT LENSES AND IMMEDIATELY FLUSH EYES WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES, COLD WATER MAY BE USED, GET MEDICAL ATTENTION IF NEEDED.

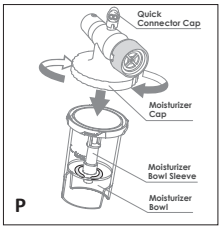
The following steps **must be completed** as part of the weekly disinfection procedure:

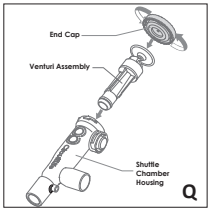
1. Perform a full cleaning of the CLT-210 as per the "Cleaning Protocol".
2. Pour 3% hydrogen peroxide solution into a clean basin.
3. Completely immerse all separated parts in 3% hydrogen peroxide solution and ensure all air bubbles are removed from the surface of the parts by stirring or shaking them while submerged.
4. Allow the parts to soak for 30 minutes.
5. After soaking for 30 minutes, remove the parts from the hydrogen peroxide solution and shake all parts free of excess hydrogen per-oxide solution.
6. Rinse all parts under warm running tap water, to remove any residual hydrogen peroxide.
7. Allow the rinsed parts to air dry on an absorbent clean surface, such as a lint-free cloth.

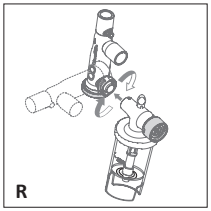
RE-ASSEMBLY AFTER CLEANING AND DISINFECTION

The following steps must be completed in order to **re-assemble the CLT-210** post-disinfection:









1. Clean hands thoroughly with soap and water prior to assembling the Circuit.
2. Inspect components of the CLT-210 for visible damage or wear. If any damage is observed, do not use the CLT-210, and contact the distributor.
3. **If the Moisturizer Bowl Sleeve was accidentally removed, reseat it** - Ensuring the bottom face of the sleeve fully contacts the bottom face of the moisturizer bowl (**Fig O**)
4. Re-Assemble the Moisturizer Bowl Assembly by pushing the two parts together and rotating the Moisturizer Cap clockwise (**Fig P**)
5. Re-Assemble the Shuttle Chamber Assembly by first seating the Venturi assembly into the Shuttle Chamber Housing and then pushing and rotating the End Cap clockwise until a positive connection is felt (**Fig Q**)
6. Position the Shuttle Chamber Assembly so that the patient interface delivery port is pointed upwards, then push and rotate to attach the Shuttle Chamber Assembly to the Moisturizer Housing (**Fig R**)

Procedure for Prolonged Storage (Longer than one (1) month)

1. Ensure the CLT-210 is cleaned, disinfected and completely dry before storing.
2. Place the CLT-210 components into a clean plastic bag.
3. Place the plastic bag in a cool location away from sunlight.
4. If the CLT-210 has been stored for longer than 1 month, follow the specific instructions of the Cleaning Protocol.

VENTILATOR COMPATIBILITY

IPV Percussionaire Family of Ventilators

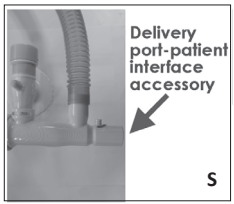
The CLT-210 Breathing Circuit is be used as an accessory to the IPV Percussionaire family of ventilators and their accessories. The colored tubes (Harness Assembly) provided with the CLT-210 Breathing Circuit are compatible with the connection ports of the IPV Percussionaire family of ventilators and their accessories.

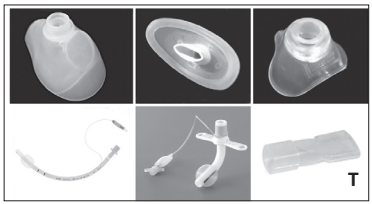
PATIENT INTERFACE ACCESSORIES

The CLT-210 Breathing Circuit will interface with the patient's airways through standard 15mm/22mm respiratory connections, such as an endotracheal tube, tracheostomy tube, face mask, or mouthpiece. The Patient Interface Accessories are to be connected to the patient interface delivery port of the Shuttle Chamber (**Fig S**).

All Patient Interface Accessories must have standard 15mm/22mm con-nections (**Fig T**).

Depending on the demand and the place where the breathing circuit is distributed, some packaging may contain a corrugated breathing tube and a mouthpiece **(Fig S -T)**.





CLV-210 BREATHING CIRCUIT DISPOSAL INSTRUCTIONS

Medical Facility Disposal Instructions

After the CLT-210 Breathing Circuit has reached the end of its use life, it should be disposed of as per the standard waste disposal protocol of the medical facility. Standard healthcare facility procedures should be followed to avoid contamination from potentially infectious substances.

Home Use Disposal Instructions

The CLT-210 Breathing Circuit shall be cleaned as per the cleaning protocol. Following this, the CLT-210 can be disposed of with regular household waste.

Limited Warranty

CircuitLife LLC warrants that your CLT-210 Breathing Circuit will be free from defects in material and workmanship during the shelf-life indicated; and the CLT-210 can be used by a single patient for up to 120 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; (c) any damage or contamination due to non-compliance with the applicable Instructions for Use (e.g., cleaning or disinfection instructions); or (d) any damage or contamination due to cigarette, pipe, cigar or other smoke or other abnormal environmental conditions. 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, INCLUD-ING ANY (A) WARRANTY OF MERCHANTABILITY; (B) WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE; OR (C) WARRANTY AGAINST IN-FRINGEMENT 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 FORESEE-ABLE, (B) WHETHER OR NOT CIRCUITLIFE WAS ADVISED OF THE POSSI-BILITY 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 REM-EDY OF ITS ESSENTIAL PURPOSE.

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