OWNER'S MANUAL

INSTRUCTIONS TO USE
CEREZEN

Legal Manufacturer:

Renew Group Private Limited
463 Macpherson Road
Singapore 368181
Tel: +65 6587 7383

EC Representative:

Renew Health Limited
IDA Business & Technology Park
Garrycastle, Dublin Road
Athlone, Co Westmeath, N37 F786
Ireland
Tel: 353 90 646 5460

CE 2797

TABLE OF CONTENTS

PREFACE

Purpose of this Manual

This manual provides instructions for the setup and the operation of Cerezen. Instructions are included in this manual for routine care and Operator maintenance.

Renew Group Private Limited recommends that Operators complete formal training before operating the Cerezen system. Consult the Training Manual for Cerezen for detailed training and treatment instruction.

This Owner's manual includes a summary of the technical procedures used to provide treatment with the Cerezen system.

Proprietary Information

Manual

The contents of this manual are the property of Renew Group Private Limited. Information contained in this manual may not be copied or reproduced (in part or in whole) without the expressed written permission of Renew Group Private Limited.

Software

All software used with the Cerezen system is copyright protected with all rights reserved. No part of the software may be copied, reproduced, or translated to any machine-usable form without the prior written consent of Renew Group Private Limited.

Definitions and Acronyms

The terms and acronyms used in this document are provided and defined as a reference for the Operator.

Terms and Acronyms	Descriptions
Adverse Event (AE)	A event that must be reported if it has led to one of the following outcomes: • A serious threat to public health; • Death of a patient, user, or other person; • Serious deterioration in state of health of patient, user, or other person; • No death or serious injury occurred but the event might lead to death or serious injury of a patient, user or other person if the event recurs.

Terms and Acronyms	Descriptions
artifact	Electrical interference, or noise, that is recorded from sources other than electronic signals of the heart.
arterial pressure wave	Patient's pulse.
baseline	Section of the ECG trace that displays on the PC as a straight line between the waveforms of the ECG pattern.
bladder	Flexible air chamber that fits into the cuff system that inflates and applies pressure to the patient's lower extremities.
BPM	Abbreviation for beats per minute.
CAD	Abbreviation for coronary artery disease.
catheterization	Process of inserting a tubular instrument into a body cavity to permit passage of fluid.
CHD	Abbreviation for coronary heart disease.
cuff system	Set of garments worn by the patient that houses air bladders that apply pressure to the large muscle mass of their lower extremities (calves, thighs, and buttocks).
diastole	Period when the heart refills with blood following systole.
elbow	Fitting installed between two lengths of tubing to allow a change of direction.
ECG (or EKG)	Abbreviation(s) for electrocardiogram.
ECP	Abbreviation for external counterpulsation.
external counterpulsation	Noninvasive treatment used to assist the heart by applying positive pressure to one or more of the body's limbs in synchrony with the heart cycle.

Terms and Acronyms	Descriptions
ferrite clamp	Device that clamps around a wire that conducts electricity to reduce the amount of interference (noise).
firmware	Software program or set of instructions programmed on a hardware device; provides the necessary instructions for how the device communicates with other computer hardware.
IEC 60601	Series of technical standards for the safety and effectiveness of medical electrical equipment published by the International Electrotechnical Commission (IEC)
LED	Abbreviation for light-emitting diode.
MHz	Abbreviation for megahertz.
mmHg	Abbreviation for millimeters of mercury.
ms	Abbreviation for millisecond(s).
Cerezen	Portable, self-contained enclosure that contains electric controls and mechanical components of the Cerezen system; includes patient treatment platform and PC.
Operator	Person administering ECP therapy with the Cerezen system.
patient	Person receiving ECP therapy with the Cerezen system.
platform, patient treatment	Part of the Cerezen unit where patient reclines, wrapped in cuff system, while receiving ECP therapy with the Cerezen system.
plethysmograph	Instrument that measures changes in volume within an organ or whole body (usually resulting from fluctuations in the amount of blood or air it contains); on the Cerezen, a plethysmograph is used to generate the Pulse waveform.
psi	Abbreviation for pounds per square inch.
pump	ECP system air compressor; it is housed in the Cerezen unit.
QRS complex	Part of ECG waveform that marks beginning of systole.

Terms and Acronyms	Descriptions
revascularization	Restoration by surgical means of blood flow to an organ or a tissue (as in bypass surgery).
R-wave	Part of QRS complex that represents first part of cardiac cycle.
system	Combination of Cerezen's air pump, electric controls, mechanical components, PC, cuff system, and treatment table.
systole	Time period when heart is contracting.
trace	Line displayed on PC that represents the cardiac signal, the inflation/deflation signal, and the pulse wave of the patient.

Warnings, Cautions, and Notes

These icons precede important information in the form of warnings, cautions, and notes:

Indicates a **WARNING**; requires immediate response by the Operator.

Indicates a **CAUTION**; requires prompt response by the Operator.

Indicates a **NOTE**; provides additional information to the Operator.

CHAPTER 1: INTRODUCTION

System Overview

The Cerezen system uses a microprocessor-controlled air pump to inflate and deflate three sets of inflatable air bladders housed within a cuff system that wrap around the patient's calves, thighs, and buttocks with hook-and-loop fasteners. Inflating these cuffs squeeze the calves, the thighs, and the buttocks and force blood to the heart during each heart beat cycle. Results are displayed on the user interface of the Cerezen system's PC through the use of Renew Group Private Limited proprietary software.

The Cerezen system includes a unit that consists of an air pump, electric controls, mechanical components, and an external PC. The patient (person receiving treatment) reclines upon the treatment platform while wrapped in the cuff system.

WARNING: The Cerezen system is authorized only for use as an external counterpulsation treatment. Unauthorized use may cause injury.

Specifications

Physical Dimensions of Cerezen Unit

Dimensions of the Cerezen unit when it is ready for use is:

- 76 inches (approximately 193.04 cm) in length
- 28.25 inches (approximately 71.76 cm) in width
- 36.5 inches (approximately 92.71 cm) in height

The Cerezen unit has wheels for easy transport and it folds for compact storage. Dimensions of the unit when it is folded and ready for transport and/or storage is:

- 37.5 inches (approximately 95.25 cm) in depth
- 28.25 inches (approximately 71.76 cm) in width
- 38.0 inches (approximately 96.52 cm) in height

The PC

The laptop PC has a 15.6-inch video monitor with 1920 × 1080 resolution that is integrated with an Intel® processor and loaded with Windows 10 operating system.

System Weight
225 lbs (102 kg)

Pressure Setting
0 to 8 psi

Treatment Duration
10 to 60 minutes (5-minute increments)

Allowable Heart Rate Treatment Range
36 to 124 minutes BPM (beats per minute)

Rated Power
100-240V
14A
1400 Watts

Safety
Emergency stop switch

System Protection
15A circuit breaker

Plethysmograph
Finger or ear style

Weight Capacity
The Cerezen unit has a maximum patient weight limit of 135 kg (297 pounds).

WARNING: Never exceed the recommended weight capacity of 135 kg (297 pounds) on unit as this may cause injury to the Operator and/or patient or damage to the equipment.

The PC mount has a weight limit of 2.3 kg (5 pounds).

WARNING: Do not place anything weighing more than 2.3 kg (5 pounds) on monitor mount as this may cause injury to the Operator and/or patient or damage to the equipment.

Height Capacity
The Cerezen unit has a maximum patient height limit of 188 cm (approximately 74 inches).

Power Supply
The Cerezen system requires clean, preferably hospital-grade, power. Voltage spikes or

surges may cause instabilities of the PC display.

NOTE: If clean power is not available, an external power conditioner may be useful.

WARNING: Do not operate the Cerezen in the vicinity of electrosurgery equipment as this may cause injury to the Operator and/or patient or damage to the equipment.

The Cerezen system must be connected to a 3-wire electrical outlet providing 100V-240V at 50/60Hz with a power rating of 1400 watts.

CAUTION: Refer all service maintenance to certified Renew Group Private Limited service personnel to avoid electrical hazard and damage to the Cerezen system.

Environmental Conditions

The Cerezen system requires specific environmental conditions for its use, transport, and storage in order to maintain the integrity of its components.

Normal Use

The Cerezen system is for use indoors only within the following range of environmental conditions:

- Maximum operating temperature: +30°C (+86°F).

WARNING: Use of the Cerezen system at temperatures greater than +30°C (+86°F) could create risk of burn.

- Maximum altitude: 3,000 meters (9,842 feet).

NOTE: Performance of the Cerezen system may be reduced under conditions of high altitude or high temperature or both.

- Humidity: 30 to 70% RH (non-condensing).
- Barometric pressure: +100 to +80 kPa (equivalent to 0 to +1,981 meters elevation).

For optimum comfort, the system must be operated in a well-ventilated, temperature-controlled environment that is approximately +20 to +25°C (about +68 to +77°F).

Transport and Storage

The Cerezen system is transported only under the following environmental conditions:

- Temperature: –15 to +50°C (about +5 to +122°F).
- Maximum altitude: 3,000 meters (about 9,842 feet).
- Humidity: 10 to 95% RH (non-condensing).
- Barometric pressure: +105 to +45 kPa (equivalent to –305 to +6,096 meters elevation).

Safety Features

Safety features have been incorporated into the Cerezen system to ensure safe operation and to prevent adverse patient events.

Electrical and Mechanical

All of the Cerezen system's control electronics are contained within the Cerezen unit. The proprietary user-interface software runs on a PC that is placed on a Control Console that is connected to the Cerezen unit with a mounting arm.

The mechanical features of the Cerezen system are also located within the Cerezen unit.

CAUTION: Do not place liquids on any part of the Cerezen system.

Safety features include:

- Factory-set pressure relief valve to prevent patient exposure to excessive cuff pressures.
- Mains power control switch.
- Operator and patient access to **Emergency Stop**.
- Automatic deflation of cuffs when power loss or system shutdown occurs.
- Electrical isolation circuitry for the protection of Operator and patient.
- Non-inflation of cuffs if pump is activated before the ECG signal is present and deflation valves are turned on.
- No activation of pump unless system software and PC are operating.

Software

Features include:

- System sounds an informational signal and suspends inflation/deflation triggering if heart rate exceeds the normal range of operation (less than 35 or greater than 125 BPM).
- System sounds an informational and suspends inflation/deflation triggering when an external ECG signal is not available or reliable.
- System software sounds an informational signal and stops the air pump if the PC is unable to display data.

Standards

- IEC 60601-1 :2005 + CORR. 1:2006 + CORR. 2:2007 + AMD1:2012 + AMD2:2020 (Ed. 3.2) Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance
- CSA C22.2#60601-1:2014 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- AAMI ES60601-1:2005+A1 +A2 Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-6:2010 +A1+A2 Medical Electrical Equipment – Part 1-6: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Usability
- IEC 60601-1-2:2014+ AMD 1:2020 / KN 60601-1-2:2016 Class A for Emissions, Immunity for Professional Healthcare Facility

TEST STANDARD	TEST
IEC 60601-1-2	Radiated Emissions
IEC 60601-1-2	Conducted Emissions
IEC 60601-1-2	Harmonic Current Emissions
IEC 60601-1-2	Electrostatic Discharge Immunity
IEC 60601-1-2	Radiated RF Electromagnetic Fields Immunity
IEC 60601-1-2, 8.10	Immunity to proximity fields from RF wireless communications equipment
IEC 60601-1-2	Electrical Fast Transients and Burst Immunity
IEC 60601-1-2	Surges Immunity
IEC 60601-1-2 / KN 61000-4-6	Conducted Disturbances, Induced by RF Fields Immunity
IEC 60601-1-2	Power Frequency Magnetic Fields Immunity
IEC 60601-1-2	Voltage Dips Immunity
IEC 60601-1-2	Voltage Interruptions Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Cerezen is intended for use in the electromagnetic environment specified below. The customer or the user of the Cerezen should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms (ISM) 80% AM at 1kHz	3 V, 6V	Portable and mobile RF communications equipment should be used no closer to any part of the Cerezen, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7GHz 80% AM at 1kHz	3 V/m	$d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Cerezen is used exceeds the applicable RF compliance level above, the Cerezen should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Cerezen.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Cerezen

The Cerezen is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Cerezen can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cerezen as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Cerezen is intended for use in the electromagnetic environment specified below. The customer or the user of the Cerezen should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The Cerezen uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Cerezen is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	
Radiated RF Electromagnetic Fields IEC 61000-4-3	80 MHz to 1000 MHz 1.0 GHz to 2.7 GHz 3V/m @ 2.5m 4 sides of EUT AM: 80% Sinusoidal 1000Hz 1% with 3 sec dewll time Horizontal, vertical Equipment Verification	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Cerezen is intended for use in the electromagnetic environment specified below. The customer or the user of the Cerezen should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ±4 kV, ± 8 kV, ±15 kV air	± 8 kV contact ± 2 kV, ±4 kV, ± 8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	380-390 MHz, 27 V/m 430-470 MHz, 28V/m 704-787MHz, 9V/m 800-960 MHz, 28 V/m 1700-1990 MHz, 28V/m 2400-2570MHz28V/m 5100-5800MHz, 9V/m 10 sec frequency step dwell time 2.5m	380-390 MHz, 27 V/m 430-470 MHz, 28V/m 704-787MHz, 9V/m 800-960 MHz, 28 V/m 1700-1990 MHz, 28V/m 2400-2570MHz28V/m 5100-5800MHz, 9V/m 10 sec frequency step dwell time 2.5m	Keep separation as large as possible.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0,5 kV, ±1 kV line(s) to line(s) ± 0,5 kV, ±1 kV, ± 2 kV line(s) to earth	±0,5 kV, ±1 kV line(s) to line(s) ± 0,5 kV, ±1 kV, ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Conducted Disturbances, Induced by RF Fields Immunity IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % *U*T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0° 0 % *U*T; 250/300 cycle	0 % *U*T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0° 0 % *U*T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cerezen requires continued operation during power mains interruptions, it is recommended that the Cerezen be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE	*U*T is the a.c. mains voltage prior to application of the test level.		

Notes

The Cerezen system requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the User's Manual.

WARNING: The use of accessories and cables other than those specified by Renew Group Private Limited may result in an ineffective treatment and/or interference with other equipment.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Cerezen, including cables specified by the manufacturer. Otherwise, degredation of the performance of this equipment could result.

WARNING: The Cerezen system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is unavoidable, the Cerezen system should be observed to verify normal operation in the configuration in which it will be used.

The Cerezen is designed to deflate all air bladders deflate automatically when:

1. A timed treatment ends
2. The Emergency Stop Button is activated
3. Disconnection from, or loss of mains power

WARNING: Failure to assure the electromagnetic environment specified could lead to system malfunction and loss of the safety features listed above. This could lead to patient discomfort, and limb ischemia.

NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Intended Use

Cerezen is intended for use as a component in the overall management of symptoms of cognitive and/or functional impairment experienced by patients with mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease. It is intended for use under the oversight of a healthcare professional.

Indication for Use

Cerezen is indicated for the treatment of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease.

Intended Patient Population

Cerezen is intended for use in adults suffering from mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease.

Operator Training

Cerezen is intended for use by an Operator who:

- Has successfully completed the manufacturer's training course
- Is, or is working under the oversite of, a registered nurse (RN); a cardiovascular technician (CVT),physician (MD or DO) or a licensed practical nurse (LPN)
- Has electrocardiograph (ECG) interpretation skills
- Has basic life support (BLS) training and card.

Contraindications

The Cerezen system is contraindicated in the treatment of patients who have a history of the following:

- Surgery in the six weeks before ECP session.
- Cardiac catheterization within one to two weeks before ECP treatment.
- Arrhythmia that could interfere with ECP inflation and deflation triggering.
- Dual-chamber pacemaker (atrial component may interfere with ECP inflation timing sequence).

- Aortic insufficiency (regurgitation can prevent diastolic augmentation).
- Severe pulmonary disease.
- Limiting peripheral vascular disease involving the ileofemoral arteries.
- Current or past blood clot, venous thrombosis or thromboembolism.
- Severe hypertension (≥ 180 mmHg systolic or ≥ 110 mmHg diastolic).
- Bleeding disorder.
- Anti-coagulation therapy with INR > 1.5.
- Heart rates < 35 or >125 beats per minute (BPM) at the time of treatment.
- Presence of infection, open wound, burn or fracture of the legs or pelvis.
- Presence of aneurysm (aortic, cerebral or other).
- Pregnancy.
- Anyone with active, or history of, cerebral hemorrhage including subdural & subarachnoid or cerebral aneurysm
- Presence of a burn, open wound or bone fracture on any limb subject to ECP treatment.

CAUTION: The Cerezen system is not intended for use as an ECG monitor or for diagnostic purposes.

NOTE: Operator must ensure patient has been checked for contraindications prior to use.

Possible Risks

In appropriate patients, ECP is a low-risk procedure with minimal side effects. The most common side effect is skin irritation. This includes chafing, bruising, or skin breakdown related to the compression or friction of the cuff system. Operators can adjust the cuffs and provide padding to reduce any skin irritation the patient may experience.

Other possible side effects include mild headaches or dizziness, muscle aches, and fatigue. Such symptoms are normally resolved within the first two weeks of treatment.

WARNING: If symptoms of side effects persist, **IMMEDIATELY** consult the healthcare professional in charge before resuming ECP treatment.

Precautions

1. United States Federal Law restricts this medical device to sale by or on order of a licensed healthcare professional.

2. The Cerezen system should only be operated under the direct supervision of a licensed healthcare professional by personnel who have completed the requisite training and certification in the use of the Cerezen system.

3. Technicians must be thoroughly familiar with the system's controls, safety features, and functions detailed in this manual. Consult the *Training Manual for the Renew® Cerezen External Counterpulsation System* for detailed training and treatment instruction. Training must be successfully completed prior to use of the device on patients.

4. The Cerezen unit must be connected to a properly grounded electrical outlet for safe operation.

5. With the exception of a few specified minor routine maintenance procedures contained in the manual, the Cerezen system is not user-serviceable. To avoid electrical hazard or damage to the system or danger to Operator or patient, refer all service maintenance to certified Renew Group Private Limited service personnel.

6. Do not use the Cerezen system in the presence of flammable anesthetics or in an oxygen-rich environment (such as ICU, CCU, ER, or surgical operating suite).

7. Do not use the Cerezen system in close proximity to strong magnetic fields (such as found near an MRI).

8. Do not connect any other informational signal source to the electrocardiogram cable or the patient's plethysmograph sensor without first consulting Renew Group Private Limited.

9. No part of this medical device requires sterilization. Do not autoclave or immerse any component of this system in fluids.

10. Do not perform treatment if the system fails to initialize properly.

11. Do not connect the PC to the Internet or to any other network (such as LAN, WAN, etc.). No connections are to be made to the Ethernet (RJ-45) connector on the PC.

12. Do not touch contacts of electrical or data connectors on the Cerezen unit.

IT-Network Risk

Do not connect the Cerezen system to an IT-network. Connection of the Cerezen system to an IT-network that includes other equipment could result in previously unidentified risks to patients, Operators, or third parties. The responsible organization should identify, analyze, evaluate, and control these risks.

NOTE: IEC 80001-1:2010 provides guidance for the responsible organization to address these risks.

Electromagnetic Disturbance

The Cerezen system is compliant with the requirements of IEC 60601-1-2 Medical electrical equipment – Parts 1–2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

In some conditions of electromagnetic disturbance, the pulse (plethysmograph) waveform on the computer display may be corrupted. This waveform is provided for informational purposes only and this condition does not affect the treatment. *These artifacts do not affect the timing or pressure of cuff inflation.*

Adverse Event Reporting

Any serious incident or adverse event that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

To report any adverse event to Renew Group Private Limited contact:

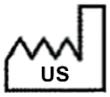
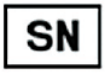
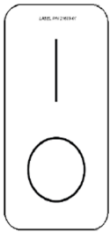
	Telephone Number	E-mail Address
Europe	353 90 646 5460	info@renewgroup.eu

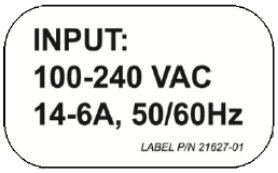
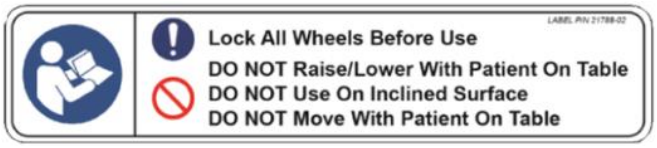
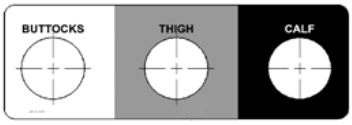
Upon receipt of an **Adverse Event Report**, Renew Group Private Limited will investigate to determine whether the episode requires an MDR Reportable Event.

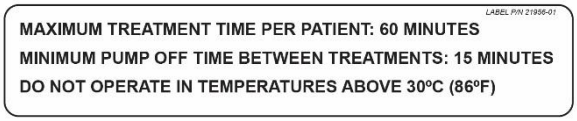
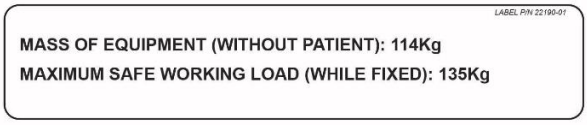
Symbols

These symbols apply to the Cerezen system and appear on the back and top of the device:

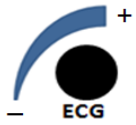
SYMBOL	MEANING
	Manufacturer
	Date of manufacture
	Country of manufacturer

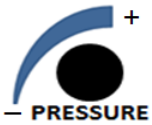
SYMBOL	MEANING
	Date of manufacture
	Country of manufacturer
	Catalog (model) number
	Serial number
	Consult accompanying documents before use
	Intertek ETL Listed; this device complies with the requirements of IEC 60601-1 Standard, Edition 3.2 and IEC 60601-1-2 Standard, Edition 4.1
	Conformity marking for certain products sold within the European Economic Area
	On/Off
	Caution; consult accompanying documents
	EU Representative

SYMBOL	MEANING
	Emergency stop indicator
	Power
	Input/output
	Monitor mount safety
	Platform safety
	Hose connections
	Serial number

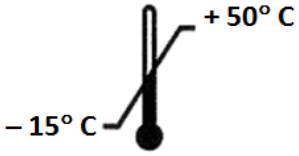
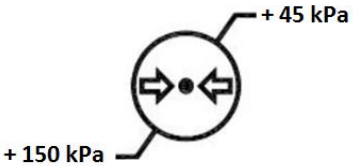
SYMBOL	MEANING
	Product
	Operation time and temperature
	Maximum Allowable Weight

These symbols appear on the Cerezen control console:

SYMBOL	MEANING
	ECG Gain knob
	Pulse Gain knob
	Inflation Time Decrease button
	Inflation Time Increase button
	Deflation Time Increase button

SYMBOL	MEANING
	Deflation Time Decrease button
	Calf Inflation Valve Control button
	Thigh Inflation Valve Control button
	Buttocks Inflation Valve Control button
	Deflation Valve Control button
	Pressure knob
	Start Pump/Stop Pump button
	ECG button
	Reset button
	Duration (length) of time button

These symbols apply to the shipment of the Cerezen system and appear on its packaging:

SYMBOL	MEANING
	Handle with care
	This end up
	Fragile
	Keep out of the rain; do not store in damp conditions
	Do not stack
	Indicates temperature range within which package must be stored and handled
	Indicates atmospheric pressure limitation range within which package must be stored and handled
	Indicates humidity range within which package must be stored and handled

CHAPTER 2: DELIVERY AND SETUP

Contents of Delivery

The Cerezen system arrives as a single shipment. The shipment consists of:

- Cerezen unit
- Laptop PC
- Accessories (cables, hoses, and supplies)

Refer to **Appendix A** for the packing list.

WARNING: No modification of this equipment is allowed as this may cause injury to the Operator and/or patient or damage to the equipment.

Purchase of the Cerezen system includes factory installation and setup.

Before the technician departs from the installation site, or when a service technician visits, the technician completes a checklist. A signature of confirmation is required from the site manager. Refer to this checklist periodically to check the condition of the Cerezen system.

Cerezen System

The Cerezen system consists of a laptop PC and the Cerezen unit, which houses its air pump, electric controls, and mechanical components. The unit is also the patient treatment platform.

WARNING: Do not use other manufacturers' components as this may cause injury to the Operator and/or patient or damage to the equipment.

Cerezen Electronics and Mechanical Features

The Cerezen system has a microprocessor-controlled air pump contained within the Cerezen unit. The pump inflates and deflates three pairs of bladders enclosed within three types of cuffs – calf, thigh, and buttocks. The patient has access to a call button that connects to the system to alert the Operator if a problem is perceived to have occurred.

The microprocessor's primary functions are to:

- Serve as an R-wave detector;
- Calculate the R-wave rate (heart rate); and
- Deliver triggering signals to engage the valves.

This allows the cuffs to be filled with air from the air pump and then emptied.

All of the Cerezen system electronics are contained within the Cerezen unit. The mechanical features are also located within the Cerezen unit.

The manifold, located at the foot of the Cerezen unit, allows three air hoses to pass through and to connect directly to the air pump.

Internal mechanical components include:

- Air pump
- Pressure tank
- Valve module (with inflation/deflation valves/cuff pressure safety valves)
- Air distribution system

Internal electrical component include:

- ECG and Plethysmograph signal processing circuitry
- Microprocessor

There are no user-serviceable components within the Cerezen unit.

CAUTION: Unauthorized access within the Cerezen unit may invalidate your warranty. Refer all service requirements to local sales representative.

Cerezen Unit

The Cerezen unit that houses the air pump, electric controls, and mechanical components is designed for the patient's comfort as they receive treatment.

Treatment Platform

The treatment platform has a water- repellent and washable covering. It is cushioned with two to four inches of special foam padding for the patient's comfort and stability during treatment.

WARNING: Casters must be locked before use as this may cause injury.

WARNING: Do not stand on treatment platform or injury may occur.

WARNING: Do not raise or lower treatment platform with patient on it as this may cause injury to the Operator and/or patient or damage to the equipment.

WARNING: Do not move treatment platform with patient on it as this may cause injury to the Operator and/or patient or damage to the equipment.

Cooling Air Exhaust

A vent that exhausts warm air is located at the foot of the Cerezen unit.

***NOTE*:** Exhaust air may be as warm as +32°C (+90°F). This is normal.

The PC

The PC provides continuous real-time treatment information for:

- Heart rate
- Inflation and deflation timing
- Treatment Duration

WARNING: Do not connect any PC other than the one provided with the Cerezen system as this may cause injury to the Operator and/or patient or damage to the equipment.

There are two ports for use with the laptop PC: the power connector (refer to Figure 2-1, item 1) and a USB port (refer to Figure 2-1, item 2) that provides signals from the Cerezen unit to the laptop PC. Additional ports are not authorized for use.

Figure 2-1. Usable ports.

WARNING: Do not use any devices and/or components with the Cerezen system other than those authorized by Renew Group Private Limited as this may cause injury to the Operator and/or patient or damage to the equipment.

Control Console

The laptop PC is mounted on the Control Console that is attached to the Cerezen unit.

The Control Console can be rotated to be alongside the unit so as to always be easily accessible to the Operator.

The Control Console is designed to hold only the PC (refer to Figure 2-2). The Control Console has a weight limit of 2.3 kg (5 lbs).

WARNING: Never sit on the Control Console as this could cause the Cerezen to over-balance posing an injury risk to the patient and/or the Operator.

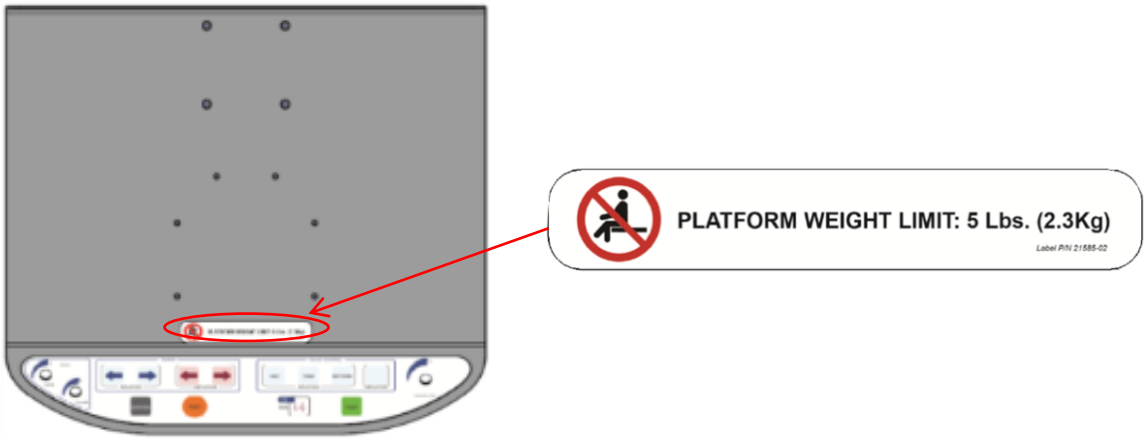


Figure 2-2. No Sitting label.

WARNING: Do not place liquids on the Control Console as this may cause injury to the Operator and/or patient or damage to the equipment.

Treatment Room

NOTE: Complete the preparation of the treatment room before delivery of the Cerezen system.

The Cerezen system operates in a typical office environment. There are no set dimensions for a treatment room as long as there is enough room for the patient and Operator to move freely around the Cerezen unit and PC and into their treatment positions.

CAUTION: The Cerezen system is intended for indoor use only.

- The patient requires space to settle onto the treatment table.
- The Operator must have access to both the left and the right sides of the patient.
- The patient must have access to the **Emergency Stop**, which is located on the right-side of the Cerezen unit.
- The access door to the treatment room must be a minimum of 30 inches (76 cm) in width to allow the system to roll through it.
- A carpeted floor to reduce any noise produced by the system during operation.
- A well-ventilated, temperature-controlled room for the patient's comfort since the air that inflates the cuff system is typically warmer than the ambient temperature.

Other environmental considerations are:

- An area free of electromagnetic interference in the area (such as an MRI device).
- An area free of flammable gases and liquids, including anesthetics.

NOTE: Although the Cerezen system is not certified for use in an oxygen-rich environment, patients who need supplemental oxygen (for example, O_2 by mask or nasal cannula) may use it during treatment.

Room configuration calls for:

- A 3-wire electrical outlet providing 100V-240V at 50/60Hz with a power rating of 1400 watts. The Cerezen unit is labeled as to voltage required.
- The Cerezen system must be located a sufficient distance from a wall so that the cooling air intake and exhaust are clear of obstructions.

CAUTION: Do not block air intake.

- Operator's side of the Cerezen unit must allow sufficient space, a minimum of 29 inches (approximately 74 cm), for the Operator's access to the unit's controls and to assist patient.

WARNING: No other equipment or devices are to be positioned within arm's reach, approximately one meter (about 36 inches), of the patient while on the treatment table as this may cause injury to the Operator and/or patient or damage to the equipment.

Cerezen Assembly

The Cerezen unit consists of a patient treatment platform with two folding cushioned leaves, one on the head side (refer to Figure 2-3, item 5) of the unit and one on the foot side (refer to Figure 2-3, item 3) of the unit and a mount (refer to Figure 2-3, item 2) that supports the system's Control Console (refer to Figure 2-3, item 1). The unit has four casters that allow it to be moved for easy transport and during use and storage.

Figure 2-3. The Cerezen unit.

WARNING: Do not operate the Cerezen in the vicinity of electrosurgery equipment as this may cause injury to the Operator and/or patient or damage to the equipment.

WARNING: Do not set up patient treatment platform on inclined surface as this may cause injury to the Operator and/or patient or damage to the equipment.

Lifting Points

The Cerezen unit should only be lifted in the folded configuration. Lifting points are located at the bottom-left and bottom-right edges (refer to Figure 2-3, item 4).

Setting Up the Treatment Platform

1. Roll Cerezen unit into treatment location.

WARNING: Do not set up patient treatment platform on inclined surface as this may cause injury to the Operator and/or patient or damage to the equipment.

2. Secure casters pressing locks with foot. At least two of the unit's four casters must be secured to prevent the unit from rolling out of place.

WARNING: Casters must be locked *before* patient gets on the treatment platform as this may cause injury to the Operator and/or patient or damage to the equipment.

3. Rotate Control Console arm (refer to Figure 2-4) out so Control Console is alongside the unit and within easy access of the Operator.

Position Control Console mount so it does not interfere with patient access to/from the treatment platform (refer to Figure 2-4.).

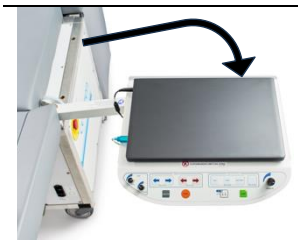


Figure 2-4. Control Console arm.

WARNING: Do not place liquids on the Control Console as this may cause injury to the Operator and/or patient or damage to the equipment.

4. Remove arm cushion (refer to Figure 2-5, item 1) and head cushion (refer to Figure 2-5, item 2) from storage positions

Figure 2-5. Arm and head cushions.

5. Insert rods at bottom of arm cushion (refer to Figure 2-6) into holes on right hand side of unit.

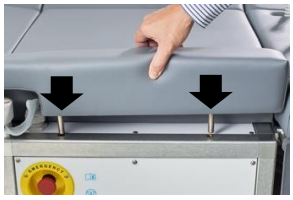


Figure 2-6. Arm cushion placement.

6. Pull downward on black locking pin (refer to Figure 2-7) at foot of bed and swing foot cushion upwards.

Figure 2-7. Locking pin.

7. Continue pulling on locking pin (refer to Figure 2-8) to remove leg from clamp.

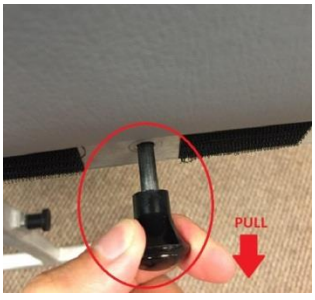


Figure 2-8. Pull locking pin.

8. Pivot leg outward (refer to Figure 2-9) and pull it down toward floor into a vertical position (refer to Figure 2-10).

Figure 2-9. Pivot leg.

Figure 2-10. Pull leg down.

CAUTION: Leg is spring loaded and once unlocked will swing free.

Lengthen leg by pulling until there is an audible click. Verify leg is in correct position supporting the head of the treatment platform. Leg will be perpendicular to floor.

9. Pull downward on black locking pin at head of bed and swing head cushion upwards.

10. Continue pulling on locking pin to remove leg from clamp. Pivot leg outward and pull it down toward floor. Verify leg is locked and perpendicular to floor.

    Pull leg until there is an audible click. Verify leg is in correct position supporting the head of the treatment platform. Leg will be perpendicular to floor

11. Insert head cushion (refer to Figure 2-11) into place at top edge of head leaf.

Figure 2-11. Head cushion placement.

12. Verify USB cable is securely inserted into laptop PC (refer to Figure 2-12).

Figure 2-12. USB cable inserted.

13. Connect power cord into unit pin (refer to Figure 2-13) and plug into electrical outlet.

Figure 2-13. Connect power cord.

Cables

The Cerezen system's cables connect the patient to the Cerezen system and provide display on the PC of the:

- ECG signal
- Inflation/deflation signal
- Pulse wave

A USB cable is attached to the Cerezen unit. This must be manually connected to the PC. Insert the cable into the **USB** port on left-hand side of PC.

The remaining cables are inserted into the system at the head side of the Cerezen unit in their appropriate connectors.

- Insert ECG cable into **ECG** input connector (refer to Figure 2-14, item 1). The ECG cable has a keyed connector and can only be installed into ECG port.
- Insert Pulse cable into **Pulse** input connector (refer to Figure 2-14, item 2). The Pulse cable has keyed connector and can only be installed into **Pulse** port.

Figure 2-14. Cable

- Insert call button cable into **Call Button** connector (refer to Figure 2-14, item 3). patient call button cable is jack-style connector and can only be installed into **Call Button** port.

WARNING: Do not touch the pins on the connectors and patient simultaneously as this may cause injury to the Operator and/or patient or damage to the equipment.

WARNING: Do not allow the conductive parts of the patient cable, or electrodes, to come into contact with other conductive parts, including earth ground as this may cause injury to the Operator and/or patient or damage to the equipment.

CAUTION: Be careful to arrange all cables so they do not present a tripping or entanglement risk to Operator, patient, or passers-by.

Hoses

The hoses on the Cerezen system deliver air from the air pump, housed within the unit, to the bladders in the cuffs. The connectors are inserted into the foot of the Cerezen unit. They are color-coded and keyed to ensure the correct hose is attached to the correct cuff and to the correct connector.

CAUTION: Disconnect air hoses before moving the patient treatment platform.

- Press release button on white **Buttocks** hose coupling and insert hose into white connector (refer to Figure 2-15, item 1).
- Press release button on gray **Thigh** hose coupling and insert hose into gray connector (refer to Figure 2-15, item 2).

Figure 2-15 .Hose connectors.

- Press release button on black **Calf** hose coupling and insert hose into black connector (refer to Figure 2-15, item 3).

Thread the hoses through the openings of treatment platform's foot cushion:

- The **Buttocks** hoses (white connectors) are threaded through the outermost openings in cushion (refer to Figure 2-16, item 1).
- The **Thigh** hose (gray connectors) is threaded through the opening center opening in cushion (refer to Figure 2-16, item 2).
- The **Calf** hoses (black connectors) are threaded through the lower opening in cushion (refer to Figure 2-16, item 3).

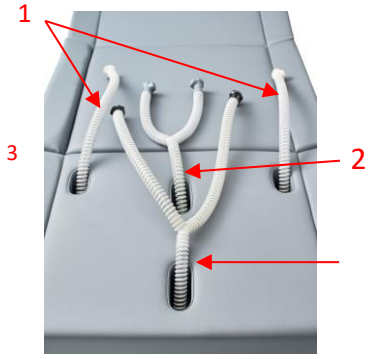


Figure 2-16. Hose connectors.

Power Connection

One 10-foot, heavy-duty power cord is included with the delivery of the Cerezen system. The power cord inserts into the power inlet on the head of the Cerezen unit (refer to Figure 2-17).

Figure 2-17. Power connector.

This power cord is then connected to a 3-wire electrical outlet providing 100V-240V at 50/60Hz with a power rating of 1400 watts.

CAUTION: Only peripherals that are compliant with IEC 60601 are allowed for use with the Cerezen system.

Skirt Panels

After the treatment platform has been assembled, attach the skirt panel set. Skirt panels consist of four water-repellent and washable textile lengths that are secured to the unit with hook-and-loop fasteners.

The four pieces of the skirt panel set are:

- Two caster panels (refer to Figure 2-18) measuring approximately 19 cm by 68 cm (7.5 inches by 27 inches).

Figure 2-18 Caster panels.

- One foot panel (refer to Figure 2-19), identifiable by its one notch and rectangular shape; measuring approximately 63.5 cm by 167.5 cm (25 inches by 66 inches).

Figure 2-19. Foot panel.

- One head panel (refer to Figure 2-20), identifiable by its two notches and curved edge; its two end panels measuring approximately 66 cm by 168 cm (25 inches by 66 inches) and its center panel measuring approximately 71 cm by 169 cm (28 inches by 66.5 inches).

Figure 2-20. Head panel.

Attach the skirt panel set:

1. Secure hook-and-loop fastener on edges of caster panel to hook-and-loop fasteners located along bottom edges of unit that face the head and foot.

   The caster panels are attached to the bottom of the unit (refer to Figure 2-21). These panels are attached before other panels are secured.

Figure 2-21. Caster panel attached.

NOTE: It does not matter which one of the caster-covering panels is secured first.

2. Secure hook-and-loop fastener on edge of foot panel to hook-and-loop fastener found along the top and bottom edges of the unit beneath cushioned leaf (refer to Figure 2-22).

Figure 2-22. Foot panel attached.

3. Secure hook-and-loop fastener on edge of head panel to hook-and-loop fastener found along the top and bottom edges of the unit beneath cushioned leaf (refer to Figure 2-23).

Figure 2-23. Head panel attached.

NOTE: Make sure panels are secured as cited.

CAUTION: Be certain that hoses or cables to not protrude from under the skirts so as to present a tripping or entanglement risk.

Installation

Consult the accompanying documents to verify the Cerezen system is installed correctly.

CHAPTER 3: CONTROLS

Cerezen System Controls

The Operator controls the Cerezen system using buttons and knobs located on the Control Console.

The user interface uses a proprietary software program that displays data on the PC generated by electronic circuits housed within the Cerezen unit.

WARNING: Do not use other manufacturers' components as this may cause injury to the Operator and/or patient or damage to the equipment.

Features of Control Console and Firmware

The Control Console and firmware have the following control features:

- Automatic firmware detection of the QRS complex and the R-wave.
- Three-stage sequential counterpulsation.
- Detection of high (> 125 BPM) heart rate or low (< 35 BPM) heart rate.
  - Audible and visual notification for low heart rate:
    The PC displays a flashing LOW HEART RATE message.
  - Audible and visual notification for high heart rate:
    The PC displays a flashing HIGH HEART RATE message.

  When either occurs, the actual heart rate is displayed and inflation/deflation is suspended.
- Cuff pressure control knob.
- Positive cuff inflation up to an indicated pressure of 6.0 psi.

WARNING: Do not set treatment pressure above 6.0 psi as this may cause injury to the Operator and/or patient or damage to the equipment.

- Automatic inflate/deflate start time setting ensuring that counterpulsation occurs only during diastole.

  Buttons for manual fine-adjustment of the Inflation and Deflation times.
- Simulated ECG (internal triggering wave) with five test settings: 30, 60, 80, 100, and 125 BPM.

Simulated ECG automatically returns to 80 BPM upon power-up or system reset.

- Eleven preset Treatment Duration options: 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, and 60 minutes.

  Treatment automatically stops at completion of chosen Treatment Duration.

NOTE: Treatment Duration automatically defaults to 60 minutes at power up or reset.

- Software options provide ability to review treatment data or individual ECG events that occurred during treatment or previous treatment sessions.
- Maximum power consumption is 1400 watts (nominal).

Graphical Display

The interface has a graphical display on the PC with continuously updated ECG display (refer to Figure 3-1, item 1), as well as superimposable graphical display of pressure cuff inflation and deflation (refer to Figure 3-1, item 2). The PC also displays the blood pressure (Pulse) waveform (refer to Figure 3-1, item 3). The system permits the Operator to enter the patient's demographic information and allows the Operator to set and adjust the inflation pressure and the timing of cuff inflation and deflation relative to the patient's ECG (Inflation Time and Deflation Time).

Figure 3-1. Synchronous display (On-screen data is for illustration only.)

The PC provides continuous real-time treatment information for:

- Heart rate
- Inflation Time and Deflation Time
- Treatment Duration
- Treatment pressure (psi)
- Diastolic to systolic Peak to Peak (P/P) ratio

Control Console

Buttons and knobs on the Control Console control the function of the Cerezen and adjust the data displayed on the user interface PC. Many buttons on the Control Console are illuminated when activated.

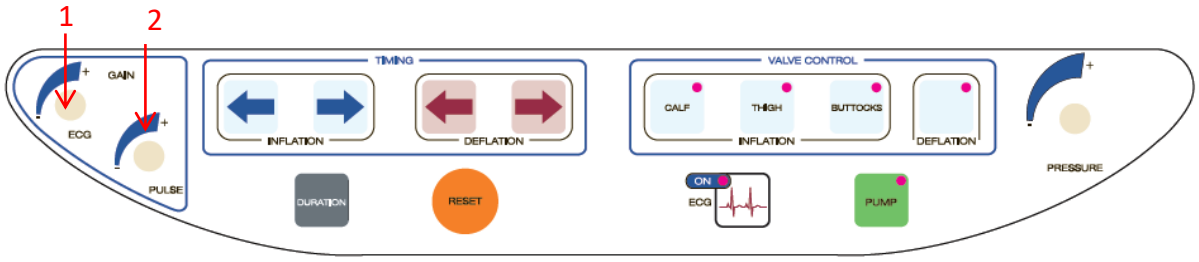
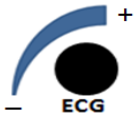


Figure 3-2. Control Console.

ECG GAIN KNOB

This knob (refer to Figure 3-2, item 1) adjusts the amplitude (size) of the **ECG** signal that the system displays on the PC. The size of the on-screen ECG display can be adjusted from the PC keyboard by pressing F1, then the, <+>, <–> keys.



- If the ECG signal is too large or too small, it may interfere with the machine's ability to identify the patient's reference R-wave.

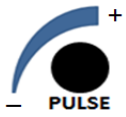
  Rotate the knob to the left to decrease gain.

- If the ECG signal is too small, it also may be more susceptible to an artifact interfering with the machine's ability to identify the patient's R-wave.

  Rotate the knob to the right to increase gain.

PULSE GAIN KNOB

This knob (refer to Figure 3-2, item 2) adjusts the amplitude of the **Pulse** signal that the system displays on the PC. The size of the on-screen Pulse display can be adjusted from the PC keyboard by pressing F3, then the <+>, <–> keys.



An amplitude signal that is too large may cause the appearance of abnormal waveforms (such as flat peak or flat bottom).

- Rotate the knob to the right to increase gain.
- Rotate the knob to the left to decrease gain.

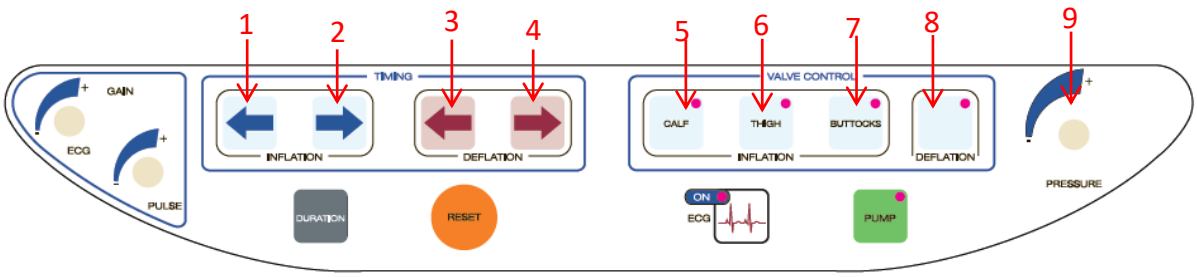


Figure 3-3. Control Console.

INFLATION TIMING ← and →

These buttons are used to finely adjust inflation time with respect to the reference ECG R-wave.

The time (in milliseconds) from the R-wave to the beginning of inflation is called the Inflation Start Time. This value is displayed on the PC.

- Press **Inflation ←** (refer to Figure 3-3, item 1) button to move the Inflation Start Time to the left on the screen, i.e., closer to the reference R-wave (earlier).

- Press **Inflation →** (refer to Figure 3-3, item 2) button to move the Inflation Start Time to the right on the screen, i.e., away from the reference R-wave (later).

To make timing adjustments, press the appropriate button and release immediately. This action results in a 10 millisecond (ms) change. If the button is pressed and held for longer periods, the adjustment continues until the button is released or until the system reaches its limit.

If an attempt is made to set the Inflation Start Time earlier than the default minimum, or later than the default maximum, the unit will re-adjust to the limit.

DEFLATION TIMING ← and →

These buttons are used to finely adjust Deflation Start Time with respect to the reference ECG R-wave.

The time (in milliseconds) from the R-wave to the beginning of deflation is called the Deflation Start Time. This value is displayed on the PC.

- Press **Deflation ←** (refer to Figure 3-3, item3) button to move Deflation Start Time to the left on the screen, i.e., closer to the reference R-wave (earlier).

- Press **Deflation →** (refer to Figure 3-3, item 4) button to move Deflation Start Time to the right on the screen, i.e., away from the reference R-wave (later).

VALVE CONTROLS

These buttons control the **Inflation** and **Deflation** valves. Operator may use this feature to selectively activate or deactivate cuffs that are wrapped about the patient.

There are three **Inflation** valves labeled: **Calves**, **Thighs**, and **Buttocks**.

- Press **Calf** (refer to Figure 3-3, item 5) button to activate the cuffs wrapped around the patient's *calves*.

- Press **Thigh** (refer to Figure 3-3, item 6) button to activate the cuffs wrapped around the patient's *thighs*.

- Press **Buttocks** (refer to Figure 3-3, item 7) button to activate the cuffs wrapped around the patient's *buttocks*.

NOTE: Flashing lights on the three inflation control switches indicate the sequence of valve activation.

- Press **Deflation** (refer to Figure 3-3, item 8) button to activate all the deflation valves at once, causing the cuffs to deflate simultaneously.

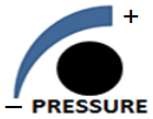
NOTE: The air pump will not function unless **Deflation** button is activated.

The pump starts only when the **Deflation** switch is activated and stops automatically when treatment is terminated.

When the pump is stopped, the pressure cuffs automatically deflate.

PRESSURE ADJUSTMENT KNOB

This knob (refer to Figure 3-3, item 9) is used to set the treatment pressure applied through the cuffs.



- Rotate the knob to the right to increase treatment pressure.
- Rotate the knob to the left to decrease treatment pressure.

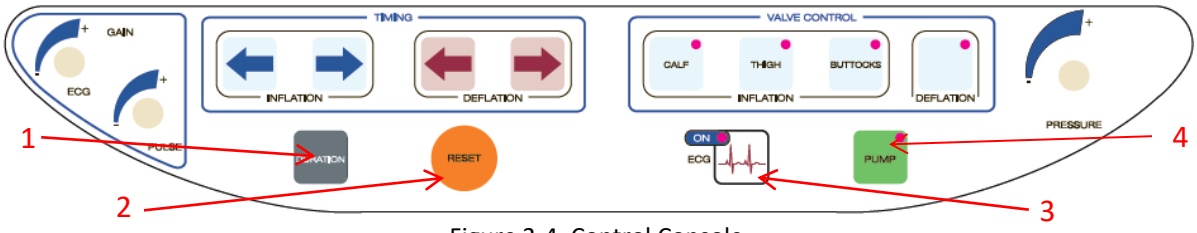


Figure 3-4. Control Console.

DURATION

This button (refer to Figure 3-4, item 1) selects a preset Treatment Duration. The Operator may select from 11 treatment duration settings: 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, or 60 minutes.

Each press of the switch selects the next higher Duration setting, except after 60, when the system returns to 10.

NOTE: Sixty-minute duration is the maximum allowable treatment.

The Treatment Duration selected is displayed on the PC. When treatment is completed, the displayed value changes to 0 (zero), the pump stops automatically, and the cuffs are completely deflated.

If treatment is stopped before time is up, it pauses the elapsed time indication.

NOTE: Treatment Duration cannot be adjusted once the **Start Pump/Stop Pump** button is activated.

RESET

Whenever this button (refer to Figure 3-4, item 2) is pressed,

- Any treatment in progress is halted.
- All cuffs are deflated
- Treatment Duration is automatically reset to 60 minutes.
- Inflation Start Time and Deflation Start Time are automatically reset to default settings.

As a result of a reset, fine adjustment of Inflation Start Time and Deflation Start Time might again be required to achieve optimum counterpulsation results.

ECG

This button (refer to Figure 3-4, item 3) enables the patient's ECG signal.

NOTE: If the ECG input is inadvertently switched off for any reason, turn off the air pump and reduce Pressure before restarting treatment to maximize patient comfort. It takes a few seconds for the inflation to restart after the machine begins to process an external ECG signal.

PUMP (START /STOP)

This button (refer to Figure 3-4, item 4) controls the power to the air pump. This will begin or resume a treatment, provided the following are true.

- The ECG button must have been pressed, enabling ECG input.
- At least one Inflation Valve must be enabled.
- The Deflation Valve must be enabled.

If these conditions are not met, an informational signal will sound, rather than the system starting the air pump.

The patient or Operator can stop treatment at any time by pushing the Emergency Stop located on the right side of the Cerezen unit.

EMERGENCY STOP

When the patient or Operator pushes the Emergency Stop located on the right side of the Cerezen unit (refer to Figure 3-5), power to the control system is immediately disconnected and treatment stops. The Operator should attend to the patient immediately.

Figure 3-5. Emergency Stop.

To engage the **Emergency Stop**,

- **Push the Emergency Stop red button (refer to Figure 3-6) firmly until audible click is heard.**

  The Cerezen unit's pump and fan stop. The PC continues operating.

Figure 3-6. Engage Emergency Stop.

To disengage the **Emergency Stop**,

- Turn the **Pressure** knob (refer to Figure 3-3, item 9) all the way counterclockwise (zero pressure).
- Rotate the red **Emergency Stop** button (refer to Figure 3-7) to the right, as indicated by the arrows displayed on it.
- Pull out the red **Emergency Stop** button.

Figure 37. Disengage Emergency Stop.

When patient is ready to resume treatment,

- Follow **Power Up Procedures** (refer to **Chapter 4: Counterpulsation Basics**), including resetting all switches and **Duration** time.
- Start treatment again.

NOTE: **Emergency Stop** affects only the ECP system controls; it does not shut off power to PC. Power to the PC may be disconnected by switching off the mains power switch or by removing power cords from electrical outlet.

WARNING: If one or more cuffs do not deflate after activation of Emergency Stop button or switching off mains power switch, disconnect the air hose from the affected cuff as this may cause injury to the Operator and/or patient or damage to the equipment. Should this occur, contact your Service Representative immediately.

Keyboard Commands

The Operator can use a wide range of keyboard commands for such functions as:

- Adjusting the distance between traces.

NOTE: Do not to position the **Pulse** wave at the extreme bottom of the PC. This may cause the displayed waveform to be cut off, resulting in a squared-off bottom portion of the waveform.

- Freezing the display of the PC to review a single event.
- Switching between viewing options: a split screen mode or a full screen mode.
- Consulting the program's Help function.

System Error Messages

System error codes will display in the software program. Table 3-1 contains each error message, its description (the text of the error message), and prescribed action.

NOTE: Spelling matches how it appears in the code.

Table 3-1. System errors messages.

Error	What it means	What to do
An Unexpected Treatment Interruption has Occured!	The computer has lost contact with the unit.	Verify the USB cable is securely plugged in. If problem persists, contact Renew Group Private Limited representative.
Error! Cannot find hh.exe program.	The help file is missing or corrupted.	Contact Renew Group Private Limited representative.
Cannot continue. Cannot open file.	Could not open file. File is missing, locked, or corrupt.	Contact Renew Group Private Limited representative.
Error accessing patient records.	Database file may be corrupted.	Attempt opening the patient's record again. If problem persists, contact Renew Group Private Limited representative.
Error opening PDF file.	Faiure to open the printed PDF.	Attempt printing again. If problem persists, contact your Renew representative.
Serial Port Error.	The computer is having trouble connecting to the unit.	Verify the USB cable is securely plugged in. If problem persists, contact Renew Group Private Limited representative.

CHAPTER 4: COUNTERPULSATION BASICS

Concept of Operation

Inflation and Deflation Sequence

1. The inflation and deflation sequence begins at the start of diastole, no earlier than 100 milliseconds (ms) after the reference R-wave.

2. At 50 ms intervals, each pair of cuffs inflates for 100 ms.

   Inflation is sequential, starting with the calves, then the thighs, and lastly, the buttocks.

3. Pressure is maintained until the cuff deflation cycle signals 150 ms prior to the next R-wave.

4. At the end of diastole and just before the next QRS complex, the deflation cycle opens for 120 ms.

   The cuffs for all three zones simultaneously deflate.

System Timing

The Cerezen system automatically calculates heart rate and sets inflation and deflation signals to occur between the R-waves during diastole. This is considered the default setting.

A trained Operator can use visual cues to move the inflation and deflation signals closer to or farther from the reference R-wave. This is performed to obtain the optimum timing of counterpulsation for each patient.

The plethysmograph uses an optical sensor to measure the patient's arterial pressure wave (pulse). The system processes and displays this waveform on the PC.

General Operating Procedures

Power up Procedures

CAUTION: Do not use Cerezen unit or store it on inclined surfaces.

Perform the following steps in preparation for a treatment:

1. Insert power cord into Cerezen unit.

2. Plug power cord into an electrical outlet.

3. Engage the mains switch of the Cerezen system.

   This must be performed before any parts of the system other than the PC receive power.

4. Press the power button on the PC.

5. Double-click **NCP heart** icon on the desktop to launch software.

6. Navigate through **Main Operating Menu** to select appropriate screen.

NOTE: Consult the *Training Manual for Cerezen* to review procedures for accessing screens.

An informational signal will sound will sound when the system has completed its self-diagnostics.

Patient Preparation

Cuff movement during treatment may cause friction on the patient's skin. As a result, irritation or lesions may occur particularly among diabetic patients, patients with circulatory problems, or patients prone to skin breakdown.

To reduce skin breakdown, cuffs must be properly sized, padded, and wrapped over the patient's clothing. The patient's legs must be covered by trousers, leggings, or other type of long pant.

CAUTION: Leg covering must be worn; cuffs must not be applied to bare skin.

NOTE: Patients may also wear tight-fitting pantyhose under their pants to add an extra layer of skin protection.

When wrapping cuffs, make sure pants lie flat (unwrinkled) against skin. Smooth pants over patient's legs before wrapping the cuffs. Wrinkles cause pressure points that can lead to skin breakdown.

Encourage patients to inspect skin for skin irritation, bruises, or lesions. Defer treatment if patient displays any open skin wounds. Refer the patient to a healthcare professional when necessary. With permission, the patient may continue ECP therapy. However, the cuff should be turned off for the affected area.

Skin Preparation and Electrode Placement

The Cerezen system uses a three-lead (single channel) ECG system to display the patient's heartbeat (R-wave). Renew Group Private Limited provides one standard ECG cable configuration:

- White negative (**–**)
- Red positive (**+**)
- Black ground (**G**)

NOTE: Many patient electrodes are unsuitable for use with the Cerezen system. Renew Group Private Limited recommends the specific brand and type that are included with the system at delivery. These electrodes are available for purchase through your local sales representative.

Skin Preparation

Prepare the patient's body for placement of the electrodes:

1. Shave areas where electrodes will be placed (refer to Figure 4-1).

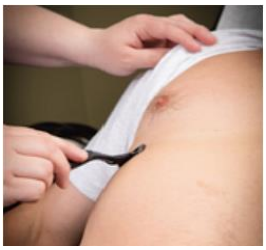


Figure 4-1. Shave area.

2. Wipe shaved areas with alcohol pad (refer to Figure 4-2).

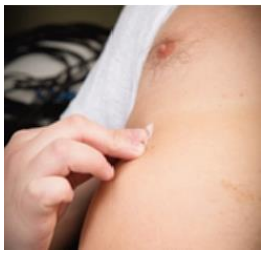


Figure 4-2. Clean area.

3. Abrade shaved areas 2 to 3 times with scrub pad (refer to Figure 4-3).

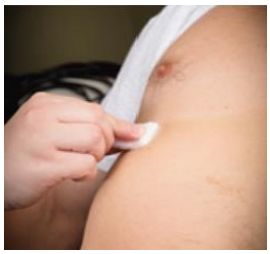


Figure 4-3. Abrade skin.

4. Connect ECG cables to electrodes (refer to Figure 4-4).

Figure 4-4. Connect cable.

5. Peel backing from electrodes (refer to Figure 4-5).

Figure 4-5. Peel backing.

6. Place electrodes directly over prepared sites and secure (refer to Figure 4-6).

Figure 4-6. Place electrode.

After the electrodes have been placed on the body and attached to the Cerezen system, tap electrode sites and observe the ECG on the PC. Re-prep and move electrodes if artifact is present or triggers notification.

NOTE: This three-lead (single channel) ECG monitor does not qualify as a diagnostic instrument.

Electrode Positioning

Note the patient's body type. Select areas that will not move during the sudden motion of the inflation cycle. Flat bony areas where skin is stretched tight work well. Avoid fleshy areas, such as the breast or the abdomen.

Artifact from poor electrode positioning will produce a repeatable, rhythmic distortion after the R-wave.

Place electrodes on the patient. Optimal placement should produce the clearest signal with the least artifact.

For most patients, position electrodes as illustrated in Figure 4-7.

- The white negative (**–**) electrode is on the front of the right chest, and at the bottom of the rib cage (refer to Figure 4-7, item 1).
- The black ground (**G**) electrode is over the bone of the left shoulder (first rib) on or below the clavicle (refer to Figure 4-7, item 2).
- The red positive (**+**) electrode is below the left shoulder and on the bottom of the rib cage (refer to Figure 4-7, item 3).

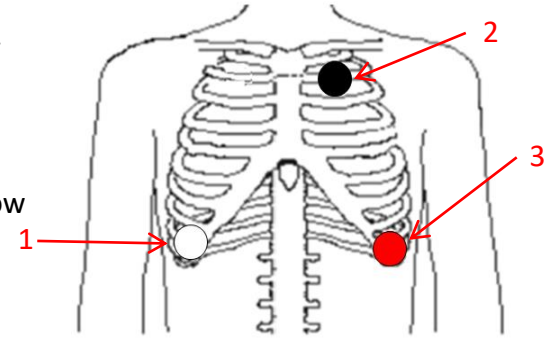


Figure 4-7. Electrode Placement.

This should produce a positive R-wave with good amplitude. Variations of this electrode placement may be used to optimize the ECG signal in individual patients.

CAUTION: Take care to arrange all cables so they do not present a tripping or entanglement risk to Operator, patient, or passers-by.

The Cuff System

The cuff system encloses bladders that inflate and deflate the cuffs with compressed air. Cuffs should be wrapped tightly with the bladder over the largest muscle mass available. This ensures optimal counterpulsation. Securement straps are provided to secure the cuffs, to help prevent over-inflation, and to aid in patient comfort.

Select Appropriate Sizes

Proper cuff selection and snug wrapping are important to effective diastolic augmentation and successful treatment. Loose cuffs increase the likelihood of the patient experiencing skin irritation and/or excessive movement on the treatment platform.

Seven sizes of cuffs: Extra-Small, Small, Large, Extra-Large, Small Short, Large Short and Extra-Large Short (refer to **Appendix B**) are available with the Cerezen system. The design of these cuffs ensures their ability to fit a wide range of patient sizes.

NOTE: Short thigh cuffs are available in sizes Extra-small, Small, Large, and Extra-large.

Determine the size of cuffs for each patient. Sizes can be mixed and matched among the buttocks, thigh, and calf cuffs in any combination in order to provide the best fit for each ECP patient. Cuffs should have adequate overlap of the hook-and-loop surfaces for a tight closure (a minimum of one to two (1 to 2) inches).

Loose or ill-fitting cuffs may lead to a loss of diastolic augmentation or skin breakdown. In addition, excessive motion produces artifact on the ECG tracing and may interfere with the triggering of the device.

NOTE: Cuffs should fit tightly around the target muscle mass. When cuff fits properly, no more than one finger should be able to fit inside it. Rewrap any cuff that appears to be loose.

Select appropriate size cuffs. Insert hose connector elbows protruding from cuffs through holes in securement straps in order to connect the air bladders to the air hoses.

Apply Cuffs

Cuffs should be wrapped snugly with the bladder over the largest muscle mass available. This ensures optimal counterpulsation.

NOTE: When wrapping cuffs, make sure clothing lies flat (unwrinkled) against skin. Smooth fabric over patient's legs before wrapping the cuffs. Wrinkles cause pressure points that can lead to skin breakdown.

Before patient gets on treatment platform, stow hoses and connectors into their openings in foot cushion (refer to Figure 4-8).

NOTE: A foot stool is recommended to help assist the patient onto the treatment platform.

Figure 4-8. Stow hoses and connectors.

Assist patient onto treatment platform. Have patient sit on the cuffs. Operator must make sure the long thigh cuff straps are placed between patient's legs before strapping on cuffs.

WARNING: Never leave a patient unattended on the table or injury may occur.

Thigh and Buttocks Cuffs

Wrap thighs first as they require larger cuffs that they secure to buttocks cuff.

As a general guideline, the lower edge of each thigh cuff should stop above the patella (kneecap). If the cuff appears to be over the knee, padding can be added for protection.

Make sure hose connector elbow is placed in middle of the thigh. Adjust the position as necessary.

Make sure the two small attachment straps of thigh cuff are free from buttocks cuff. These straps will be attached to the buttocks cuff later.

1. Pull top of thigh cuff high on patient's groin and position cuff so it does not cause the patient any discomfort (refer to Figure 4-9).
2. Secure top hook-and-loop closure flap of thigh cuff around upper thigh to hold the cuff in place (refer to Figure 4-10).
3. Hold thigh cuff in order to keep it in place. Tighten bottom hook-and-loop closure flap around lower thigh (refer to Figure 4-11). Closure should be snug.

Figure 4-9. Place thigh cuff.

Figure 4-10. Secure thigh cuff.

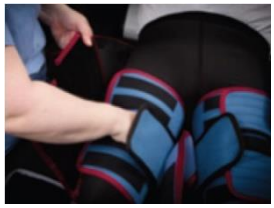


Figure 4-11. Tighten bottom of thigh cuff.

4. Tighten top hook-and-loop closure flap of thigh cuff around upper thigh. This closure should be snug. Operator should not be able to insert more than one finger inside cuff (refer to Figure 4-12).

Figure 4-12. Tighten top of thigh cuff.

NOTE: Fastening securement straps directions are found in step 9.

Repeat steps 1 through 4 to apply cuff to other thigh.

Align top of buttocks cuff with the patient's waist.

5. Arrange buttocks cuff so "v" at the top of long thigh straps is visible between the patient's legs. Make sure patient is centered on buttocks cuff.

NOTE: Patient is centered when each side of the buttocks cuff is approximately the same length. The elbows should be mid-buttocks level.

6. Fasten attachment straps of thigh cuff to buttocks cuff once both cuffs are in place (refer to Figure 4-13).

Figure 4-13. Fasten thigh and buttocks cuffs.

7. Secure buttocks cuff with hook-and-loop thin strap around patient's waist. (refer to Figure 4-14).

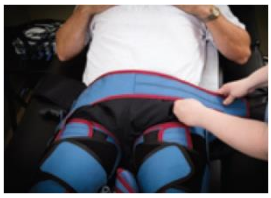


Figure 4-14. Secure strap around buttocks.

8. Wrap hook-and-loop thick securement strap of buttocks cuff securely around patient. (refer to Figure 4-15).

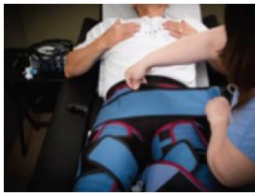


Figure 4-15. Wrap strap around buttocks.

NOTE: Closure in step 8 can be adjusted for patient comfort as it is placed over the bladder.

9. Secure thigh cuff securement strap by positioning hook-and-loop closure flap at a 45° angle across thigh to get a tight fit. (refer to Figure 4-16).

Figure 4-16. Secure thigh cuff at 45°.

10. Wrap long thigh strap around upper thigh and secure to hook-and-loop surface on buttocks cuff (refer to Figure 4-17).

Figure 4-17. Secure thigh cuff.

NOTE: These steps secure the thigh cuffs and keep both the buttocks cuff and thigh cuffs together.

Calf Cuffs

When wrapping the calves, make sure each cuff is centered below the knee and above the ankle. As a general guideline, the calf cuffs should be positioned a minimum of two fingers below the knee.

For patients who are below average height, calf cuffs may extend pass the patella. Be sure to provide extra padding on front and back of each knee if this occurs. If this is not possible, add padding where appropriate. The knee support can be placed beneath the patient's knees to provided additional comfort.

NOTE: Short calf cuffs are available in sizes small and large.

Make sure hose connector elbow is placed in middle of calf. Adjust position as necessary.

Tug patient's pant legs to smooth out any wrinkles or creases before applying cuffs as these may cause skin injury.

1. Secure top of hook-and-loop closure flap around calf (refer to Figure 4-18).

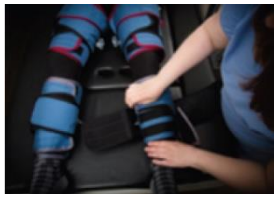


Figure 4-18. Secure top of calf cuff.

2. Secure bottom of hook-and-loop closure flap around calf. No more than one finger should be able to insert between cuff and skin (refer to Figure 4-19).

Figure 4-19. Secure bottom of calf cuff.

3. Secure calf cuff securement strap by positioning hook-and-loop closure flap at a 45° angle to get a tight fit (refer to Figure 4-20).

Figure 4-20. Secure calf cuff at 45°.

NOTE: Make sure bottom of hook-and-loop closure flap is as snug as the top because the bottom of the calf is smaller than its top.

Repeat steps 1 through 3 to apply cuff to other calf.

NOTE: If patient complains of discomfort during treatment, check position and alignment of the cuffs. Add padding and re-wrap cuffs as necessary. Consider reducing treatment pressure.

Connect Hoses

Connect the hoses to the bladder elbows of the pneumatic cuffs. The hoses on the Cerezen are color coded to ensure the correct hose is attached to the correct cuff.

CAUTION: Disconnect air hoses before moving the patient treatment platform.

1. The hose with the white attachment end is used for the buttocks cuff. **Note:** the buttocks cuff end is also white. (refer to Figure 4-21).
2. The hose with the gray attachment end is used for the thigh cuff. **Note:** the thigh cuff end is also gray. (refer to Figure 4-22).
3. The hose with the black attachment end is used for the calf cuff. **Note:** the calf cuff end is also black. (refer to Figure 4-23).

Figure 4-21. Connect buttocks hose.

Figure 4-22. Connect thigh hose.

Figure 4-23. Connect calf hose.

4. Connect air hoses to manifold at foot of treatment platform.

NOTE: Use the provided knee support under the patient's knees to raise them a few inches for comfort.

Starting Treatment

NOTE: Interuption of power will cause all settings to revert to default values.

Establish Patient ECG Signal

After the patient is wrapped and properly positioned on the treatment table, turn **ECG** knob to the right to display the patient's heart signal on the PC.

WARNING: This three-lead (single channel) ECG does not qualify as a diagnostic instrument and must not be used for diagnostic purposes.

CAUTION: The Cerezen does not provide pacemaker pulse suppression or rejection.

WARNING: This system is not designed to be connected to the patient during defibrillation as this may cause injury to the Operator and/or patient or damage to the equipment.

Apply Plethysmograph Sensor

Clip either ear or finger plethysmograph onto patient.

Position lead wire to minimize movement of the plethysmograph. Adjust **Pulse Gain** knob, if necessary, to resize the Pulse waveform on the PC display. The size of the Pulse display is also adjustable on the PC by pressing the F3 key, then (<+>, <–>).

NOTE: Use a pillow to rest the patient's hand if using a finger plethysmograph sensor to prevent hand motion during treatment for a more stable reading, if necessary.

CAUTION: Take care to arrange all cables so they do not present a tripping or entanglement risk to Operator, patient, or passers-by.

Select Valves

Activate desired inflation (calves, thighs, or buttocks) valves by pressing corresponding button on Control Console. All three sets of valves will be used for almost all patients.

The maximum operating pressure for Cerezen system is limited by a pressure relief valve to approximately 8.0 pounds per square inch (psi). This setting is not adjustable.

Operator can use the Inflation Valve Control buttons to turn off air pressure to individual cuffs during treatment. The green LED indicator light adjacent to each button indicates whether or not pressure is being delivered to those cuffs. Verify by watching the cuffs inflating and deflating.

Valve Control Switches

Select and press **Inflation** (**Calves**, **Thighs**, and **Buttocks**) and **Deflation** buttons.

NOTE: The pump cannot be operated unless **Deflation** button is pressed.

Set Treatment Times

Tap **Duration** button to adjust the length of treatment desired, from 10 to 60 minutes, in 5-minute increments.

NOTE: Sixty minutes is the default amount of treatment time when the machine is turned on. Sixty minutes is also the maximum allowable duration of a treatment.

The amount of treatment time selected is displayed on the PC. After treatment has been running for one minute, verify the countdown timer at the top of the PC display is counting down.

NOTE: Treatment time cannot be adjusted once the treatment **Start** button has been selected.

Fine Adjustment of Inflation/Deflation Timing

After target treatment pressure has been established, it may be necessary to tap **Inflation** ← and → buttons or **Deflation** ← and → buttons to adjust timing.

Adjust the inflation or deflating timing with respect to the R-wave. Refer to the pulse waveform for reference when making inflation and deflation timing adjustments.

Refer to *Training Manual for Cerezen* for detail on timing adjustments.

Adjust Pressure

WARNING: Do not treat patients with air pressure above 6.0 psi as this may cause injury to the Operator and/or patient or damage to the equipment.

Adjust **Pressure** knob to reduce pressure setting to zero (0) before turning the pump on. Press **Pump** button and turn **Pressure** knob to incrementally adjust the pressure slowly to identified target pressure, giving the patient time to adapt to the rising pressure.

CAUTION: In patients with heart rates greater than 100 beats per minute, the temperature within the cuffs may reach 43°C (approximately 110°F) when the Cerezen system is operated at high pressure settings. This may pose a risk of minor burns, particularly in patients with impaired lower extremity blood flow (e.g., peripheral artery disease) and/or impaired sensation in the lower extremities (e.g., neuropathy).

CAUTION: In patients with heart rates greater than 100 beats per minute, the Operator should check the temperature between cuffs and the patient's skin periodically over the course of a treatment. In all patients, if discomfort is experienced, treatment should be stopped until the cause of the discomfort had been determined and assessed.

Closely monitor the computer display in order to verify that the correct air pressure is being delivered.

CAUTION: In the event fluid is present on the unit (i.e., carbonated beverage, coffee, urine, excessive perspiration, etc.), treatment should cease until the unit can be cleaned with Formula 409® or Simple Green® All-Purpose Cleaner, warm water, and a soft cloth and allowed to dry (refer to **Chapter 5: Maintenance**).

Stopping Treatment

When the timer has counted down to 0 (zero), the pump stops, the cuffs automatically deflate, a beep sounds, and the PC displays **End of Treatment** pop-up window.

Click **OK** or press <**Enter**> to accept and close the record.

Routine Shutdown

Operator then completes these steps:

NOTE: Leading up to the end of Treatment Duration, the patient may prefer for the Operator to gradually decrease pressure in the cuff system.

1. Turn **Pressure** knob to all the way to the left.
2. If pump has not stopped automatically, press **Pump** button to stop pump.
3. Disconnect and stow the ECG, plethysmograph, and patient call cables.
4. Remove plethysmograph.
5. Press **Reset** button.
6. Remove cuffs and hoses from patient.
7. Disconnect ECG leads from patient'atientect ECG
8. Stow hoses and connectors into their openings in foot cushion.

WARNING: Patient's feet may have become tangled and/or trapped by the air hoses, which may cause injury to the patient. Make sure patient is clear of hoses before assisting from treatment platform.

9. Remove electrodes from patient.

CAUTION: Take care to arrange all cables so they do not present a tripping or entanglement risk to Operator, patient, or passers-by.

10. Assist patient to an upright position.
11. Assist patient from treatment platform.

NOTE: A foot stool is recommended to help assist the patient from the treatment platform.

Cerezen Cool-down

Wait a minimum of 15 minutes before starting new treatment.

NOTE: Do not give more than one immediately consecutive treatment to a patient. The maximum duration for a treatment is 60 minutes.

During this cool-down period, the Operator:

- Allows patient time to leave treatment area.
- Cleans and disinfects the unit.
- Prepares for next treatment.

Emergency Shutdown

In response to any emergency, immediately press the **Pump** button or engage **Emergency Stop** (refer to **Chapter 3: Controls**).

CAUTION: In the event patient experiences discomfort during treatment, the patient may engage the **Emergency Stop** located on the right side of the treatment platform. The air hoses have quick release connectors and the cuffs have hook-and-loop fasteners that permit rapid release.

Adverse Event during Treatment

Record any adverse events that occur during treatment.

NOTE: Any adverse event must be reported to Renew Group Private Limited by phone (353 90 646 5460 for Europe)

or email (info@renewgroup.eu for Europe) within 24 hours of occurrence.

Total System Shutdown and Stowage

When no further use of the Cerezen system is required, complete these steps:

1. Disengage the mains power switch. Unplug power cord from electrical outlet.
2. Perform required daily cleaning and maintenance (refer to **Chapter 5: Maintenance**).
3. Remove head and arm cushions.
4. Disconnect and stow the ECG, plethysmograph, and patient call cables.
5. Unscrew knob to shorten leg; pivot leg upward and secure in clamp. Lower leaf. Repeat action for other leg.
6. Place arm and head cushions along the hinges of treatment platform and leaves.

7. Rotate Control Console mount arm so Control Console and PC are over top of treatment platform.

8. Stow hoses and connectors into their openings in foot cushion.

9. Unlock casters. Roll Cerezen unit into storage location. Lock casters.

WARNING: Do not store Cerezen system on inclined surface as this may cause injury to the Operator and/or patient or damage to the equipment.

CHAPTER 5: MAINTENANCE

Warranty

Refer all warranty conditions to local sales representative.

CAUTION: With the exception of a few specified minor routine maintenance procedures contained in this Owner's manual, the Cerezen system is not in-house serviceable.

CAUTION: Refer all service maintenance to certified Renew Group Private Limited service personnel to avoid electrical hazard, damage to the Cerezen system, or danger to Operator or to patient or to both.

Consumable Parts and Supplies

For replacement of consumable parts and supplies refer to **Appendix C** through **Appendix L** and contact local service representative.

WARNING: Replacement of a component may result in an unacceptable risk. Do not replace if Renew Group Private Limited specifies the component as replaceable by service personnel only.

Risk of Electronic Component Waste Disposal

Electronic equipment and components (such as the control circuit boards) contain many different toxic materials. If electronic equipment is placed in a landfill or incinerated, these hazardous materials can be released into the environment. Dispose of e-waste in an approved manner.

NOTE: The presence of these materials does not make the equipment dangerous during its use.

Maintenance

Routine Maintenance

Most maintenance for the Cerezen system can only be provided by a factory-trained service technician. Operators are cautioned against attempting unauthorized maintenance; such activities could jeopardize the patient, damage the machine, and invalidate the warranty.

ECG cables should be visually inspected for damage before each use.

Unscheduled Maintenance

In any case described under **Routine Maintenance**, or in any case not specifically described, the owner is required to notify local service representative to obtain assistance or service.

However, it is important for the Operator to observe the performance of the Cerezen system and complete several routine maintenance tasks.

The Cerezen system's Operator is responsible for the cleanliness and appearance of the Cerezen system, as well as for these maintenance tasks:

- Replace items such as cuffs, bladders, and electrodes as needed.
- Clean ECG and pulse cables with Formula 409® or Simple Green® All-Purpose Cleaner, warm water, and a soft cloth after each use. Wipe dry.

NOTE: The vinyl table skirts can be cleaned as needed using the same methods. The metal frame and hoses can be cleaned using warm water and a soft cloth. Wipe dry.

- Store unused plethysmograph sensors and ECG cables flat to prolong their use.
- Spray cuffs lightly with a Formula 409® or Simple Green® All-Purpose Cleaner solution and allow them to dry overnight. If necessary, cuffs may be hand-washed in a Formula 409® or Simple Green® All-Purpose Cleaner solution, rinsed, and air dried overnight. Do not tumble dry.
- Clean bladders as needed by wiping with a solution o Formula 409® or Simple Green® All-Purpose Cleaner, warm water. Air dry.

  Bladders do not need regular cleaning.
- Clean hoses and couplings as needed by wiping with a solution of Formula 409® or Simple Green® All-Purpose Cleaner and warm water. Air dry.
- Dust Control Console and PC. Wipe Control Console and PC as needed with a soft cloth dampened with water.
- Apply Molykote 111 Compound (Lubricant) to the elbow's ring whenever tightness observed when connecting the Hose to Cuff elbow.

Replacing Bladders

Bladders are subject to considerable physical stress and wear that may occasionally develop into small holes causing leaks. Should this occur, contact the local service representative to obtain replacement bladder(s). Follow the steps below to replace an air bladder.

1. Determine size and of bladder (refer to Figure 5-1).

Figure 5-1. Determine size.

2. Place clamp around opening (refer to Figure 5-2).

Figure 5-2. Place clamp.

3. Use wrench to close clamp (refer to Figure 5-3).

Figure 5-3. Close clamp.

4. Place bladder in cuff (refer to Figure 5-4).

Figure 5-4. Place bladder.

5. Push the largest part of clamp through hole in cuff (refer to Figure 5-5). Work elbow through the hole.

Figure 5-5. Push clamp.

6. Make sure bladder opening is completely through cuff opening (clamp will be visible) (refer to Figure 5-6).

Figure 5-6. Visible clamp.

7. Attach correct elbow[2] (refer to Figure 5-7).

Figure 5-7. Attach elbow.

8. Push elbow into bladder (refer to Figure 5-8). Fittings should be tight, but should be able to turn.

Figure 5-8. Push elbow.

9. For buttocks cuff only, ensure elbow is facing hook-and-loop fasteners so that elbow is pointing upward (refer to Figure 5-9) when reconnected to patient.[3]

Figure 5-9. Position elbow.

[2] White for buttocks cuff; gray for thigh cuffs; and black for calf cuffs.

[3] For calf and thigh cuffs, make sure elbow is facing toward the bottom of cuff.

During Treatment

If a cuff becomes inoperative because of bladder failure, replace the bladder immediately. If a treatment is in progress:

1. Press **Pump (Start/Stop)** button to pause the treatment.

   The system keeps a record of treatment duration elapsed.

2. Refer to **Replacing Bladders** steps.

CHAPTER 6: TROUBLESHOOTING

System Does Not Turn On

If the Cerezen system does not work, check to see whether:

- **Emergency Stop** is disengaged.
- Mains power switch is engaged.
- Power switch on PC is engaged.
- Power cord securely inserted into power inlet.
- Power cord is securely inserted into electrical outlet.

Treatment Interruption

If a power fluctuation or **Emergency Stop** interrupts a treatment session, a new treatment must be initiated. Be sure the **Pressure** knob has been turned all the way to the left (zero pressure).

Set all control buttons to the state they were in at the beginning of the interrupted treatment.

Reset the Treatment Duration; the Treatment Duration must be reset to account for any elapsed time.

Consult the *Training Manual for Cerezen* for detailed training and treatment instruction to establish patient treatment records.

Improper ECG Signals

If distortion of the ECG wave occurs or if ECG wave drifts from the baseline occurs, check electrodes and cable connections. Check that:

- All three electrodes are properly adhered to patient.
- ECG wires are properly connected to electrodes.
- The ECG button is enabled (green indicator light is on).

PC Display

If data is not visible on the laptop PC, check to see whether:

- Laptop PC is on.
- Power cable is plugged into the laptop PC.
- Power cables are plugged into Cerezen unit and electrical outlet.
- USB cable is plugged into the laptop PC.

If data is still not visible on the laptop PC,

- Restart the laptop PC.
- Quit, then restart the NCP software program.

Indicator Lights

If a switch indicator light does not illuminate when the switch is engaged, the LED may be defective. Contact local sales representative for assistance.

Inflation/Deflation Timing

If the Inflation/Deflation start time cannot be adjusted, make sure Operator presses only one button at a time.

Consult the *Training Manual for Cerezen* for detailed training and treatment instruction.

Inflation/Deflation

If a **Valve Control** button indicator light does not illuminate when the button is engaged, the LED may be defective. Contact local sales representative for assistance.

If one or more cuffs fail to inflate properly, check for leaking bladders or hoses and replace as necessary. Tighten connections as applicable.

If one set of cuffs fails to inflate:

- Check to make sure **Inflation** (**Calves**, **Thighs**, and **Buttocks**) buttons are pressed and are flashing.
- Reduce treatment pressure at once.
- Press **Pump** button to turn off pump and deflate all cuffs.
- Press **Inflation Valve Control** button for the non-inflating cuff.

If appropriate, treatment can sometimes be resumed using only the properly functioning cuffs. Be sure to check frequently for patient discomfort.

If the steps above do not remedy the problem, contact the local sales representative for assistance.

If air pressure is insufficient, try rotating the **Pressure Adjust** knob to the right. At high heart rates, the system will **not** achieve maximum pressures.

If this is not sufficient, check for the following:

- Air hoses are leaking.
- Cuff are fastened loosely.
- Air bladders are leaking.

If maximum air pressure is excessive (readings above 8.0 psi):

- Turn the **Pressure Adjust** knob to the left.

If air pressure remains excessive *stop the treatment* by depressing the **Pump** button or, if necessary, the **Emergency Stop** button.

WARNING: Do not treat a patient at pressures higher than 6.0 psi as this may cause injury to the Operator and/or patient or damage to the equipment.

APPENDICES

Appendix A: Packing List

Item Description	QTY
Cerezen Unit	1 ea
PC	1 ea
Calf Hose Assembly	1 ea
Thigh Hose Assembly	1 ea
Buttocks Hose Assembly	1 ea
Patient Call Cable	1 ea
Finger Plethysmograph Extension Cable	1 ea
Finger Plethysmograph Sensor	1 ea
ECG Patient Cable	1 ea
Spare Bladder Kit (2 each size)	1 kit
Patient Call Cable/Switch	1 ea
Patient Electrodes (packs of 3)	17 ea
Alcohol Prep Pads (200 count)	1 box
Patient Scrub Pad (500 count)	1 box
Cuff Set, XSM (6 pieces)	1 set
Cuff Set, SM (6 pieces)	1 set
Cuff Set, LG (6 pieces)	1 set
Cuff Set, XLG (4 pieces)	1 set
Cuff Set, SM Short (4 pieces)	1 set
Cuff Set, LG Short (4 pieces)	1 set
Cuff Set, XLG Short (2 pieces)	1 set

Item Description	QTY
Strap, Leg Control	1 ea
Strap, Calf Closure, Universal Black	2 ea
Strap, Thigh Closure, Universal Black	2 ea
Calf Bladders	14 ea
Thigh Bladders	6 ea
Buttocks Bladders	8 ea
XSM Calf-Thigh Bladders	4 ea
Detachable Power Cord	1 ea
PC	1 ea
Serial Cable	1 ea

Appendix B: Cuff Sizes

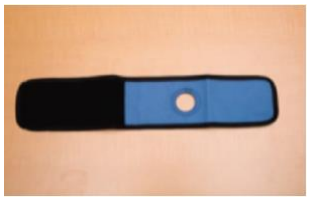
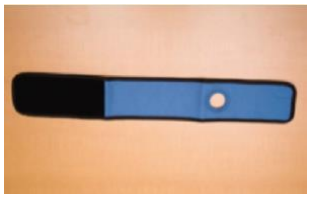
Cuff Sizes		Buttocks		Thigh		Calf	
		Circ.	N/A	Circ.	Length	Circ.	Length
Extra Large	cm	102 to 142	N/A	51 to 74	29.2	N/A	N/A
	inch	40 to 56	N/A	20 to 29	11.5	N/A	N/A
Extra Large-Short	cm	N/A	N/A	51 to 74	24.1	N/A	N/A
	inch	N/A	N/A	20 to 29	9.5	N/A	N/A
Large	cm	91 to 130	N/A	48 to 66	29.2	38 to 51	29.2
	inch	38 to 51	N/A	19 to 26	11.5	15 to 20	11.5
Large-Short	cm	N/A	N/A	48 to 66	24.1	38 to 51	24.1
	inch	N/A	N/A	19 to 26	9.5	15 to 20	9.5
Small	cm	92 to 122	N/A	46 to 56	29.2	36 to 46	29.2
	inch	36 to 94	N/A	18 to 23	11.5	14 to 18	11.5
Small-Short	cm	N/A	N/A	46 to 56	24.1	36 to 46	24.1
	inch	N/A	N/A	18 to 23	9.5	14 to 18	9.5
Extra Small	cm	66 to 94	N/A	33 to 48	21.6	28 to 38	21.6
	inch	26 to 37	N/A	13 to 19	8.5	11 to 15	8.5

N/A = Not Applicable

– 5^{th} to 95^{th} percentile both genders combined, US population, all races.
Source: US Centers for Disease Control, Anthropometric Reference Data

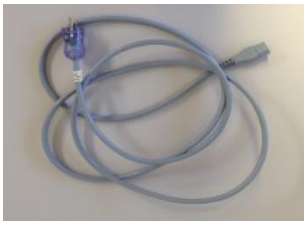
Appendix C: Cuff Set Kit Box

Product Code	Item Description	Quantity	Representation of Product
21819	Cuff Kit, Extra Small Forest Green	1 set	
21827	Cuff Kit, Small, Burma Ruby	1 set	
21836	Cuff Kit, Large, Tundra Gray	1 set	
21843	Cuff Kit, Extra Large, Black	1 set	
21848	Cuff Kit, Small Short, Red	1 set	
21853	Cuff Kit, Large Short, White	1 set	

21858	Cuff Kit, Extra Large Short, Blue	1 set	
21875	Strap, Calf Closure, Universal, Black	2 each	
21874	Strap, Thigh Closure, Universal, Black	2 each	
21876	Strap, Leg Control	1 each	

Appendix D: Accessories Box

Product Code	Item Description	Quantity	Representation of Product
20347	Cable, Patient Call, with Stereo Plug (2.3m)	1 each	
20381 Mfg PN: 42316-1	ECG Cable, 3-Wire, Merit Cable (2.4m)	1 each	
21871 Mfg PN: R-00-S/25	Blue Sensor, Adult Foam Electrode 48mm w/Snap (25 Count)	2 packages	
21872	Curity™ Alcohol Prep Pads (200 Count)	1 box	
20597	Patient Scrub Pad (500 Count)	1 box	
20642 Mfg PN: AMD-SC-IX0245-L	Cable, Patient Pulse (Finger Plethysmograph extension), Grounded (1.5m)	1 each	

22706 Mfg PN: A1411-SA103PV	Reusable SpO2 Sensor Finger Sensor	1 each	
21484 Mfg PN: SA15E-16	Sensor, Ear Clip Plethysmograph (Reusable) (1.5m)	1 each	
20640	Installation Tool, Clamp	1 each	
20644	Dow Corning® Molykote® 111 Lubricant, 6g Pillow Pack	1 each	
22210	Owner's Manual	1 each	
21768 (USA)/ 20425 (UK/IRELAND/SINGAPORE/ UAE (1 Count)	Power Cord (1 Count) (3m)	1 each	

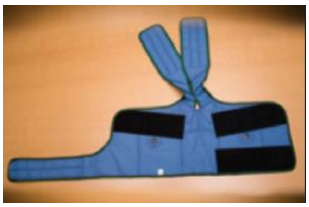
Appendix E: General Consumable Items

Product Code	Product Description	Price	Representation of Product
20347	Cable, Patient Call, with Stereo Plug (2.3m) (1 Count)	N/C	
20381 Mfg PN: 42316-1	ECG Cable, 3-Wire, Merit Cable (2.4m) (1 Count)	N/C	
21871 Mfg PN: R-00-S/25	Blue Sensor, Adult Foam Electrode 48mm w/Snap 2 Package (25 Count)	Contact local sales representative for price	
21872	Curity™ Alcohol Prep Pads (200 Count)	Contact local sales representative for price	
20644	Dow Corning® Molykote® 111 Lubricant, 6g Pillow Pack (1 Count)	Contact local sales representative for price	
20640	Installation Tool, Clamp (1 Count)	N/C	

20597	Patient Scrub Pad (500 Count)	Contact local sales representative for price	
20642 Mfg PN: AMD-SC-IX0245L	Cable, Patient Pulse (Finger Plethysmograph Extension) Grounded (1.5m) (1 Count)	N/C	
22706 Mfg PN: A1411-SA103PV	Sensor, Finger Plethysmograph (1.5m) (1 Count)	N/C	
21873	Strap Kit, Universal	N/C	
21875	Strap, Calf Closure, Universal, Black (1 Count)	N/C	
21874	Strap, Thigh Closure, Universal, Black(1 Count)	N/C	
21876	Strap, Leg Control, Black (1 Count)	N/C	

N/C = No Charge

Appendix F: Consumable Items: Extra Small Cuff (Forest Green) Assembly and Components

Product Code	Product Description	Price	Representation of Product
21807	Cuff Assembly, Extra-Small, Forest Green (1 Set) — the set comes fully assembled with bladders, connection elbows, clamps, and poly bag to store set	N/C	
21820	Belt, Buttocks, Extra-Small, Forest Green (1 Count)	N/C	
21821	Cuff, Buttocks, Extra-Small, Forest Green (1 Count)	N/C	
21814	Bladder, Buttocks (2 Count)	N/C	
21816	Elbow, CPC 3418900 White (2 Count)	N/C	
21815	Clamp P-23.6 (2 Count)	N/C	

21822	Cuff, Right Thigh, Extra-Small, Forest Green (1 Count)	N/C	
21826	Bladder, Calf and Thigh, Extra-Small (1 Count)	N/C	
21817	Elbow, CPC 3418700 Gray (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	
21823	Cuff, Left Thigh, Extra-Small, Forest Green (1 Count)	N/C	
21826	Bladder, Calf and Thigh, Extra-Small (1 Count)	N/C	
21817	Elbow, CPC 3418700 Gray (1 Count)	N/C	

21815	Clamp P-23.6 (1 Count)	N/C	
21825	Cuff, Calf, Left, Extra-Small, Forest Green (1 Count)	N/C	
21826	Bladder, Calf and Thigh, Extra-Small (1 Count)	N/C	
21818	Elbow, CPC 3418800 Black (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	
21824	Cuff, Calf, Right, Extra-Small, Forest Green (1 Count)	N/C	
21826	Bladder, Calf and Thigh, Extra-Small (1 Count)	N/C	

21818	Elbow, CPC 3418800 Black (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	

N/C = No Charge

Appendix G: Consumable Items: Small Cuff (Burma Ruby Color) Assembly and Components

Product Code	Product Description	Price	Representation of Product
21808	Cuff Assembly Small, Burma Ruby (1 Set) — the set comes fully assembled with bladders, connection elbows, clamps, and poly bag to store set	N/C	
21828	Belt, Buttocks Cuff, Universal, Black (1 Count)	N/C	
21829	Cuff, Buttocks, Small Burma Ruby (1 Count)	N/C	
21814	Bladder, Buttocks (2 Count)	N/C	
21816	Elbow, CPC 3418900 White (2 Count)	N/C	
21815	Clamp P-23.6 (2 Count)	N/C	

21830	Cuff, Right Thigh, Small, Burma Ruby (1 Count)	N/C	
21834	Bladder, Thigh (1 Count)	N/C	
21817	Elbow, CPC 3418700 Gray (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	
21831	Cuff, Left Thigh, Small, Burma Ruby (1 Count)	N/C	
21834	Bladder, Thigh (1 Count)	N/C	
21817	Elbow, CPC 3418700 Gray (1 Count)	N/C	

21815	Clamp P-23.6 (1 Count)	N/C	
21830	Cuff, Right Calf, Small, Burma Ruby (1 Count)	N/C	
21835	Bladder, Calf (1 Count)	N/C	
21818	Elbow, CPC 3418800 Black (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	
21833	Cuff, Left Calf, Small, Burma Ruby (1 Count)	N/C	
21835	Bladder, Calf (1 Count)	N/C	

21818	Elbow, CPC 3418800 Black (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	

N/C = No Charge

Appendix H: Consumable Items: Large Cuff (Tundra Gray Color) Assembly and Components

Product Code	Product Description	Price	Representation of Product
21809	Cuff Assembly, Large, Tundra Gray (1 Set) — the set comes fully assembled with bladders, connection elbows, clamps, and poly bag to store set	N/C	
21837	Cuff, Buttocks, Large, Tundra Gray (1 Count)	N/C	
21814	Bladder, Buttocks (2 Count)	N/C	
21816	Elbow, CPC 3418900 White (2 Count)	N/C	
21815	Clamp P-23.6 (2 Count)	N/C	
21838	Cuff, Right Thigh, Large, Tundra Gray (1 Count)	N/C	

21834	Bladder, Thigh (1 Count)	N/C	
21817	Elbow, CPC 3418700 Gray (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	
21839	Cuff, Left Thigh, Large, Tundra Gray (1 Count)	N/C	
21834	Bladder, Thigh (1 Count)	N/C	
21817	Elbow, CPC 3418700 Gray (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	

21840	Cuff, Right Calf, Large, Tundra Gray (1 Count)	N/C	
21835	Bladder, Calf (1 Count)	N/C	
21818	Elbow, CPC 3418800 Black (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	
21841	Cuff, Left Calf, Large, Tundra Gray (1 Count)	N/C	
21835	Bladder, Calf (1 Count)	N/C	
21818	Elbow, CPC 3418800 Black (1 Count)	N/C	

21815	Clamp P-23.6 (1 Count)	N/C	

N/C = No Charge

Appendix I: Consumable Items: Extra-Large Cuff (Black Color) Assembly and Components

Product Code	Product Description	Price	Representation of Product
21810	Cuff Assembly, Extra-Large, Black (1 Set) — the set comes fully assembled with bladders, connection elbows, clamps, and poly bag to store set	N/C	
21844	Belt, Buttocks, Extra-Large, Black (1 Count)	N/C	
21845	Cuff, Buttocks, Extra-Large, Black (1 Count)	N/C	
21814	Bladder, Buttocks (1 Count)	N/C	
21816	Elbow, CPC 3418900 White (1 Count)	N/C	

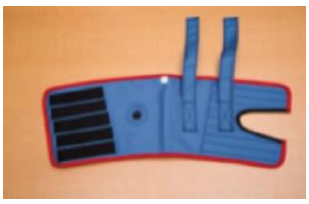
21815	Clamp P-23.6 (1 Count)	N/C	
21846	Cuff, Right Thigh, Extra-Large, Black (1 Count)	N/C	
21834	Bladder, Thigh (1 Count)	N/C	
21817	Elbow, CPC 3418700 Gray (1 Count)	N/C	
21813	Clamp P-23.6 (1 Count)	N/C	
21847	Cuff, Left Thigh, Extra-Large, Black (1 Count)	N/C	
21834	Bladder, Thigh (1 Count)	N/C	

21817	Elbow, CPC 3418700 Gray (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	

N/C = No Charge

Appendix J: Consumable Items: Small Short Cuff (Ruby Color) Assembly and Components

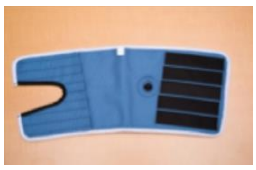
Product Code	Product Description	Price	Representation of Product
21811	Cuff Assembly, Small Short, Red (1 Set) — the set comes fully assembled with bladders, connection elbows, clamps, and poly bag to store set	N/C	
21851	Cuff, Right Calf, Small Short Red (1 Count)	N/C	
21835	Bladder, Calf (1 Count)	N/C	
21818	Elbow, CPC 3418800 Black (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	

21852	Cuff, Left Calf, Small Short, Red (1 Count)	N/C	
21835	Bladder, Calf (1 Count)	N/C	
21818	Elbow, CPC 3418800 Black (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	
21849	Cuff, Right Thigh, Small Short, Red (1 Count)	N/C	
21835	Bladder, Calf (1 Count)	N/C	
21817	Elbow, CPC 3418700 Gray (1 Count)	N/C	

21815	Clamp P-23.6 (1 Count)	N/C	
21850	Cuff, Left Thigh, Small Short, Red (1 Count)	N/C	
21835	Bladder, Calf (1 Count)	N/C	
21817	Elbow, CPC 3418700 Gray (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	

N/C = No Charge

Appendix K: Consumable Items: Large Short Cuff (White Color) Assembly and Components

Product Code	Product Description	Price	Representation of Product
21812	Cuff Assembly, Large Short, White (1 Set) — the set comes fully assembled with bladders, connection elbows, clamps, and poly bag to store set	N/C	
21856	Cuff, Right Calf, Large Short, White (1 Count)	N/C	
21835	Bladder, Calf (1 Count)	N/C	
21818	Elbow, CPC 3418800 Black (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	
21857	Cuff, Left Calf, Large Short, White (1 Count)	N/C	

21835	Bladder, Calf (1 Count)	N/C	
21817	Elbow, CPC 3418800 Black (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	
21834	Cuff, Right Thigh, Large Short, White (1 Count)	N/C	
21835	Bladder, Calf (1 Count)	N/C	
21817	Elbow, CPC 3418700 Gray (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	

21855	Cuff, Left Thigh, Large Short, White (1 Count)	N/C	
21835	Bladder, Calf (1 Count)	N/C	
21817	Elbow, CPC 3418700 Gray (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	

N/C = No Charge

Appendix L: Consumable Items: Extra-Large Short Cuff (Blue Color) Assembly and Components

Product Code	Product Description	Price	Representation of Product
21813	Cuff Assembly , Extra-Large Short, Blue (1 Set) — the set comes fully assembled with bladders, connection elbows, clamps, and poly bag to store set	N/C	
21859	Cuff, Right Thigh, Extra-Large Short, Blue (1 Count)	N/C	
21835	Bladder, Calf (1 Count)	N/C	
21817	Elbow, CPC 3418700 Gray (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	
21860	Cuff, Left Thigh, Extra-Large Short, Blue (1 Count)	N/C	

21835	Bladder, Calf (1 Count)	N/C	
21817	Elbow, CPC 3418700 Gray (1 Count)	N/C	
21815	Clamp P-23.6 (1 Count)	N/C	

N/C = No Charge

Patient Work-up Sheet

Patient _____

Ordering Healthcare Professional _____

Date _____

Projected ECP Start Date _____

_____ _____

Status of pre-approval _____

DOCUMENTATION

_____ Prescription for ECP in chart

_____ Certification by healthcare professional that patient meets criteria for ECP

_____ 12-lead ECG (if available) Date: _____

_____ Documentation of presence CAD MCI or AD in chart

Canadian Classification of Angina III: IV:

YES	NO	PATIENT WORK-UP				
_____	_____	**Heart Catheterization**	Most recent date: _____			
_____	_____	**Hx of CHF**	New York Classification I:	II:	III:	IV:
_____	_____	**Ejection Fraction**	_____ %	Date measured _____		
_____	_____	**Cardiomyopathy**				
		Type: Ischemic	Hypertrophic	Restrictive	Dilated	
_____	_____	**Aortic Insufficiency Grade:**	Mild I	Moderate II	Severe III	
_____	_____	**Mitral Valve Prolapse**	Mild	Moderate	Severe	
_____	_____	**Abdominal Aortic Aneurysm**	_____ cm			

Congenital Heart Defects

Pulmonary Disease Mild Moderate Severe

Peripheral Vascular Disease Mild Moderate limiting Severe

especially Ileofemorals? Date last vascular study

Thrombophlebitis, pulmonary embolism or problem with blood clots

Bleeding Diathesis

Anti-Coagulation Therapy (PT > 15 or INR > 2.6)

PT INR Last Date:

Severe Hypertension (> 180 Systolic or > 110 Diastolic)

Severe Hypotension (< 80/50)

Heart Rates < 35 or > 125

Current Arrhythmias PACs PVCs Frequency?

Chronic Atrial Fibrillation Controlled at Rate

Hx clinically evident stroke

Hx Head Trauma **Mild** **Moderate** **Sever**

Intracranial pressure **Mild** **Normal** **Severe**

Decreased sensation in lower extremities

Pacemaker VVI AAI DDD AICD

Rate Responsive? Date Activity Sensor Programmed OFF

Diabetes

Any limb restrictions (Vasculitis, infection, burns, wounds, etc.)

Specify: _____

_____

Pregnancy Yes/No

Date of (–) test for women of childbearing age

Survey Completed by: Date

Healthcare
Professional
Review/Cleared by Date

P/N: 22210-R03 June 2025