Maximus™ System, Model POPT1

User Manual

Product No. POPT1

Rx only: Federal USA law restricts this device to sale by or on the order of a physician.

196286 REV H

Enhancing outcomes for patients and their caregivers.

Hill-Rom

REVISION

© 2019 by Hill-Rom Services PTE Ltd. ALL RIGHTS RESERVED.

PATENTS / PATENT www.hill-rom.com/patents

The Maximus™ System, Model POPT1 may be covered by one or more patents. See the Internet address above.
The Hill-Rom companies are the proprietors of European, US, and other patents and pending patent applications.

Manufactured by:

HILL-ROM SERVICES PRIVATE LIMITED
1 YISHUN AVENUE 7
SINGAPORE 768923

AUTHORIZED EUROPEAN UNION REPRESENTATIVE:

REGULATORY AFFAIRS REPRESENTATIVE
WELCH ALLYN LIMITED
NAVAN BUSINESS PARK
DUBLIN ROAD
NAVAN, COUNTY MEAD,
REPUBLIC OF IRELAND

No part of this text shall be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording, or by any information or retrieval system without written permission from Hill-Rom Services, Inc. (Hill-Rom).

The information in this manual is confidential and may not be disclosed to third parties without the prior written consent of Hill-Rom.

The information in this manual is subject to change without notice. Hill-Rom makes no commitment to update or keep current, the information in this manual.

Hill-Rom reserves the right to make changes without notice in design, specifications, and models. The only warranty Hill-Rom makes is the express written warranty extended on the sale or rental of its products.

This manual (196286) was originally released and supplied in English. For a list of available translations, contact Hill-Rom Technical Support.

Product images and labels are for illustrative purposes only. Actual product and label may vary.

Draft H, 2019-04

Bluetooth® is a registered trademark of Bluetooth Sig, Inc.

Hill-Rom® is a registered trademark of Hill-Rom Services, Inc.

Maximus™, Volara™ and Synclara™ are trademarks of Hill-Rom Services PTE Ltd.

Replace this manual (196286) if it is damaged and/or can not be read.

For product support or to order additional copies of this manual (196286), contact your distributor, local Hill-Rom representative, or go to www.hill-rom.com.

Reference Documents

Synclara™ Cough System Single Patient Use Circuit Instruction Sheet (202722)

Volara™ System Single Patient Use Circuit Instruction Sheet (206703)

Maximus™, Volara™, and Synclara™ Systems Stand and Pole Clamp (M08177) Assembly Instructions (209109)

Maximus™, Volara™, and Synclara™ Systems Pole Clamp (M08143) Assembly Instructions (208011)

Maximus™, Volara™, and Synclara™ Systems Service Manual (194922)

Table of Contents

Revision i
Intended Use 1
Introduction 1
Important Information 2
    Theory of Operation 2
    Indications for Use 3
    Contraindications 3
    Absolute Contraindications 3
    Relative Contraindications 4
    Possible Adverse Conditions 4
Symbols and Acronyms 6
    Document Symbols 6
    Product Symbols 6
    Common Screen Symbols 9
    Acronyms 10
Safety Instructions 11
Features 15
    Control Unit 15
        Front 15
        Back 16
    Synclara™ Cough System Single Patient Use Circuit 17
    Volara™ Single Patient Use Circuit 18
Assemble and Connect the Patient Circuit 19
    Connect the Synclara™ Patient Circuit 20
    Connect the Volara™ Patient Circuit 21
        Connect the Volara™ Patient Circuit for In-line Ventilation Therapy 24
        Assemble the Nebulizer Kit and Add Medication 26
Set up and Power on the Control Unit 28
Power off the Control Unit and Store the System 29
Getting Started 30
    About the Home Menu 30
    About the Options Menu 31
    Select a Therapy 32

Synclara™ Therapy 32
Start a Therapy 32
Synclara™ Therapy in Automatic Mode 34
Basic View in Automatic Mode 34
Start a Therapy in Automatic Mode 35
Adjust the Patient Synchrony and End with Sigh settings . 37
Access the Advanced View 38
Synclara™ Therapy in Manual Mode 39
Start a Therapy in Manual Mode 40
Advanced Synclara™ Therapy Settings 43
Create a New Preset Therapy Plan 43
Modify a Preset Therapy Plan 46
Rename a Preset Therapy Plan 49
Delete a Preset Therapy Plan 50
Volara™ Therapy 51
Start a Therapy 51
Volara™ Therapy in Automatic Mode 53
Basic View in Automatic Mode 53
Start a Therapy in Automatic Mode 54
Adjust Cough Pause Settings 56
Access the Advanced View 57
Volara™ Therapy in Manual Mode 57
Basic View in Manual Mode 57
Start a Therapy in Manual Mode 58
Advanced Volara™ Therapy Settings 61
Modify a Preset Therapy Plan 63
Rename a Preset Therapy Plan 66
Delete a Preset Therapy Plan 67
Volara™ Therapy with an In-line Ventilator 68
Frequency 68
Procedures 68
Device Settings 69
Adjust Screen Brightness 69
Adjust Date and Time settings 70
Change the System Language 70

Enable or Disable Clinical Access 71
Set the Pressure Ceiling Limit 72
Connect a Barcode Reader or Pulse Oximeter 74
Connect to a WIFI Network. 75
Connect to a Local WIFI Network. 75
Connect to a Public Network. 77
Connect to an Enterprise Network 78
Configure Network Settings 79
Test the Connection to VisiView™ Health portal. 81
Test the Connection to Electronic Medical Records (EMR) . 82
Retrieve Logs 83
Retrieve the Therapy Logs 83
Retrieve the Error Log 84
Import and Export Device Settings 86
View the Firmware Version and System Information 87
Accessories 88
Replaceable Battery. 89
Install the Battery. 90
Charge the Battery 92
Pulse Oximeter 93
Foot Switch 94
Mobile Stand and Pole Clamp Assembly 95
Install the Stand 95
Install the Tray and Pole Clamp 97
Install the Control Unit on the Cart and Stand Assembly . . 98
Move the Stand 99
Install the Control Unit on a Medical Rail or IV pole 100
Replacement Parts/Kits. 102
Cleaning and Disinfecting 103
Clean the Control Unit, Stand with Cart, and Foot Switch. 104
Clean the Pulse Oximeter 105
Clean the Single Patient Use Circuit 105
Disinfect. 108

Maintenance 109
Inlet Filter 109
Nebulizer Filter 110
Fuse 110
Expected Life 111
Service calls 111
Troubleshooting 112
Control Unit Does Not Power On 112
On-screen Help 112
Information Indicators 113
Audio Alerts 113
Notification Messages 113
Warning Messages 114
Caution Messages 115
Storage and Handling 119
Shipping and Packaging 120
Shipping for Repair 120
Specifications 121
Product Identification 121
Product Specifications 121
Dimensions 122
Power Requirements 122
Replaceable Battery (Optional) 122
Environmental Conditions for Use 123
Environmental Conditions for Transport and Storage 123
System Cool Down 123
Wireless Communication 124
Classification and Standards 125
Essential Performance 125
Federal Communications Commission (FCC) Compliance Statement 126
Electromagnetic Compatibility Guidance 128
Electromagnetic Immunity to Wireless Communications 132

INTENDED USE

The Maximus™ System, Model POPT1 provides features of both the Synclara™ System and the Volara™ System.

The **Maximus™ System, when used as a Synclara™ Cough System** is intended for use on patients who are unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, as a result of high spinal cord injuries, neuromuscular deficits, or severe fatigue associated with intrinsic lung disease.

The **Maximus™ System, Model POPT1, when used as a Volara™ System** is intended for the mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and has the ability to provide supplemental oxygen when used with oxygen supply.

INTENDED PATIENT POPULATION

The Maximus™ System, when used as a Synclara™ Cough System, is intended to deliver therapy to the population of pediatric to adult patients.

The Maximus™ System, when used as a Volara™ System, is intended to deliver therapy to adults and children over the age of 2.

INTRODUCTION

This manual includes instructions for setup, use, and maintenance of the Maximus™ System, Model POPT1. Before you operate the system, make sure you have read and understand in detail the contents of this manual. It is important that you read and strictly obey the safety aspects contained in this manual.

NOTE:

To identify the revision of your system, see the serial number label on the back of the control unit.

Draft_H_2019-Apr-26_Cleaned

IMPORTANT INFORMATION

This section contains information about the Maximus™ System:

- Theory of operation (See page 2)
- Indications for Use (See page 2)
- Contraindications (See page 3)

It is important that you read and understand the information in this section before you use the system.

THEORY OF OPERATION

The **Maximus™ System, when used as a Synclara™ Cough System** provides a noninvasive therapy that is a safe alternative to invasive suctioning. The system is designed for use by patients, caregivers, and healthcare providers. The system will simulate a cough to remove secretions in patients with a compromised peak cough flow.

The system supplies positive insufflatory pressure (Inhale) to the airway with the intended goal of inflating the lungs. The system then rapidly shifts to supply negative exsufflatory pressure (Exhale) with the intended goal of rapidly deflating the lungs to simulate a high expiratory flow which stimulates an effective cough. After exhale, the system moves into a paused state and maintains a positive pressure flow to the patient, if programed. This is referred to as Positive Airway Pressure on Pause (PAP). An optional Sigh stage can also be included after the therapy to inflate the patient's lungs after the last exhale of the therapy.

The **Maximus™ System, when used as a Volara™ System** provides a therapy that enhances secretion removal and helps prevent or resolve patchy atelectasis.

The system delivers therapy in two modes:

- **CHFO (Continuous High Frequency Oscillation)**—a pneumatic form of chest physiotherapy that delivers medicated aerosol while oscillating the airways with continuous pulses of positive pressure.
- **CPEP (Continuous Positive Expiratory Pressure)**—supplies continuous positive pressure to help hold open and expand the airways.

With both therapy, the system can also deliver aerosolized medications and supplemental oxygen. The nebulizer kit of the Volara™ patient circuit is designed to aerosolize medication approved for nebulization and prescribed by a physician.

Indications for Use

The **Maximus™ System, when used as a Synclara™ Cough System** is indicated for, but is not limited to patients with these conditions:

- Muscular dystrophy
- Spinal muscular atrophy
- Amyotrophic lateral sclerosis
- Spinal cord injuries
- Myasthenia gravis
- Post polio
- COPD patient with a weak and ineffective cough

The **Maximus™ System, when used as a Volara™ System** is indicated for, but is not limited to patients with these conditions:

- Difficulty in clearance of secretions
- Pulmonary atelectasis

Contraindications

CONTRAINDICATION:

Contraindication—If patient conditions exist that cause the use of the system to be a risk to the patient, do not use the unit. Death or serious injury could occur.

Absolute Contraindications

The **Maximus™ System, when used as a Synclara™ Cough System** is contraindicated if these patient conditions exist:

- History of bullous emphysema, known susceptibility to pneumothorax, or pneumo-mediastinum, or known to have had any recent barotraumas
- Severe airway obstruction

The **Maximus™ System, when used as a Volara™ System** is contraindicated if this patient condition exists:

- Untreated tension pneumothorax

Draft_H_2019-Apr-26_Cleaned

Relative Contraindications

When you use the **Maximus™ System as a Synclara™ Cough System**, patients with these conditions should be carefully evaluated before a decision is made to use the therapy:

- Inability to tolerate the increased work of breathing
- Hemodynamic instability
- Intracranial pressure (ICP) > 20 mm Hg
- Acute sinusitis
- Recent facial, oral, or skull surgery or trauma
- Epistaxis
- Esophageal surgery
- Active hemoptysis
- Nausea
- Known or suspected tympanic membrane rupture or other middle ear pathology

When you use the **Maximus™ System as a Volara™ System**, patients with these conditions should be carefully evaluated before a decision is made to use the therapy:

- History of pneumothorax
- Pulmonary air leak
- Recent pneumonectomy
- Pulmonary hemorrhage
- Myocardial infarction
- Vomiting

Possible Adverse Conditions

When using the **Maximus™ System as a Synclara™ Cough System**, patients may experience one or more of these effects:

- Increased work of breathing leading to hypoventilation and hypercarbia.
- Cardiovascular compromise such as myocardial ischemia and decreased venous return.
- Swallowing too much air resulting in the likelihood of vomiting and aspiration.
- Claustrophobia.
- Skin break down and discomfort from face mask.
- Pulmonary barotraumas.

- Disruption of the healing process on patients who have had recent surgical procedures. Muscle contractions during the therapy could disrupt the healing process.

NOTE:

Patients with cardiac instability should be monitored closely for pulse and oxygen saturation.

When using the **Maximus™ System as a Volara™ System**, patients may experience one or more of these effects:

- Hyperventilation
- Gastric distension
- Decreased cardiac output
- Increased intracranial pressure
- Increased air trapping
- Hyperoxygenation
- Pneumothorax
- Pulmonary air leak
- Pulmonary hemorrhage

Draft_H_2019-Apr-26_Cleaned

SYMBOLS AND ACRONYMS

DOCUMENT SYMBOLS

This manual contains different typefaces and symbols to make the content easier to read and understand:

- Standard text—used for regular data.
- **Boldface text**—emphasizes a word or phrase.
- **NOTE:**—sets apart special data or important instruction clarification.
- CONTRAINDICATION, WARNING or CAUTION

  - A CONTRAINDICATION identifies situations or actions that may have an effect on patient safety.
  - A WARNING identifies situations or actions that may have an effect on patient or user safety. To ignore a warning could cause patient or user injury.
  - A CAUTION identifies special procedures or precautions that persons must obey to help prevent equipment damage.

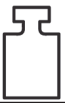
PRODUCT SYMBOLS

The following symbols may or may not be used on your Maximus™ System:

Symbol	Definition
	WARNING or CAUTION
	The Maximus™ System, Model POPT1 conforms to the European Medical Device Directive 93/42/EEC ***<Pending info from C&S>***
	***<Pending info from C&S>***
	Follow the operating instructions

Symbol	Definition
IP22	Rating for ingress protection in accordance with IEC 60259
	Unique Device Identification information
	Type B equipment with an F-type applied part, according to EN 60601-1
	Class II equipment (double insulated), according to EN60601-1
	Manufacturer or distributor complies with the Waste Electric and Electronic Equipment Directive 2002/96/EC
	Manufacture date
	Manufacturer
	Serial number
	Identifies a replaceable fuse link in an electronic circuit
	Catalog number
	Non sterile

Draft_H_2019-Apr-26_Cleaned

Symbol	Definition
	Single patient use
	Physician prescription required (for US only)
	Safe Working Load—this includes weight of control unit and accessories such as patient circuits
	Mass of the medical equipment
	Mass of the medical equipment including the mass of the control unit, accessories, patient circuits, and the pole clamp assembly
	Warning—Read the User Manual for safety information for the battery
	Physician prescription required. This system is certified for use on aircrafts. Complies with RTCA/DO-160G Section 21 Category M
	Nebulizer port
	Foot switch port (Available only on custom-configured systems.)
	USB port
	Power On/Off control

Common Screen Symbols

The following symbols may or may not be shown on the touchscreen.

Symbol	Description
	The system is connected to the AC power and not powered by the battery.
	The system is powered by the battery.
	The system is connected to a WiFi network.
	The system is transmitting data to the connected WiFi network.
	The system is connected to a cellular network.
	A Bluetooth® device is connected to the system.
	A USB drive is connected to the system.
	A foot switch is connected to the system and can be used to control Synclara™ therapy.
	Clinical Access is enabled. The user is able to access all features on the system.
	Clinical Access is disabled. Some features are not available to the user.

Draft_H_2019-Apr-26_Cleaned

Symbol	Description
	Heart rate of the patient.
	Blood oxygen saturation level of the patient.
	Strength of the cough flow.
	Tidal volume delivered to the patient during the therapy.

ACRONYMS

Acronym	Meaning
CHFO	Continuous High Frequency Oscillation
CPEP	Continuous Positive Expiratory Pressure
HPP	Highest Programed Pressure
PC	Pressure Ceiling
PAP	Positive Airway Pressure
PCF	Peak Cough Flow
SpO2	Blood Oxygen Saturation
Vt	Tidal Volume

SAFETY INSTRUCTIONS

When using electrical products, especially when children are present, basic safety precautions should always be followed, including the following important safeguards.

READ ALL INSTRUCTIONS BEFORE USING

Training shall be provided by a Hill-Rom qualified trainer or respiratory therapist before the user uses the system for therapy delivery.

WARNING:

Obey all **warnings** throughout the manual and also those below to help prevent injury and/or equipment damage:

- **Warning**—Only facility-authorized persons should open and service this system.
- **Warning**—Federal USA law restricts this product to sale by or on the order of a physician. Sale by or on the order of unauthorized persons can cause patient injury.
- **Warning**—We recommend your first use of this product be in a supervised setting such as a doctor's office or at home with a clinical trainer.
- **Warning**—This system should only be used by trained persons.
- **Warning**—Use this product only for its intended use as described in this manual. Do not use attachments not recommended by the manufacturer.
- **Warning**—Do not operate this system if it shows any signs of physical damages, faulty conditions, or malfunction (e.g. damaged power cord or plug, dropped, dropped in water, or if the touchscreen does not operate).
- **Warning**—Do not use the system near to any heat source or ignition source such as a fireplace or radiant heater.
- **Warning**—Never drop or insert any object into any opening or hose.
- **Warning**—Adult supervision is required to use the therapy on children.
- **Warning**—Close supervision throughout the treatment is necessary when this product is used by children or patients with physical limitations or impaired cognitive abilities.

Draft_H_2019-Apr-26_Cleaned

WARNING:

(Warnings continued) Obey all **warnings** throughout the manual and also those below to help prevent injury and/or equipment damage:

- **Warning**—Make sure the position of the control unit is such that you can quickly, without obstruction, disconnect the power cord from the power outlet in the wall, if required.
- **Warning**—If it is necessary to disconnect/isolate the product from the main power supply, disconnect the power cord plug from the power inlet on the back of the control unit or disconnect the power cord from the power outlet on the wall.
- **Warning**—No modification of this product is permitted.
- **Warning**—Do not operate the system under harsh conditions (e.g. extreme temperature, excessive moisture, strong magnetic fields). See Environmental Conditions for Use in "Specifications" on page 121.
- **Warning**—Do not operate the system if fluid is spilled on the control unit.
- **Warning**—Do not use the system near flammable chemicals or products, including flammable anesthetics.
- **Warning**—Keep the hoses, tubings, and power cord away from toddlers and children to avoid strangulation.
- **Warning**—Keep the small parts provided with this product away from children to avoid swallowing and causing a choking effect.
- **Warning**—Do not connect any equipment or accessories to the USB port on the system, except for Hill-Rom approved accessories (See "Accessories" on page 88). The USB port on the back of the system is only for retrieving information as described in this user manual.
- **Warning**—Use only Hill-Rom authorized air hoses and accessories to avoid allergic skin reactions.
- **Warning**—Do not store or use the system around pets, pests, or unsupervised children.
- **Warning**—Keep the unit, battery, AC/DC power adapter, and power cord away from heated surfaces.
- **Warning**—Remove the rechargeable battery from the control unit if the control unit is not going to be used for an extended period of time.
- **Warning**—Before cleaning, unplug the system from its power source and remove the battery.

WARNING:

(Warnings continued) Obey all **warnings** throughout the manual and also those below to help prevent injury and/or equipment damage:

- **Warning**—Do not allow any metallic conductive objects to contact the battery terminals. Do not short circuit a battery or throw it into the fire; it can explode and cause severe personal injury.
- **Warning**—Improper battery use may result in a fire, explosion, or other hazard.
- **Warning**—Use only the supplied nebulizer kit in the patient circuit.
- **Warning**—Do not use this system without a bio-filter.
- **Warning**—Do not use the system in a dusty environment.
- **Warning**—This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.
- **Warning**—The Maximus™ System is MR Unsafe. Do not expose the system to any magnetic resonance (MR) environment.

  NOTES:

  - The system may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
  - The system may not function properly due to the strong magnetic and radio frequency fields generated by the MR equipment.

Draft_H_2019-Apr-26_Cleaned

CAUTION:

Obey all **cautions** throughout the manual and also those below to help prevent equipment damage:

- **Caution**—Read the User Manual before use.
- **Caution**—Do not block the air openings of the system or place it on a soft surface, such as a bed or couch, where the air openings may be blocked. Keep the air openings free of lint, hair, and the like.
- **Caution**—If there is an ingress of liquids through the case or as a result of not using a bio-filter, return the system for factory service.
- **Caution**—Use only parts and accessories from Hill-Rom. Do not use any unauthorized parts or accessories with this product.
- **Caution**—Use the Maximus™ System only with the Hill-Rom approved pulse oximeter (196694). The data from the pulse oximeter is for information purposes only.
- **Caution**—Use the Maximus™ System only with the Hill-Rom approved replaceable battery (194566S).
- **Caution**—Do not open, crush, puncture, or incinerate the battery. Do not immerse the replaceable battery in water, or heat it over 140°F (60°C).

NOTE:

Caution—If the replaceable battery is used, fully charge the battery to 100% before first time use. Allow up to 8 hours for the initial full battery charge to take place.For product assistance or to report issues with the Maximus™ System, Model POPT1, contact Hill-Rom:

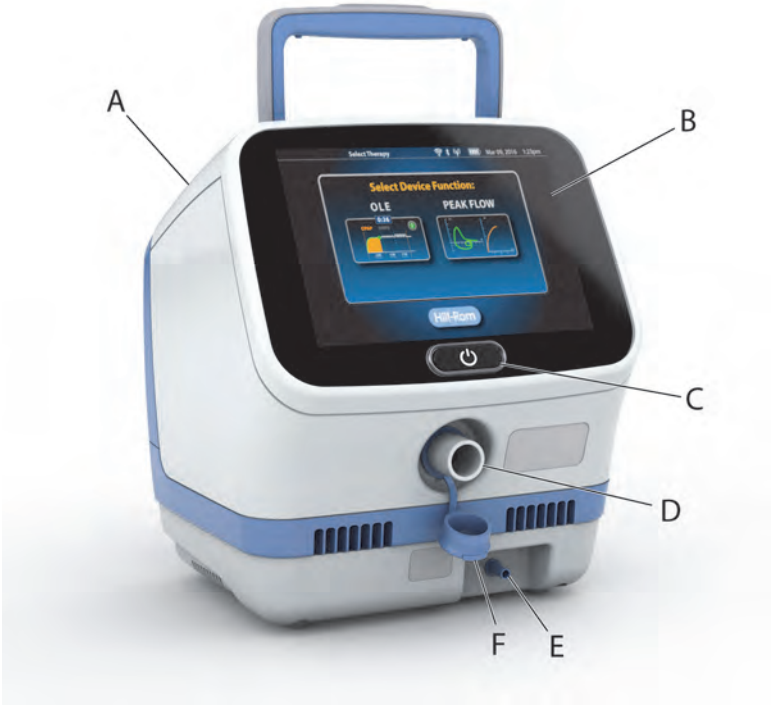
- In the USA, call Hill-Rom at 800-426-4224.
- Outside of the USA, contact your distributor or local Hill-Rom representative, or go to www.respiratorycare.hill-rom.com.

SAVE THESE INSTRUCTIONS

FEATURES

CONTROL UNIT

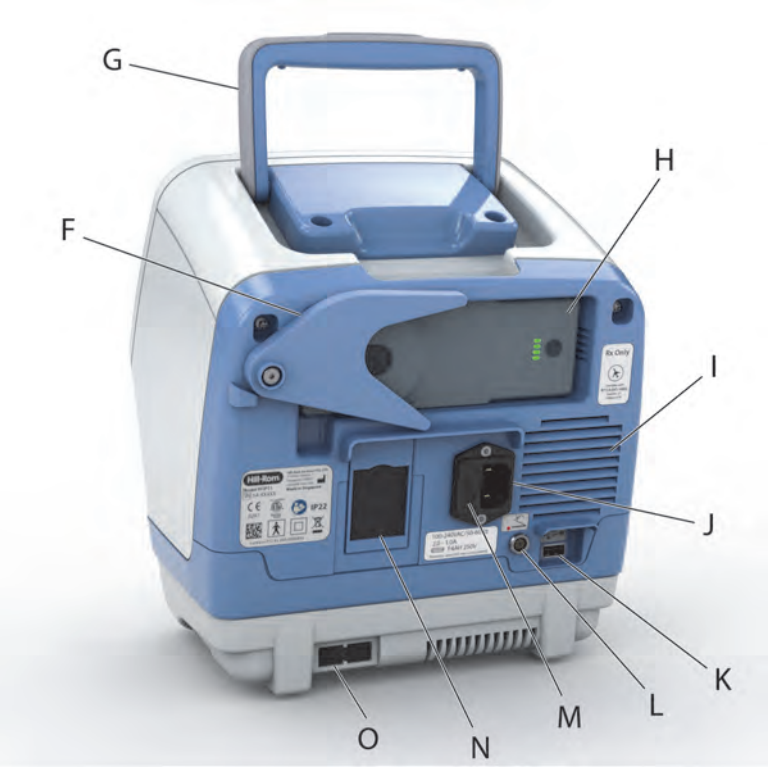
Front



Item	Description	Item	Description
A	Control unit	D	Therapy port
B	Touchscreen	E	Nebulizer port
C	Power On/Off button	F	Therapy port cap

Draft_H_2019-Apr-26_Cleaned

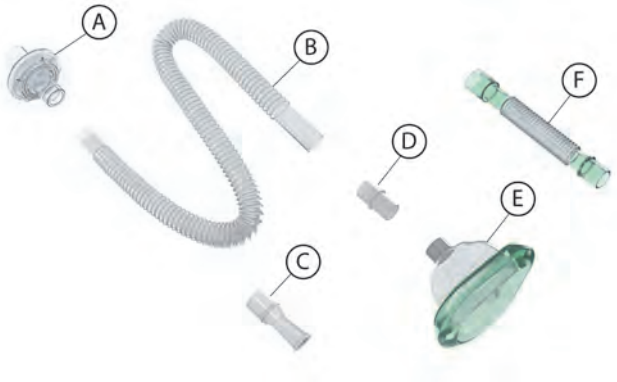
Back



Item	Description	Item	Description
F	Patient circuit hook	K	USB port
G	Handle	L	Foot switch port (optional)
H	Replaceable battery (optional)	M	Fuse holder
I	Ventilation fan	N	Air inlet filter
J	Power inlet	O	Nebulizer filter

Draft_H_2019-Apr-26_Cleaned

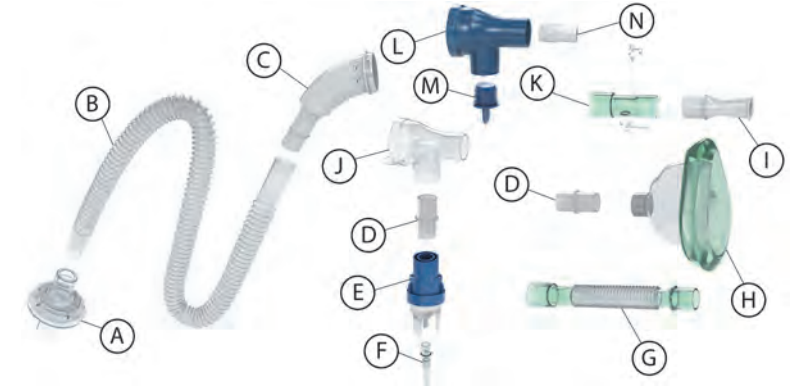
SYNCLARA™ COUGH SYSTEM SINGLE PATIENT USE CIRCUIT



Item	Description	Item	Description
A	Bio-filter	D	Adapter, 22 mm x 22 mm
B	Breathing hose	E	Face mask (optional)
C	Mouthpiece	F	Flexible tracheostomy adapter (optional)

Draft_H_2019-Apr-26_Cleaned

VOLARA™ SINGLE PATIENT USE CIRCUIT



Item	Description	Item	Description
A	Bio-filter	H	Face mask (optional)
B	Breathing hose	I	Mouthpiece
C	Handset	J	Clear spontaneous breathing adapter (optional)
D	Adapter, 22 mm x 22 mm	K	Oxygen bleed-in adapter (optional)
E	Nebulizer kit	L	Blue ventilator adapter (optional)
F	Nebulizer tubing	M	Handset plug (optional)
G	Flexible tracheostomy adapter (optional)	N	In-line ventilator adapter, 22 mm x 15 mm (optional)

Draft_H_2019-Apr-26_Cleaned

ASSEMBLE AND CONNECT THE PATIENT CIRCUIT

WARNING:

To help prevent injury and/or equipment damage, obey these **warnings**:

- **Warning**—Do not operate the system unless a bio-filter is attached to the system.
- **Warning**—Do not use excessive force when assembling or disassembling the patient circuit. This helps to avoid damage to the components.
- **Warning**—To avoid cross-contamination, always use a new patient circuit when using the system on a new patient.
- **Warning**—Discard the circuit in accordance with facility protocols.
- **Warning**—Do not attempt to sterilize the circuit for reuse.

NOTES:

- Each patient circuit is for use by a single patient and intended for 30 days of treatment or a maximum of 90 treatment sessions.
- If the circuit and/or bio-filter are damaged or visibly soiled, replace them. See "Replacement Parts/Kits" on page 102.
- The system keeps a log of the number of use cycles for the patient circuit. If a patient circuit is used beyond its recommended usable life, the system notifies the user.

For assistance with setup, use, or maintenance of the system, contact Hill-Rom:

- In the USA, call Hill-Rom at 800-426-4224.
- Outside the USA, contact your distributor or local Hill-Rom representative, or go to www.respiratorycare.hill-rom.com.

Connect the correct patient circuit for each form of therapy:

- For connecting the Synclara™ patient circuit, see page 20
- For connecting the Volara™ patient circuit, see page 21.

Draft_H_2019-Apr-26_Cleaned

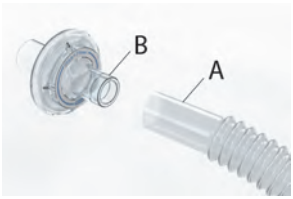
CONNECT THE SYNCLARA™ PATIENT CIRCUIT

WARNING:

Warning—The patient circuit is for single patient use only. Always use a new patient circuit when using the system on a new patient. Failure to do so could cause cross contamination.

CAUTION:

1. Attach one end of the breathing hose (A) to the smaller end of the bio-filter (B).

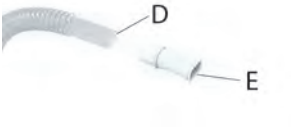


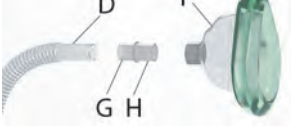
2. Align the larger end of the bio-filter (C) with the therapy port on the control unit.
3. Gently turn the bio-filter (C) to secure it to the therapy port.

NOTE:

Make sure the frosted part of the bio-filter covers the therapy port entirely.

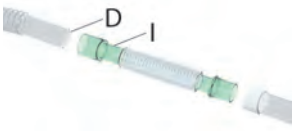
4. Connect the appropriate patient interface:
   - **Mouthpiece** (E)—Insert and gently twist the mouthpiece into the free end (D) of the breathing hose.
   - **Face mask** (F)—
     a. Insert and gently twist the adapter (G) into the free end (D) of the breathing hose.
     b. Connect the other end of the adapter (H) to the face mask (F).





Draft_H_2019-Apr-26_Cleaned

- **Flexible tracheostomy adapter** (I)—



  a. Insert and gently twist the tracheostomy adapter (I) into the free end (D) of the breathing hose.
  b. Connect the other end of the flexible tracheostomy adapter to the tracheostomy tube (patient's own).

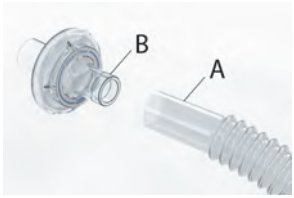
CONNECT THE VOLARA™ PATIENT CIRCUIT

WARNING:

Warning—The patient circuit is for single patient use only. Always use a new patient circuit when using the system on a new patient. Failure to do so could cause cross contamination.

CAUTION:

1. Attach one end of the breathing hose (A) to the smaller end of the bio-filter (B).



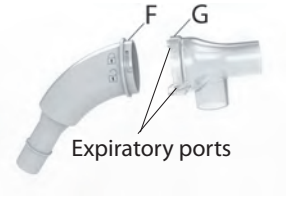
2. Align the larger end of the bio-filter (C) with the therapy port on the control unit.
3. Gently turn the bio-filter (C) to secure it to the therapy port.

NOTE:

Make sure the frosted part of the bio-filter covers the therapy port entirely.

4. Connect the other end of the breathing hose (D) to the inlet port of the handset (E).

5. Connect the other side of the handset (F) to the front of the clear spontaneous breathing adapter (G).



WARNING:

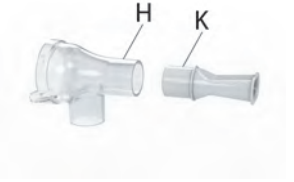
Warning—During the therapy, make sure the expiratory ports on the clear spontaneous breathing adapter (G) are not blocked. This prevents carbon dioxide from accumulating in the system.

6. Connect and twist the parts until they lock into position.

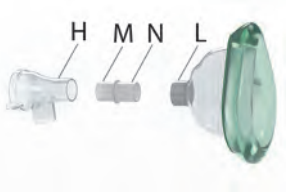
7. Connect the appropriate patient interface:

NOTE:

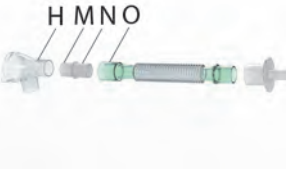
- **Mouthpiece** (K)—Insert and twist the mouthpiece (K) into the output port of the clear spontaneous breathing adapter (H).



- **Face mask** (L)—
  a. Insert and gently twist the adapter (M) into the output port of the clear spontaneous breathing adapter (H).
  b. Connect the other end of the adapter (N) to the face mask (L).



- **Flexible tracheostomy adapter** (O)—
  a. Insert and gently twist the adapter (M) into the output port of the clear spontaneous breathing adapter (H).
  b. Connect the other end of the adapter (N) to the flexible tracheostomy adapter (O).
  c. Connect the other end of the flexible tracheostomy adapter to the tracheostomy tube (patient's own).



Draft_H_2019-Apr-26_Cleaned

8. Assemble the nebulizer kit and add the prescribed medication. See page 26.

NOTE:

If the nebulizer kit is not used, make sure the handset plug is installed tightly to cover the nebulizer port on the handset.

Draft_H_2019-Apr-26_Cleaned

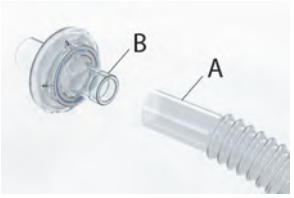
Connect the Volara™ Patient Circuit for In-line Ventilation Therapy

WARNING:

To help prevent injury and/or equipment damage, obey these **warnings**:

- **Warning**—The patient circuit is for single patient use only. Always use a new circuit when using the system on a new patient. Failure to do so could cause cross contamination.
- **Warning**—Only persons trained to use the Maximus™ System and ventilators should provide the therapy to ventilated patients.

1. Attach one end of the breathing hose (A) to the smaller end of the bio-filter (B).



2. Align the larger end of the bio-filter (C) with the therapy port on the control unit.
3. Gently turn the bio-filter (C) to secure it to the therapy port.

NOTE:

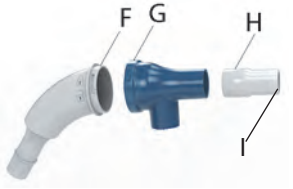
Make sure the frosted part of the bio-filter covers the therapy port entirely.

4. Connect the other end of the breathing hose (D) to the inlet port of the handset (E).

NOTE:

If the clear spontaneous breathing adapter is connected to the handset, disconnect it before you do the next step.

5. Connect the handset (F) to the front of the blue ventilator adapter (G) and twist the parts until they lock into position.
6. Connect the in-line ventilator adapter (H) to the output port of the blue ventilator adapter (G).



Draft_H_2019-Apr-26_Cleaned

7. Connect a spring-valve "tee" adapter into the inspiratory limb of the patient circuit (I). See Step 6.

NOTE:

If required, attach the oxygen bleed-in adapter to the output port of the blue ventilator adapter (G).

8. Assemble the nebulizer kit and add the prescribed medication. See page 26.
    - If the nebulizer is not required, make sure the handset plug is installed tightly to cover the nebulizer port on the blue ventilator adapter.

Connect the Volara™ Patient Circuit to an Oxygen Source

WARNING:

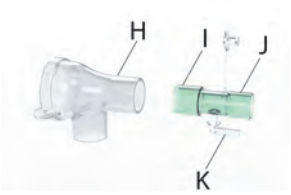
To help prevent injury and/or equipment damage, obey these **warnings**:

- **Warning**—Do not connect the system to an unregulated or high-pressure oxygen source.
- **Warning**—The patient circuit is for single patient use only. Always use a new patient circuit when using the system on a new patient. Failure to do so could cause cross contamination.

CAUTION:

Caution—When using oxygen with this system, power on the system before you turn on the oxygen source. Before you power down the system, turn off the oxygen source. This helps to prevent oxygen from accumulating in the system.

1. Connect the patient circuit following Step 1 to Step 6 in section "Connect the Volara™ Patient Circuit" on page 21.
2. Connect one end of the oxygen bleed-in adapter (I) to the output port of the clear spontaneous breathing adapter (H).
3. Connect the patient circuit to the other end of the oxygen bleed-in adapter (J).
4. Connect the oxygen bleed-in adapter (K) to the oxygen tubing from the oxygen source (for example, a flow-meter or oxygen concentrator).



Draft_H_2019-Apr-26_Cleaned

Assemble the Nebulizer Kit and Add Medication

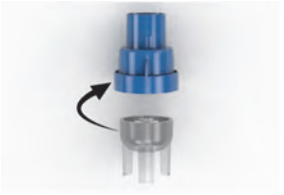
CAUTION:

Caution—The fill volume of the nebulizer cup is 2 - 10 ml. Do not fill the medication out of the limits stated above.

NOTE:

A fill volume of 2.5 ml of medication is expected to last 10 minutes of nebulization.

1. Remove the lid from the nebulizer cup.



2. Fill the nebulizer cup with the prescribed medication.

3. Replace the lid.
4. Attach one end of the nebulizer tubing to the nebulizer port on the control unit.

5. Attach the other end of the tubing to the base of the nebulizer cup.

Draft_H_2019-Apr-26_Cleaned

6. Connect the adapter (22 mm x 22 mm) to the nebulizer port of the clear spontaneous breathing adapter or blue ventilator adapter.
7. Connect the nebulizer kit to the adapter attached to the nebulizer port.
8. The nebulizer kit is now connected to the patient circuit and control unit.

Draft_H_2019-Apr-26_Cleaned

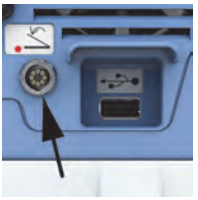
SET UP AND POWER ON THE CONTROL UNIT

Warning—Never block the air openings of the system or set it on a soft surface, such as a bed or couch, where the air openings may be blocked. Keep the air openings free of lint, hair, and the like. Otherwise, patient injury could occur.

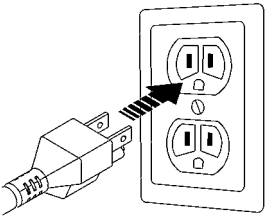
NOTES:

- If the control unit is taken out from storage, do the following before use:
  - Allow the control unit to **warm up** in an ambient environment of 68°F (20°C) for at least **45 minutes** when removed from a storage temperature of -4°F (-20°C) or colder.
  - Allow the control unit to **cool down** in an ambient environment of 68°F (20°C) for at least **80 minutes** when removed from a storage temperature of 140°F (60°C) or warmer.
- If the control unit is on the cart, make sure the casters are set. For instructions on mounting the control unit on the cart, see page 95.

1. Set the control unit on a dry, flat, and hard surface. Make sure the control unit is away from curtains, blankets, or any heat-generating devices.
   - If a foot switch[1] is used, connect the foot switch to the foot switch port on the control unit. See “Foot Switch” on page 94.



2. Follow the steps that apply to the power source used:
   - **AC power**—
     a. Connect the power cord to the back of the control unit.
     b. Connect the other end to an applicable power outlet.



1. The foot switch port is available only on custom configured systems.

Draft_H_2019-Apr-26_Cleaned

NOTE:

The power cord shown is for illustrative purposes and may differ from the one required for your country.

- **Battery power**—insert the battery into the battery compartment on the back of the control unit.

3. Press and hold the **Power** button on the control unit for **5 seconds**.

The Hill-Rom screen shows.

4. To start a therapy, see "Synclara™ Therapy" on page 32 or "Volara™ Therapy" on page 51.

POWER OFF THE CONTROL UNIT AND STORE THE SYSTEM

When the therapy is complete, do these steps:

1. Press and hold the **Power** button for **5 seconds.**
   - If the system is operating on **AC power**, it enters into sleep mode.
   - If the system is operating on **battery**, it powers off.

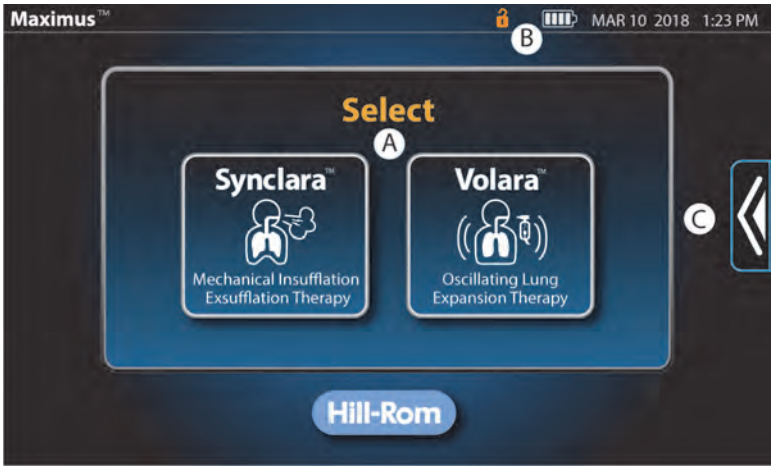
   NOTE:

   If the system is in sleep mode and a battery is installed, the system will charge the battery (if it is not fully charged).
2. Detach the patient circuit and accessories from the control unit.
3. Clean the control unit, patient circuit, and accessories. Follow the instructions in "Cleaning and Disinfecting" on page 103 or according to facility protocols.
4. Store the control unit, patient circuit, and accessories. Follow the instructions in "Storage and Handling" on page 119.

Draft_H_2019-Apr-26_Cleaned

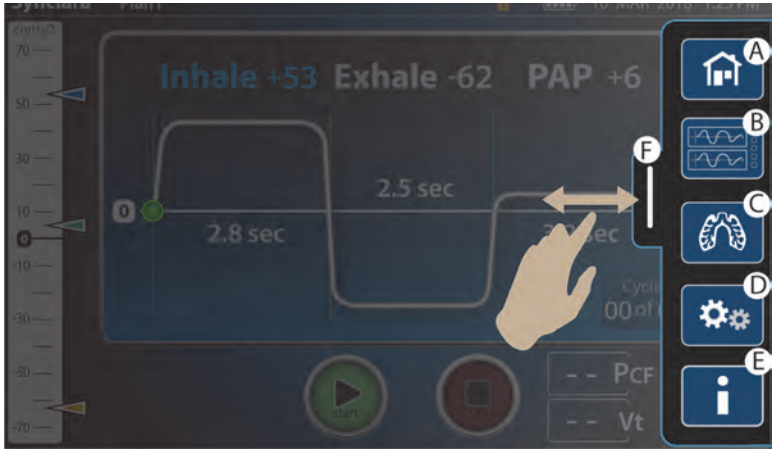
GETTING STARTED

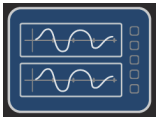
About the Home Menu



Item	Description	Item	Description
A	Therapy Selection—Synclara™ therapy or Volara™ therapy	C	Options menu
B	Status indicators		

About the Options Menu



Item	Option	Description
A		**Home**—Go to the Home menu.
B		**Advanced View**—See an advanced view of a therapy summary.
C		**Care Plan**—Access the preset therapy settings.
D		**Device Settings**—Access the device control settings, enable clinical access, retrieve logs, and configure connections to accessories (available only if enabled).
E		**Help**—View on-screen help information to guide you in using the system.
F	Pull tab	Access or exit the **Options** menu.

Draft_H_2019-Apr-26_Cleaned

SELECT A THERAPY

NOTE:
Avoid operating the touchscreen with wet fingers as this will reduce the screen response.

At the **Home** screen, select one of the therapy options:

- **Synclara™**—for Mechanical Insufflation Exsufflation therapy. See "Synclara™ Therapy" on page 32.
- **Volara™**—for Oscillation Lung Expansion therapy. See "Volara™ Therapy" on page 51.

SYNCLARA™ THERAPY

START A THERAPY

NOTES:

- Always use the settings prescribed by the physician.
- Avoid operating the touchscreen with wet fingers as this will reduce the screen response.

Synclara™ therapy is available in both automatic and manual modes.

1. Select the preferred therapy mode—
   - A—**Automatic** therapy mode
   - B—**Manual** therapy mode
2. If possible, have the patient sit in an upright position.

3. Before you begin the therapy, put the patient interface into position on the patient. Make sure the patient maintains a tight seal on the face mask or mouthpiece during the therapy.
   - **Face mask**—Tightly, but comfortably, cover the mouth and nose of the patient. Make sure the narrow end of the mask is over the patient's nose.
   - **Mouthpiece**—Put the mouthpiece lightly in the patient's mouth. Make sure that the patient maintains a tight seal on the mouthpiece during the therapy.
   - **Flexible tracheostomy adapter**—If the patient has a tracheostomy tube or endotracheal tube, use the flexible tracheostomy adapter to connect the tracheal tube to the system. See Step 4 on page 20.
     When the prescribed Inhale, Exhale, and PAP cycles are not being delivered by the system, disconnect the flexible tracheostomy adapter from the tracheostomy tube or endotracheal tube to permit the patient to breathe freely through the tracheal tube. At the same time, coach the patient to make spontaneous cough efforts to expel any mucus.
4. Follow the steps that apply to the prescribed therapy modes:
   - Automatic mode—see "Synclara™ Therapy in Automatic Mode" on page 34.
   - Manual mode—see "Synclara™ Therapy in Manual Mode" on page 39.

Draft_H_2019-Apr-26_Cleaned

SYNCLARA™ THERAPY IN AUTOMATIC MODE

Basic View in Automatic Mode

Item	Description	Item	Description
A	Name of the preset therapy selected	E	Start/stop controls
B	Pressure meter/digital manometer	F	Peak Cough Tidal Volume
C	Therapy status	G	Flow control
D	Heart rate and pulse oximeter readings (available only if a pulse oximeter is connected)		

Start a Therapy in Automatic Mode

NOTES:

- Before you start a therapy, make sure you have connected the appropriate patient circuit to the system. "Connect the Synclara™ Patient Circuit" on page 20.
- Make sure the patient circuit is put into position on the patient. See Step 4 on page 20.

1. Press **Automatic**.

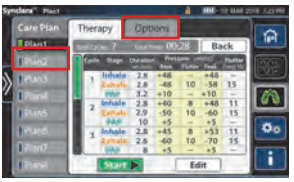
   - If prompted, scan the patient's ID barcode with the paired barcode reader. For pairing instructions, see page 74.

   The last used preset therapy is selected.

   - If required, press the **Flow** control to toggle between different intensities of air movement to deliver during the therapy.

2. To start the therapy, press **Start**.
   - To select another preset therapy, follow these steps:
     a. Swipe the **Options** tab left, and press the **Care Plan** menu control.

     b. Select the preferred preset therapy plan.
     c. Review the therapy settings to make sure they match the prescription. Select another plan if required.



     d. If required, press **Options** to enable or disable, and adjust the settings for **Patient Synchrony** and **End with Sigh**. See page 37.

Draft_H_2019-Apr-26_Cleaned

NOTE:

To modify a preset therapy plan, see page 50.

3. Press **Start**. The therapy begins.

   During the therapy, follow these guidelines:

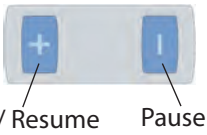
   - During the **Inhale** stage, have the patient breathe normally as directed by the clinician until his/her lungs fill to capacity.
   - During the **Exhale** stage, have the patient attempt to cough or huff.
   - Between cycles, examine the inside of the face mask, mouth piece, flexible tracheostomy adapter, and/or tracheal tube. If you see or suspect that there is mucus and the patient can not spontaneously expel it, you may pause the therapy and help the patient to clear the mucus. If necessary, use suctioning devices as directed by the physician.

   You can **Pause** or **Stop** a therapy. Or, press **Resume** to continue a paused therapy session.

NOTE:

On custom-configured systems with the foot switch option—

- To **start** or **resume** a therapy, press **+**.
- To **pause** a therapy, press **-**.

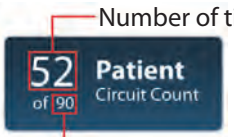


If a therapy is paused for more than 3 minutes, the therapy will stop and a warning message will show. Follow the on-screen instructions.

4. When the therapy is stopped or complete, the therapy summary shows.

NOTE:

Note the number of treatment sessions carried out with the connected patient circuit.



5. Press **Back** to go to the automatic therapy screen.

6. To go to the **Home** menu, swipe the **Options** tab left and press the **Home** menu control.

Adjust the Patient Synchrony and End with Sigh settings

NOTE:

Only available in Synclara™ Automatic mode.

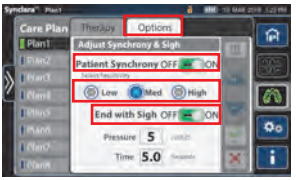
Patient Synchrony allows the system to synchronize cough cycles with the patient's breath pattern. When enabled, the therapy starts in **Pause** stage. When the patient's inhale effort is detected, the **Inhale** stage activates automatically.

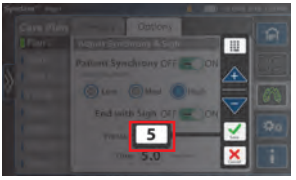
The **End with Sigh** feature allows the system to help the patient open up the collapsed alveoli during the last **Exhale** of the therapy.

1. Select a preset therapy plan.

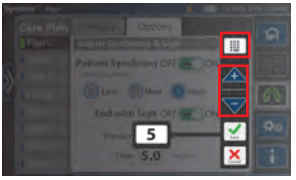
Draft_H_2019-Apr-26_Cleaned

2. Press **Options**.
3. To enable **Patient Synchrony**—
   a. Slide the setting to **ON**.
   b. Select the preferred level of sensitivity: **Low**, **Medium** or **High**.
4. To enable **End with Sigh**—
   a. Slide the setting to **ON**.
   b. Press the setting to change the **Pressure** or **Time**.





   c. Press the keypad control, and enter the required setting, or use the **+** or **–** controls to adjust the setting.



   d. Press **Save** to save the changes. Or, press **Cancel**.

Access the Advanced View

1. Before you start the therapy, swipe the **Options** tab left, and press the **Advanced View** control.

   The **Advanced View** shows.
2. Press **Start** to begin the therapy.

SYNCLARA™ THERAPY IN MANUAL MODE

Basic View in Manual Mode

Item	Description	Item	Description
A	Therapy controls	E	Start/stop control
B	Pressure meter/digital manometer	F	Flow control
C	Heart rate and pulse oximeter readings (available only if a pulse oximeter is connected).	G	Flutter (Pressure oscillation) control
D	Peak Cough Tidal Volume		

Draft_H_2019-Apr-26_Cleaned

Start a Therapy in Manual Mode

NOTES:

- Before you start a therapy, make sure you have connected the appropriate patient circuit to the system. "Connect the Synclara™ Patient Circuit" on page 20.
- Make sure the patient circuit is put into position on the patient. See Step 4 on page 20.

1. Press **Manual**.

   If prompted, scan the patient's ID barcode with the paired barcode reader. For pairing instructions, see page 74.

   The manual therapy screen shows the last used therapy settings.

2. Use the + or – control to select the pressure settings. Or, press the setting and use the keypad control to enter the required setting.
3. Press **Enter** to confirm the setting.

   NOTE:

   The maximum pressure that can be set depends on the pressure ceiling limit defined in the **Clinical Access** settings. See page 72.

   - If required, press **Flutter** to adjust the pressure, frequency, and enable or disable the Flutter feature. To return to the therapy screen, press the **Flutter** control. When therapy begins, you can not adjust **Flutter**.

- If required, press **Flow** to toggle between different intensities of air movement during the therapy.

4. Press **Start**.

When pressure is ready for therapy, the **Inhale** control is lighted.

5. Press and hold the **Inhale** control to activate the **Inhale** stage.
Or, press and hold the **Exhale** control to activate the **Exhale** stage.

   During the therapy, follow these guidelines:

   - During the **Inhale** stage, have the patient breathe normally, or as directed by the clinician, until his/her lungs fill to capacity.
   - During the **Exhale** stage, have the patient attempt to cough or huff.
   - Between cycles, examine the inside of the face mask, mouth piece, flexible tracheostomy adapter, and/or tracheal tube. If you see or suspect that there is mucus and the patient can not spontaneously expel it, you may pause the therapy and help the patient to clear the mucus. If required, use suctioning devices as directed by the physician.

   If you do not press any controls, the therapy defaults to the PAP stage.

Draft_H_2019-Apr-26_Cleaned

NOTE:

On custom configured systems with the foot switch option—

- To activate the **Inhale** stage, press and hold **+.**
- To activate the **Exhale** stage, press and hold **-**
- Release the control to deactivate each stage.

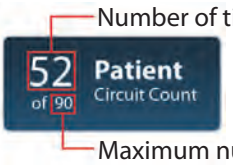
Activate **Inhale**

Activate **Exhale**

6. When the therapy is complete, press **Stop**. The therapy summary shows.

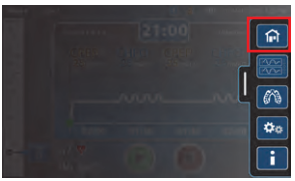
NOTE:

Note the number of treatment sessions carried out with the connected patient circuit.



7. Press **Back** to go to the initial therapy screen.

8. Swipe the **Options** tab left and press the **Home** menu control.



ADVANCED SYNCLARA™ THERAPY SETTINGS

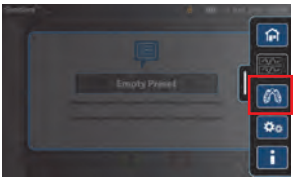
These settings allow you to create, modify, rename, and/or delete a preset therapy.

Create a New Preset Therapy Plan

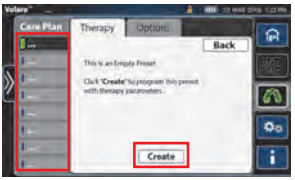
NOTE:
Available only if **Clinical Access** is enabled. See page 71.

1. Press **Automatic**.

2. Swipe the **Options** tab left, and press the **Care Plan** menu control.



3. Select an empty preset plan, and press **Create**.



4. Press **Add+** to add a new cycle after the current cycle. Or, press **Del-** to delete the current cycle.

   When a confirmation message shows, select **Proceed** or **Cancel**.

5. Swipe right or left to select a cycle.

Draft_H_2019-Apr-26_Cleaned

6. At each cycle, select the preferred option to adjust its settings:


Inhale (Blue)


Exhale (Orange)


PAP (Green)

You can adjust these settings for each cycle:

- Duration of therapy session
- Therapy pressure
- Enable, disable, or adjust **Flutter.**
  - **Flutter** refers to the fluctuations of therapy pressure, as a pneumatic form of chest physiotherapy to assist the patient loosen and remove secretions.

7. Press the setting to change it.

8. Press the keypad control and enter the required setting, or use the **+** or **–** control to adjust the setting.

NOTE:

The maximum pressure that can be set depends on the pressure ceiling limit defined in the **Clinical Access** settings. See page 72.

9. Press **Save** to save the changes.
Or, press **Cancel**.

10. To enable or disable **Flutter** pressure, slide the setting to **ON** or **OFF**.

11. To adjust **Flutter** and **Frequency,** press the setting to change it.

    a. Press the keypad control and enter the required setting, or use the **+** or **–** control to adjust the setting.

    b. Press **Save** to save the changes. Or, press **Cancel**.

12. To confirm all settings, press **Done**.

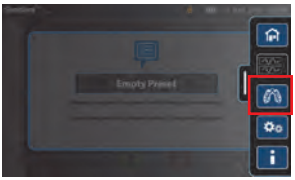
    The new therapy plan is added to the **Care Plan** menu.

    NOTE:

    To prevent unauthorized persons from adjusting the settings made, disable **Clinical Access** after you have made the settings.

    Press **Device**, then press **Control**. Slide **Clinical Access** to **OFF**.

13. To start a therapy with the new Care Plan, swipe the **Options** tab left, and press the **Care Plan** menu control.



Draft_H_2019-Apr-26_Cleaned

14. Select the new **Care Plan** and press **Start**.

The therapy begins.

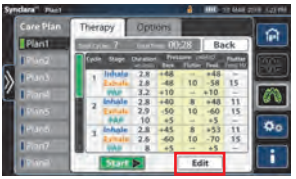
Modify a Preset Therapy Plan

NOTE:
Available only if **Clinical Access** is enabled. See page 71.

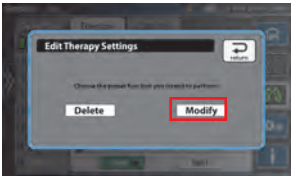
1. Press **Automatic**.

2. Swipe the **Options** tab left, and press the **Care Plan** menu control.

3. Select a preset therapy plan, and review the therapy settings.
4. Press **Edit**.

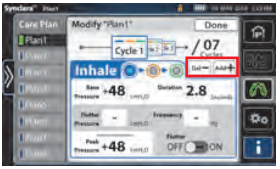


5. When prompted, press **Modify**.



6. Press **Add+** to add a new cycle after the current cycle. Or, press **Del-** to delete the current cycle.

   When a confirmation message shows, select **Proceed** or **Cancel**.



7. Swipe right or left to select a cycle.

8. At each cycle, select the preferred option to adjust its settings:

   Inhale (Blue)

   Exhale (Orange)

   PAP (Green)

   You can adjust these settings for each cycle:
   - Duration of the therapy session
   - Therapy pressure
   - Enable, disable, or adjust **Flutter**
     - **Flutter** refers to the fluctuations of therapy pressure, as a pneumatic form of chest physiotherapy assisting in loosening and removing secretions.

9. Press the setting to change it.

10. Press the keypad control and enter the required setting, or use + or – controls to adjust the setting.

   NOTE:
   The maximum pressure that can be set depends on the pressure ceiling limit defined in the **Clinical Access** settings. See page 72.

11. Press **Save** to save the changes.
    Or, press **Cancel**.

12. To enable or disable **Flutter** pressure, slide to **ON** or **OFF**.

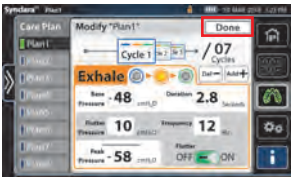
Draft_H_2019-Apr-26_Cleaned

13. To adjust **Flutter** and **Frequency,** press the setting to change it.

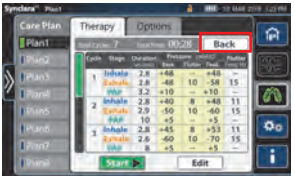
a. Press the keypad control and enter the required setting, or use the **+** or **–** control to adjust the setting.

b. Press **Save** to save the changes. Or, press **Cancel**.

14. To confirm all settings, press **Done**.



15. Press **Back** to go to the initial therapy screen.



NOTE:

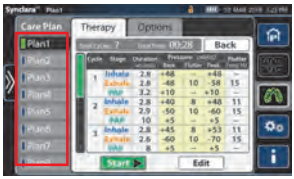
To prevent unauthorized persons from adjusting the settings made, disable **Clinical Access** after you have made the settings.

Press **Device**, then press **Control**. Slide **Clinical Access** to **OFF**.

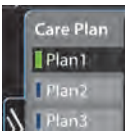
Rename a Preset Therapy Plan

NOTE:
Available only if **Clinical Access** is enabled. See page 71.

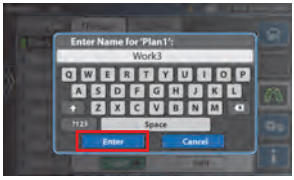
1. Select the plan to rename.



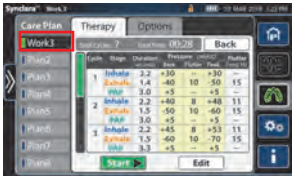
2. Press and hold the therapy plan until the on-screen keyboard shows.



3. Use the on-screen keyboard to enter any 5 alphanumeric characters, and press **Enter**.



The new name is saved.



NOTE:
To prevent unauthorized persons from adjusting the settings made, disable **Clinical Access** after you have made the settings.

Press **Device**, then press **Control**. Slide **Clinical Access** to **OFF**.

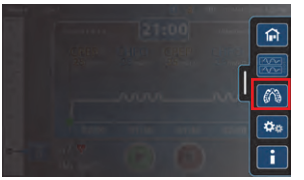
Draft_H_2019-Apr-26_Cleaned

Delete a Preset Therapy Plan

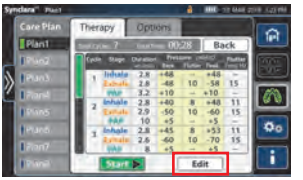
NOTE:
Available only if **Clinical Access** is enabled. See page 71.

1. Press **Automatic**.

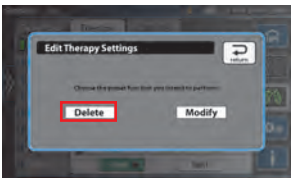
2. Swipe the **Options** tab left, and press the **Care Plan** menu control.



3. Select the plan to delete.
4. Press **Edit**.



5. When prompted, press **Delete**.



The initial care plan screen shows and the selected preset therapy is removed.

NOTE:
To prevent unauthorized persons from adjusting the settings made, disable **Clinical Access** after you have made the settings.

Press **Device**, then press **Control**. Slide **Clinical Access** to **OFF**.

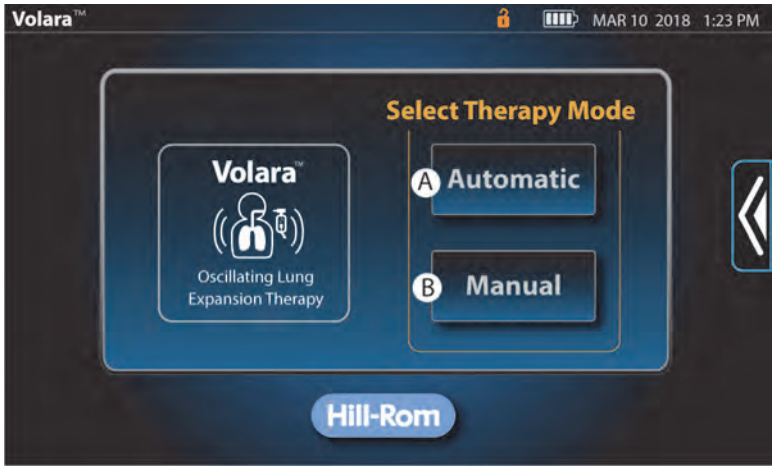
VOLARA™ THERAPY

START A THERAPY

NOTES:

- Always use the settings prescribed by the physician.
- Avoid operating the touchscreen with wet fingers as this will reduce the screen response.

Volara™ Therapy as a is available in both automatic and manual mode.



1. Select the preferred therapy mode—
   - A—**Automatic** therapy mode
   - B—**Manual** therapy mode
2. If possible, have the patient sit in an upright position.
3. Before you begin the therapy, put the patient interface into position on the patient. Make sure the patient maintains a tight seal on the face mask or mouthpiece during the therapy.
   - **Face mask**—Tightly, but comfortably, cover the mouth and nose of the patient. Make sure the narrow end of the mask is over the patient's nose.
   - **Mouthpiece**—Put the mouthpiece lightly in the patient's mouth. Make sure that the patient maintains a tight seal on the mouthpiece during the therapy.
   - **Flexible tracheostomy adapter**—If the patient has a tracheostomy tube or endotracheal tube, use the flexible

Draft_H_2019-Apr-26_Cleaned

tracheostomy adapter to connect the tracheal tube to the system. See Step 7 on page 22.

4. Follow the steps that apply to the prescribed therapy mode:
   - Automatic mode—see “Volara™ Therapy in Automatic Mode” on page 53.
   - Manual mode—see “Volara™ Therapy in Manual Mode” on page 57.

VOLARA™ THERAPY IN AUTOMATIC MODE

Basic View in Automatic Mode

Item	Description	Item	Description
A	Name of the preset therapy selected	D	Heart rate and pulse oximeter readings (available only if a pulse oximeter is connected)
B	Digital manometer	E	Start/stop control
C	Therapy status		

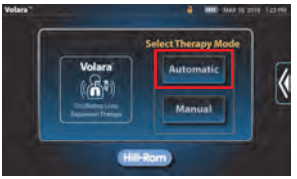
Draft_H_2019-Apr-26_Cleaned

Start a Therapy in Automatic Mode

NOTES:

- Before you start a therapy, make sure you have connected the appropriate patient circuit to the system. "Connect the Volara™ Patient Circuit" on page 21.
- Make sure the patient circuit is put into position on the patient. See Step 7 on page 22.

1. Press **Automatic**.
   - If prompted, scan the patient's ID barcode with the paired barcode reader. For pairing instructions, see page 74.



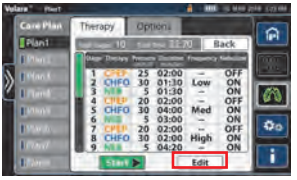
   The last used preset therapy is selected.

2. To continue with this therapy, press **Start**. Or, follow these steps to select another preset—

   a. Swipe the **Options** tab left, and press the **Care Plan** menu control.

   b. Select the preferred preset therapy plan.

   c. Review the therapy settings to make sure they match the prescription.



   d. Press **Start**. The therapy begins.

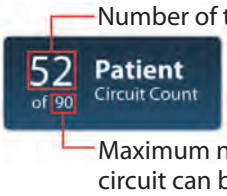
- During the therapy, you can **pause** or **stop** a therapy. Or, press **Resume** to continue a paused therapy session.

NOTE:

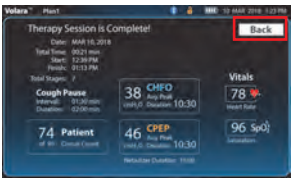
If a therapy is paused for more than 3 minutes, the therapy will stop and a warning message will show. Follow the on-screen instructions.

When the therapy is stopped or complete, the therapy summary shows.

Note the number of treatment sessions carried out with the connected patient circuit.



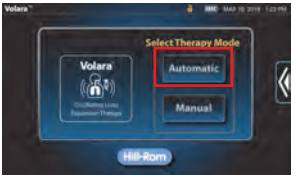
3. Press **Back** to go to the initial therapy screen.



Adjust Cough Pause Settings

NOTE:
Applicable only to preset therapy plans.

1. Press **Automatic**.
   - If prompted, scan the patient's ID barcode with the paired barcode reader. For pairing instructions, see page 74.



1. Before you start the therapy, swipe the **Options** tab left, and select the **Care Plan** menu control.

2. Select a preset therapy plan, and press **Options**.
3. Slide **Cough Pause** to **ON**.

4. To modify the interval and duration of the cough pause therapy, press the setting.
   a. Press the keypad control and enter the required setting or, use **+** or **–** controls to adjust the setting.

   b. Press **Save** to save the changes. Or, press **Cancel**.

5. When you have made all adjustments, press **Therapy**.
6. Press **Start**. The therapy begins.

Access the Advanced View

1. Before you start the therapy, swipe the **Options** tab left, and select the **Advanced View** control.

   The **Advanced View** shows.

2. Press **Start** to begin the therapy.

VOLARA™ THERAPY IN MANUAL MODE

Basic View in Manual Mode

Item	Description	Item	Description
A	Digital manometer	D	Start/stop control
B	Therapy status and control	E	CHFO frequency control
C	Heart rate and pulse oximeter readings (available only if a pulse oximeter is connected)		

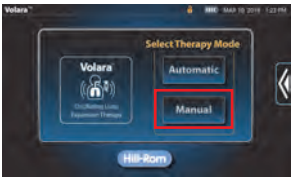
Draft_H_2019-Apr-26_Cleaned

Start a Therapy in Manual Mode

NOTES:

- Before you start a therapy, make sure you have connected the appropriate patient circuit to the system. "Connect the Volara™ Patient Circuit" on page 21.
- Make sure the patient circuit is put into position on the patient. See Step 7 on page 22.

1. Press **Manual**.

   - If prompted, scan the patient's ID barcode with the paired barcode reader. For pairing instructions, see page 74.

   The manual therapy screen shows the last used therapy settings.

2. Use the + or – control to select the pressure settings. Or, use the keypad control to enter the required setting.

3. Press **Enter** to confirm the setting.

   NOTE:

   The maximum pressure that can be set depends on the pressure ceiling limit defined in the **Clinical Access** settings. See page 72.

   - If required, press the **CHFO Freq.** control and select the preferred frequency.

   - If a nebulizer is used, press the nebulizer icon to enable therapy with a nebulizer. The nebulizer icon lights up.

4. Press **Start**.

NOTE:

This does **not** start the therapy, but starts the air pump in the control unit.

5. When the system is ready, the CPEP and/or CHFO controls are lighted. To start the therapy, press **CPEP** or **CHFO**.

NOTE:

During the therapy, follow these guidelines:

a. Encourage the patient to exhale slowly (3-4 seconds).

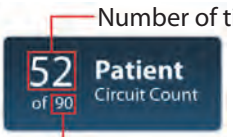
b. Encourage the patient to gently cough up secretions as they mobilize into the upper airways.

- If required, take extra care to appropriately suction secretions.

6. When the therapy is complete, press **Stop**. The therapy summary shows.

NOTE:

Note the number of treatment sessions carried out with the connected patient circuit.



Number of times the patient circuit has been used

Maximum number of treatment sessions the patient circuit can be used

Draft_H_2019-Apr-26_Cleaned

7. Press **Back** to go back to the manual therapy screen.

8. To go to the **Home** menu, swipe the **Options** tab left, and press the **Home** menu control.

NOTES:

- The system does not allow a CPEP or CHFO stage to last for more than 30 minutes.
- If the system is not used for more than 3 minutes, a warning message shows.

ADVANCED VOLARA™ THERAPY SETTINGS

These settings allow you to create, modify, rename, and delete a preset therapy.

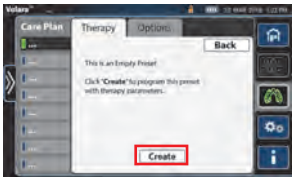
Create a New Preset Therapy Plan

NOTE:
Available only if **Clinical Access** is enabled. See page 71.

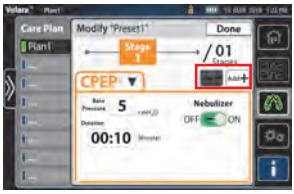
1. Press **Automatic**.

2. Swipe the **Options** tab left, and select the **Care Plan** menu control.

3. Select an empty preset plan and press **Create**.



4. Press **Add+** to add a new stage after the current stage. Or, press **Del-** to delete the current stage.
   - When a confirmation message shows, select **Proceed** to continue or press **Cancel**.



NOTE:
Default pressure limits for each new stage are:

- **CPEP**—25 cmH_2O
- **CHFO**—70 cmH_2O or the limit set in Clinical Access.
- **NEB**—5 cmH_2O

5. Press the **down** arrow and select the preferred option:

- **CPEP**—Set the therapy pressure, therapy duration, and enable or disable the use of a nebulizer.

- **CHFO**—Set the therapy pressure, therapy duration, frequency of continuous high frequency pressure, and enable or disable the use of a nebulizer.

- **NEB**—Enable or disable the therapy with the use of a nebulizer and/or adjust the duration of use with a nebulizer.

6. Press the setting to adjust the pressure setting.
7. Use the + or – control to select the pressure settings. Or, use the keypad control to enter the required setting.

NOTE:

The maximum pressure that can be set depends on the pressure ceiling limit defined in the **Clinical Access** settings. See page 72.

8. Press **Save** to save the changes.
   Or, press **Cancel**.

- If **Cough Pause** is required in this therapy, press **Options**.
  a. Slide **Cough Pause** to **ON**.
  b. Press the setting to adjust the interval and duration of the cough pause therapy.

c. Press the keypad control and enter the required setting, or use the + or – control to adjust the setting.

d. Press **Save** to save the changes. Or, press **Cancel**.

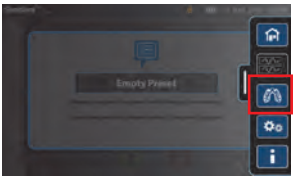
9. When you have completed the changes, press **Done**. The initial therapy screen shows.

NOTE:

To prevent unauthorized persons from adjusting the settings made, disable **Clinical Access** after you have made the settings.

Press **Device**, then press **Control**. Slide **Clinical Access** to **OFF**.

10. To start a therapy with the new Care Plan, swipe the **Options** tab left, and press the **Care Plan** menu control.



11. Select the new **Care Plan** and press **Start**.

The therapy begins.

Modify a Preset Therapy Plan

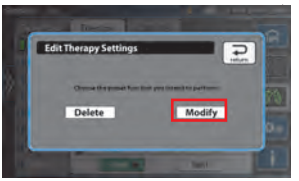
1. Press **Automatic**.

2. Swipe the **Options** tab left, and press the **Care Plan** menu control.

Draft_H_2019-Apr-26_Cleaned

3. Select a preset therapy plan and review the therapy settings.
4. Press **Edit**.

5. When prompted, press **Modify**.

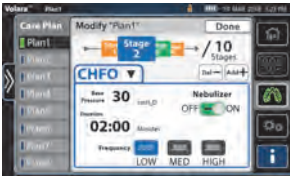


6. Swipe right or left to select the stage to modify.

7. Press the **down** arrow and select the option to modify:

- **CPEP**—Modify the therapy pressure, therapy duration, and enable or disable the use of a nebulizer.

- **CHFO**—Modify the therapy pressure, therapy duration, frequency of continuous high frequency pressure, and enable or disable the use of a nebulizer.



- **NEB**—Enable or disable the therapy with the use of a nebulizer and/or adjust the duration of use with a nebulizer.

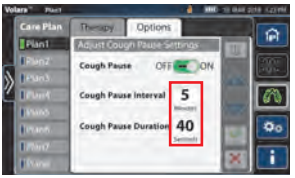
8. Press the setting to adjust the pressure setting.
9. Use the + or – control to select the pressure settings. Or, use the keypad control to enter the required setting.

NOTE:

The maximum pressure that can be set depends on the pressure ceiling limit defined in the **Clinical Access** settings. See page 72.

10. Press **Save** to save the changes.
Or, press **Cancel**.

- If **Cough Pause** is enabled, press **Options**.
  a. Press the setting to adjust the interval and duration of the cough pause,



  b. Press the keypad control and enter the required setting, or use the **+** or **–** control to adjust the setting.

  c. Press **Save** to save the changes.
Or, press **Cancel**.

11. When you have completed the changes, press **Done**. The initial therapy screen shows.

NOTE:

To prevent unauthorized persons from adjusting the settings made, disable **Clinical Access** after you have made the settings.

Press **Device**, then press **Control**. Slide **Clinical Access** to **OFF**.

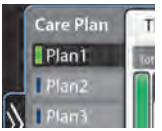
Rename a Preset Therapy Plan

NOTE:

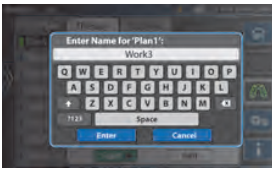
Available only if **Clinical Access** is enabled. See page 71.

1. Select the preset therapy plan to rename.

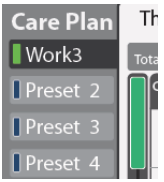
2. Press and hold the therapy plan until the on-screen keyboard shows.



3. Use the on-screen keyboard to enter any 5 alphanumeric characters for the new name.
4. When complete, press **Enter** when complete. Or, press **Cancel**.



The new name is saved.



NOTE:

To prevent unauthorized persons from adjusting the settings made, disable **Clinical Access** after you have made the settings.

Press **Device**, then press **Control**. Slide **Clinical Access** to **OFF**.

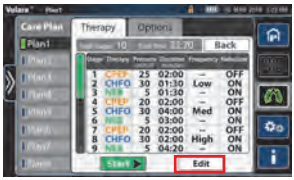
Delete a Preset Therapy Plan

NOTE:
Available only if **Clinical Access** is enabled. See page 71.

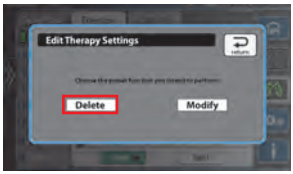
1. Press **Automatic**.

2. Swipe the **Options** tab left, and press the **Care Plan** menu control.

3. Select a preset therapy plan and review the therapy settings.
4. Press **Edit**.



5. When prompted, press **Delete**.



The initial care plan screen shows and the selected preset therapy is removed.

NOTE:
To prevent unauthorized persons from adjusting the settings made, disable **Clinical Access** after you have made the settings.

Press **Device**, then press **Control**. Slide **Clinical Access** to **OFF**.

Draft_H_2019-Apr-26_Cleaned

VOLARA™ THERAPY WITH AN IN-LINE VENTILATOR

WARNING:

Warning—Only persons trained to use the Maximus™ System and ventilators should provide therapy to ventilated patients. Failure to obey this warning could cause patient injury or equipment damage.

When you use the Maximus™ System as a Volara™ System for ventilated patients, obey these instructions:

Frequency

In-line use of the Maximus™ System with a ventilator ranges in frequency from 4 to 8 times daily as determined by the patient's response to the therapy. There is no need for CPEP as this therapy can be accomplished with the ventilator.

Procedures

1. Make sure that the system operates correctly.
2. If possible, the patient should be in a position such that the head of the bed is at an angle greater than 30 degrees.
3. Assemble the patient circuit according to the instructions in "Connect the Volara™ Patient Circuit for In-line Ventilation Therapy" on page 24.
4. Fill the nebulizer with the prescribed medication, as applicable. See "Assemble the Nebulizer Kit and Add Medication" on page 26.

Perform the therapy according to the instructions in "Volara™ Therapy in Automatic Mode" on page 53.

DEVICE SETTINGS

1. Swipe the **Options** tab left, and press the **Device Settings** menu control.

The **Device Settings** screen shows. You can view or adjust these settings:

- Screen brightness
- Date and time
- 12 hour or 24 hour clock format
- Wireless connection (WiFi)
- Bluetooth®
- Internet connection
- Logs and firmware upgrade

ADJUST SCREEN BRIGHTNESS

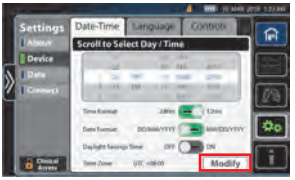
1. Press **Device** and press **Controls**.
2. At **Screen Brightness**, press and move the slider to adjust the brightness of the screen.

3. When complete, press the **Home** menu control to exit.

Draft_H_2019-Apr-26_Cleaned

Adjust Date and Time settings

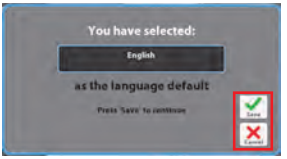
1. Press **Device** to access the **Date-Time** settings.
2. At the **Device** screen, move the slider to select the preferred setting for each item.
   a. To change the time zone, press **Modify**.
   b. Scroll up or down to select the correct time zone, and press **Save**.
3. When complete, press the **Home** menu control to exit.



Change the System Language

1. Press **Device** and press **Language**.
2. Select the preferred language. The languages available may differ depending on the country you are in.

3. To confirm your selection, press **Save**. To cancel, press **Cancel**.



4. When complete, press the **Home** menu control to exit.

Enable or Disable Clinical Access

Clinical Access allows facility-authorized persons to access and configure these advanced features:

- Adjustment of the maximum pressure ceiling setting available to the user.
- Modification of the preset therapy settings.
- Import of the device settings
- Set up and pairing of Bluetooth® devices, such as a barcode reader or pulse oximeter
- Upgrade of the system firmware (See the service manual for details.).

NOTE:

Import of the Health Level 7 (HL7) standard file

1. Press **Device,** and press **Controls**.
2. Slide the setting for **Clinical Access** to **ON**.
   - To disable, slide the setting to **OFF**. The user will not be able to access the manual modes or modify the preset therapy plans.

3. Enter the key code, and press **Enter**. If applicable, contact your facility administrator to get the key code.

4. When complete, press the **Home** menu control to exit.

Draft_H_2019-Apr-26_Cleaned

NOTE:

To prevent unauthorized persons from adjusting the settings made, disable **Clinical Access** after you have made the settings.

1. Press **Control**, then slide **Clinical Access** to **OFF**.
2. Press the **Home** menu control to exit.

SET THE PRESSURE CEILING LIMIT

The Pressure Management feature allows facility-authorized persons to control the maximum pressure selection by setting a pressure ceiling limit.The user is prevented from setting a therapy pressure that exceeds the limit defined in the device settings.

WARNING:

Warning—To avoid patient injury, this setting should only be configured by facility-authorized persons.

NOTE:

Available only if **Clinical Access** is enabled. See page 71.

1. Press **Device**, and press **Controls**.

The default pressure ceiling shows on-screen.

NOTE:

The pressure management settings show:

- **Pressure Ceiling (PC)**—the maximum therapy pressure that can be selected by the user in manual mode or when modifying a preset plan.
- **Highest Programed Pressure (HPP)**—the highest therapy pressure that has been programed in both automatic and manual modes in this system.

2. Press the **+** or **-** controls to select the required **PC** setting.

   NOTES:

   - Each press of the control increases/decreases the **PC** setting by five (5) units.
   - The PC ranges between 5 - 70 cmH2O and is limited to the HPP gathered from the system.
   - The PC must be equal or greater than the HPP.
     - *For example,*
       If HPP equals 45 cmH2O, then PC must be equal to or greater than 45 cmH2O. The user can not select a PC setting of 44 cmH2O or lower.

3. When complete, slide the **Clinical Access** setting to **OFF**. This prevents unauthorized persons from adjusting the settings.

Draft_H_2019-Apr-26_Cleaned

Connect a Barcode Reader or Pulse Oximeter

NOTES:

- Available only if **Clinical Access** is enabled. See page 71.
- For Bluetooth® detection, have the barcode reader or pulse oximeter within one meter (3') of the system.

1. Power on the control unit and the device for pairing.
2. Press **Device,** and press **Controls**.
3. Slide the setting for **Barcode Detection** to **ON**.

4. Press **Connect**.
5. Slide the setting for **Bluetooth** to **ON**.
6. Select **SpO2** to add a pulse oximeter or **Barcode** to add a barcode reader.
   - To automatically detect and pair the Bluetooth® device nearby, press **Scan**. A list of devices shows.
   - To manually add a device, press **Manual Setup**.
     a. Use the on-screen keyboard to enter the MAC address, then press **Enter** to confirm the entry.

7. When prompted to pair the new device, press **Proceed**. Or, press **Cancel**.

   When the device is paired, a check mark shows next to the device name in the list of **Available Devices**.

NOTE:

To prevent unauthorized persons from adjusting the settings made, disable **Clinical Access** after you have made the settings.

Press **Device**, then press **Control**. Slide **Clinical Access** to **OFF**.

8. When complete, press the **Home** menu control to exit.

CONNECT TO A WIFI NETWORK

This feature is only available on systems ordered with WiFi capability.

Connect to a Local WIFI Network

1. Swipe the **Options** tab left, then press the **Options** menu control.
2. Press the **Device Settings** menu control.

3. Press **Connect**.

4. Press **WiFi**.
5. Slide the setting for **WiFi** to **ON**.
6. Press **Scan** to locate the wireless networks available.

Draft_H_2019-Apr-26_Cleaned

Depending on the networks available, the scan will take a few minutes. When complete, a list of wireless networks shows.

7. Select the network to join.
8. Use the on-screen keyboard to enter the **Password**.
9. To confirm the entries, press **Proceed**. To cancel, press **Cancel**.

10. When the connection is successful, a green check mark shows next to the access point name.

- If the connection is unsuccessful, an error message shows. Press **Return** to go to the previous screens and make your entries again.

11. To view the status of the connection, press **Status**.

12. When complete, press the **Home** menu control to exit.

Connect to a Public Network

NOTES:

- After initial connection, the WiFi will automatically connect when the Maximus™ System is turned on and within WiFi range.
- Data will transmit automatically at the end of the therapy session, or when the Maximus™ System is powered up the next time.
- Do not connect to a public WiFi if any log on Terms and Conditions must be accepted to use that public WiFi.

1. Swipe the **Options** tab left, then press the **Options** menu control.
2. Press the **Device Settings** menu control.

3. Press **Connect**.

4. Press **WiFi**.
5. Slide the setting for **WiFi** to **ON**.
6. Press **Scan** to locate the wireless networks available.

Depending on the networks available, the scan will take a few minutes. When complete, a list of wireless networks shows.

7. When the connection is successful, a green check mark shows next to the access point name.

Draft_H_2019-Apr-26_Cleaned

- If the connection is unsuccessful, an error message shows. Press **Return** to go to the previous screens and make your entries again.

8. To view the status of the connection, press **Status**.

9. Press the **Home** menu control to exit.

Connect to an Enterprise Network

1. Swipe the **Options** tab left, then press the **Options** menu control.
2. Press the **Device Settings** menu control.

3. Press **Connect**.

4. Press **WiFi**.
5. Slide the setting for **WiFi** to **ON**.
6. Press **Scan** to locate the wireless networks available.

Depending on the networks available, the scan will take a few minutes. When complete, a list of wireless networks shows.

7. Select the network to join.
8. When prompted, use the on-screen keyboard to enter the **UserID** and **Password**.
9. To confirm, press **Proceed**. To cancel, press **Cancel**.

10. When the connection is successful, a green check mark shows next to the access point name.

NOTE:

To enter specific server settings, see page 79.

- If the connection is unsuccessful, an error message shows. Press **Return** to go to the previous screens and make your entries again.

11. Press the Home menu control to exit.

Configure Network Settings

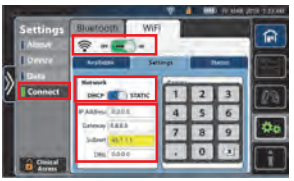
After the Maximus™ System is successfully connected to the WiFi network, you can further configure the network settings following these steps:

1. After the Maximus™ System is connected to the WiFi network, press **Settings**.

2. Slide **Network** setting to **Static**.

Draft_H_2019-Apr-26_Cleaned

3. Press on each of the empty field and use the on-screen keypad to enter the settings for:
   - **IP Address**
   - **Gateway**
   - **Subnet**
   - **DNS**



4. After all entries are made, press on the last entered yellow highlighted field to close the keypad.
5. To test the entries made, press **Test Connections**.

   If the test is complete, a confirmation screen shows.
   - If the test is unsuccessful, try again later.
   - If the test continues to fail, contact Hill-Rom.

   Press **Return** to exit the test connection screen.
6. To connect to the server, slide **WiFi** to **OFF**, then **ON** again.

   The network settings entered are submitted to the server.
7. When complete, press the **Home** menu control to exit.

8. Press the **Home** menu control to exit.

Test the Connection to VisiView™ Health portal

If you have a VisiView user account, you can transmit the therapy data directly to the VisiView Health portal. Test the connection to VisiView portal before you start the therapy.

1. After the Maximus™ System is connected to a WiFi network, press **Settings**.

2. Slide the server option to **Visiview**.
3. To test the connection. press **Test Connection**.

4. If the test is complete, a confirmation screen shows.
   - If the test is unsuccessful, try again later.
   - If the test continues to fail, contact Hill-Rom.
5. Press the **Home** menu control to exit.

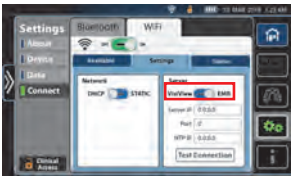
Draft_H_2019-Apr-26_Cleaned

Test the Connection to Electronic Medical Records (EMR)

If you have an EMR account assigned by the medical facility, you can submit the therapy data from the system to update your EMR. Test the connection and connect the system to the EMR portal before you start the therapy.

1. After the Maximus™ System is connected to the WiFi network, press **Settings**.

2. Slide the server option to **EMR**.



3. Press on each of the empty field and use the on-screen keypad to enter the settings for:
   - **Server IP**
   - **Port Number**
   - **NTP IP**

4. After all entries are made, press on the last entered yellow highlighted field to close the keypad.
5. To test the entries made, press **Test Connections**.

6. If the test is complete, a confirmation screen shows. Press **Return** to exit.
   - If the test is unsuccessful, try again later.
   - If the test continues to fail, contact Hill-Rom.

7. To confirm the settings entered, slide **WiFi** to **OFF**, then **ON** again.

8. Press the **Home** menu control to exit.

Retrieve Logs

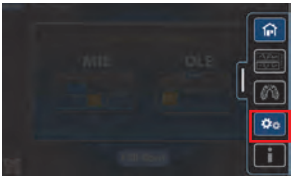
You can retrieve both the therapy log and the error log from this system.

NOTES:

- Before you start, format the USB drive to FAT16 or FAT32 format on your computer. This action deletes all information currently stored on the USB drive.
- Available only if **Clinical Access** is enabled. See page 71.

Retrieve the Therapy Logs

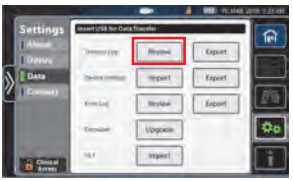
1. Swipe the **Options** tab left, and press the **Options** menu control.
2. Press the **Device Settings** menu control.



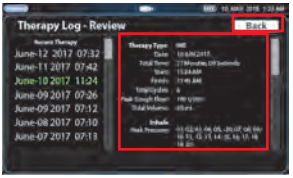
3. Press **Data**.

   NOTE:

   Not all options are available at the same time.



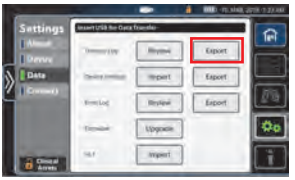
4. To view the **Therapy Log**, press **Review**. A list of therapy sessions shows.
5. Select the date and time of the session on the left hand panel. The session information shows on the right panel.
6. Press **Back** to go to the **Data** screen.



Draft_H_2019-Apr-26_Cleaned

7. To export all the therapy logs, connect a USB drive to the port on the back of the control unit.
8. At **Therapy Log**, press **Export**.

   Exporting begins. When the export is complete, a confirmation screen shows.



9. Press **Return** to go to the **Data** screen.

NOTE:

To prevent unauthorized persons from adjusting the settings made, disable **Clinical Access** after you have made the settings.

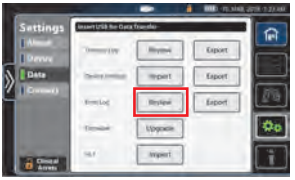
Press **Device**, then press **Control**. Slide **Clinical Access** to **OFF**.

10. Press the **Home** menu control to exit.

Retrieve the Error Log

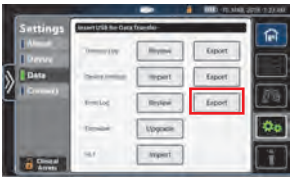
1. Swipe the **Options** tab left, and press the **Options** menu control.
2. Press the **Device Settings** menu control.

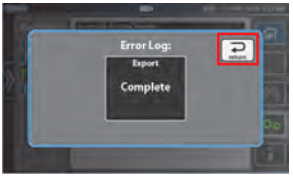
3. Press **Data**. Not all options are available at the same time.
4. To view the **Error Log**, press **Review**. A list of errors shows.



5. Select the date and time of the session on the left hand panel. Errors that occurred at that time show on the right panel.
6. Press **Back** to go to the **Data** screen.

7. To export the **Error Log**, connect the USB drive to the port on the back of the control unit.
8. At **Error Log**, press **Export**. Exporting begins. When the export is complete, a confirmation screen shows.
9. Press **Return** to go to the **Data** menu.





NOTE:

To prevent unauthorized persons from adjusting the settings made, disable **Clinical Access** after you have made the settings.

Press **Device**, then press **Control**. Slide **Clinical Access** to **OFF**.

10. Press the **Home** menu control to exit.

Draft_H_2019-Apr-26_Cleaned

Import and Export Device Settings

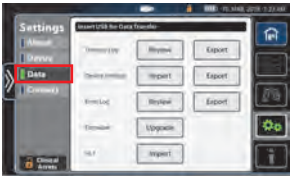
You can export the settings from one system and import the settings into another system.

NOTES:

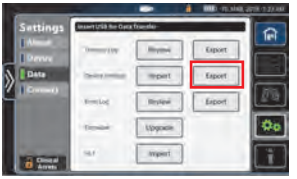
- Before you start, format the USB drive to FAT16 or FAT32 format on your computer. This action deletes all information currently stored on the USB drive.
- Available only if **Clinical Access** is enabled. See page 71.

1. Swipe the **Options** tab left, and press the **Options** menu control.
2. Press the **Device Settings** menu control.

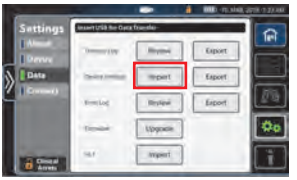
3. Press **Data**. Not all options are available at the same time.
4. Connect the USB drive to the USB port on the back of the control unit.



- To export settings, at **Device Settings**, press **Export**. When complete, remove the USB drive.



- To import settings—
  a. At **Device Settings**, press **Import**.



  b. When the settings are successfully imported, the system restarts automatically. A confirmation screen shows.
  c. Press **Return** to go to the **Home** screen.

NOTE:

To prevent unauthorized persons from adjusting the settings made, disable **Clinical Access** after you have made the settings.

Press **Device**, then press **Control**. Slide **Clinical Access** to **OFF**.

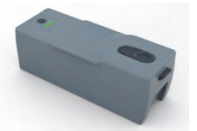
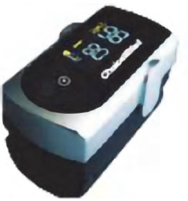
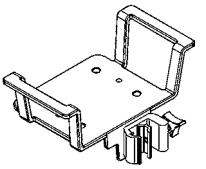
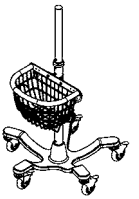
VIEW THE FIRMWARE VERSION AND SYSTEM INFORMATION

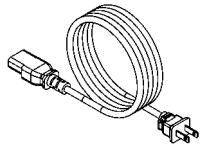
1. Swipe the **Options** tab left, and press the **Device Settings** menu control.

The **Device Information** shows.

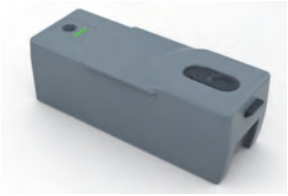
Draft_H_2019-Apr-26_Cleaned

ACCESSORIES

Item	Part Number	
Replaceable Battery See page 89.	194566S	
Pulse Oximeter, Bluetooth® See page 93.	196694	
Foot Switch (for control of Synclara™ therapy and on custom configured systems). See page 94.	204405	
WiFi Module, USB	198658	
Pole Clamp Assembly See page 95.	M08235	
Stand and Cart Assembly (with Pole Clamp) See page 95.	M08177	

Item	Part Number	
Power Cord, 3 m (10')	181995	
Carrying Case	M08083	

Replaceable Battery



Use only the Hill-Rom approved battery (194566S).

The Maximus™ System can be powered by a Lithium-ion battery when AC power is not available.

A fully charged new battery can support 6 sessions of a typical Volara™ therapy or 9 sessions of a typical Synclara™ therapy.

WARNING:

Obey these **warnings** to help prevent patient injury and/or equipment damage:

- **Warning**—Do not ship the battery with over a 30% charge.
- **Warning**—If the battery charge is below 20%, you may not be able to complete your therapy session.
- **Warning**—If the battery is stored for a long period of time, make sure to charge the battery at least once every 5 months.

Draft_H_2019-Apr-26_Cleaned

CAUTION:

Obey these **cautions** to help prevent equipment damage:

- **Caution**—Do not open, crush, puncture, incinerate, immerse in water, or heat over 140°F (60°C) the battery.
- **Caution**—Use only the Hill-Rom approved battery (194566S).
- **Caution**—Fully charge the battery to 100% before the first time use. Allow for up to 8 hours to fully charge the battery. Subsequent battery recharge periods will take less time.

NOTE:

If the replaceable battery is unable to support at least 2 therapy sessions, replace with a new and freshly charged battery. See "Replacement Parts/Kits" on page 102.

For disposal of the battery, consult your local regulations to safely discard or recycle the battery.

If you return the control unit for repairs, do not return the battery unless specifically requested by customer service.

Install the Battery

1. Turn the patient circuit hook aside to get access to the battery compartment.
2. Remove the battery cover (if installed).
3. Insert the right side of the battery (with LED indicator) into the battery compartment first.
4. Insert the left side of the battery until the battery locks into position.

NOTE:

These images show how to check that the battery is locked into position. If you see an orange colored section in the latch area, then the battery is not fully locked into position.

Press down on the battery until the orange colored section is no longer visible.

Draft_H_2019-Apr-26_Cleaned

Fully Locked

Unlocked

When the replaceable battery is installed in the control unit, the battery symbol shows on the touchscreen.

Symbol	Battery status
	The battery charge is low.
	The battery is charging.
	The battery is 25% charged.
	The battery is 50% charged.

Draft_H_2019-Apr-26_Cleaned

Symbol	Battery status
	The battery is 75% charged.
	The battery is fully charged.
	The control unit has lost communication with the battery and is not powered by the battery.

To check the battery charge, press the button beside the LED indicator on the battery.

LED indicator	Battery status
Four green bars	The battery is fully charged.
Blinking bars	The battery charge is low.
Blinking bars when the control unit is connected to AC power.	The battery is charging.

Charge the Battery

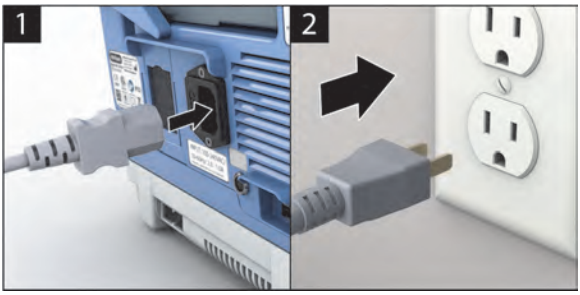
CAUTION:

Caution—Charge the battery only with the control unit to prevent equipment damage.

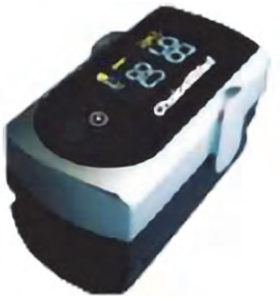
NOTE:

The power cord supplied for your country may differ from the illustration shown.

1. Plug the power cord into the back of the control unit.
2. Plug the other end of the power cord into the applicable power outlet.



PULSE OXIMETER



NOTE:

Use only the Hill-Rom approved pulse oximeter (196694).

The pulse oximeter is connected to the Maximus™ System by Bluetooth®. The pulse oximeter monitors the patient's blood oxygen level and heart rate (pulse). When the pulse oximeter is connected, you can view the readings collected from the patient on the control unit touchscreen.

Draft_H_2019-Apr-26_Cleaned

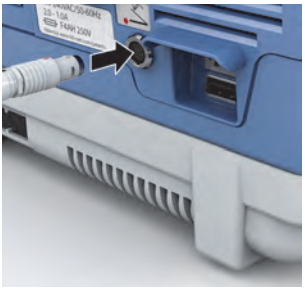
FOOT SWITCH

WARNING:

The foot switch port is available only on custom configured systems.
Warning—Use only the approved Hill-Rom foot switch (204405). The use of a different foot switch could cause the control unit to operate incorrectly, resulting in patient injury.

The foot switch can only be used for control of the Synclara™ therapy.

1. Connect the foot switch to the control unit:
   a. Hold the connector of the foot switch's cord behind its collar.
   b. Align the red dot on the cord with the red dot near the foot switch port on the control unit.



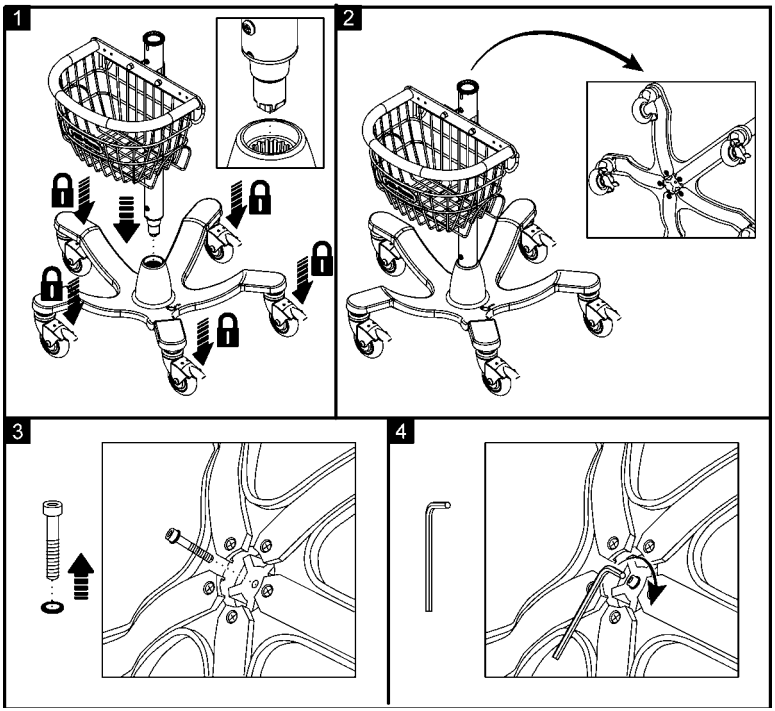
   c. Push the cord connector into the foot switch port until the connector automatically makes a 1/4 turn and you hear a click sound.

Draft_H_2019-Apr-26_Cleaned

Mobile Stand and Pole Clamp Assembly

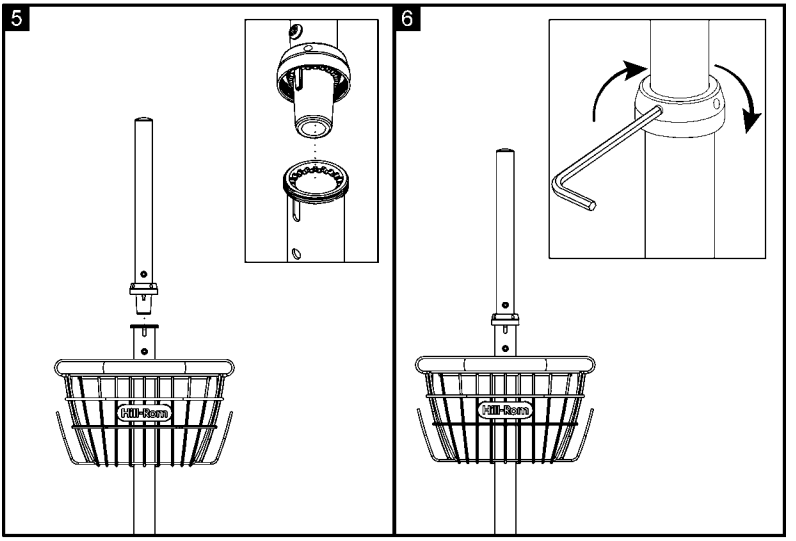
Install the Stand

1. Lock the casters. to prevent the stand base from moving. Install the pole with cart into the stand base.
2. Lay the stand base on its side.
3. Install the screw and washer to secure the stand base to the pole.
4. Turn the hex wrench clockwise to tighten the screw.



Draft_H_2019-Apr-26_Cleaned

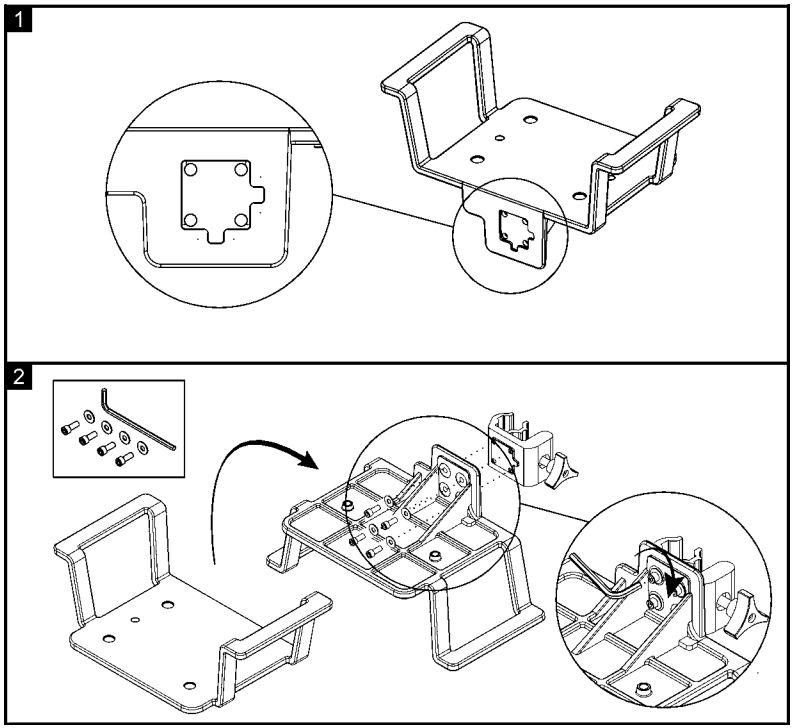
5. Install the top pole into the stand base. Make sure the groove is aligned with its opening in the bottom pole.
6. Use the hex wrench to tighten the pole connection.



Draft_H_2019-Apr-26_Cleaned

Install the Tray and Pole Clamp

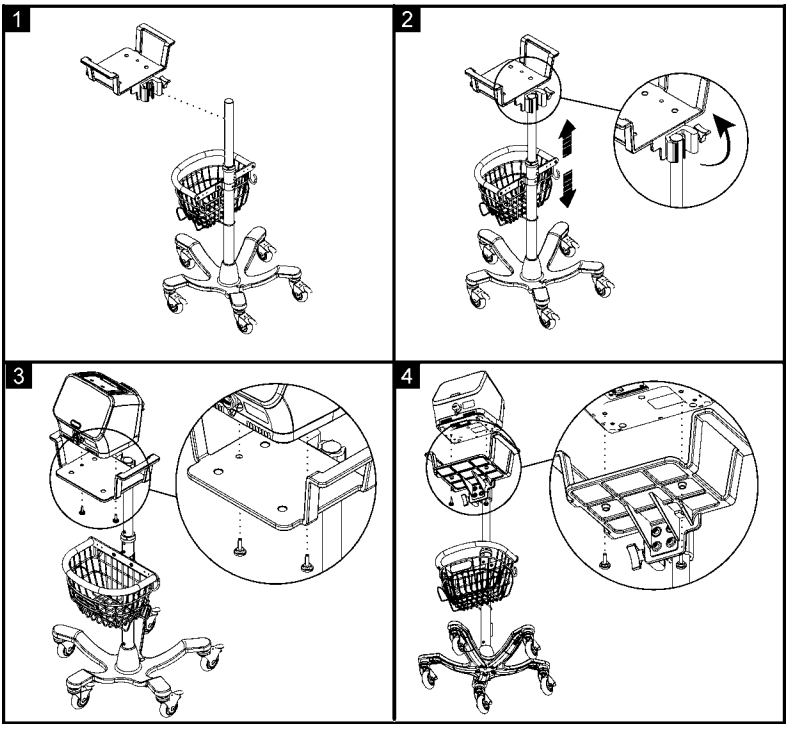
1. Note the guide on the back of the tray.
2. Turn the tray over, and attach the pole clamp to the tray with the supplied parts from the kit.



Draft_H_2019-Apr-26_Cleaned

Install the Control Unit on the Cart and Stand Assembly

1. Find the preferred position to install the tray.
2. Turn the knob on the pole clamp clockwise to hold the tray in position on the cart.
3. Put the control unit on the tray. Make sure the screw holes on the bottom of the control unit are aligned with the screw holes on the tray.
4. Attach the control unit to the tray with the supplied thumb screws.



Draft_H_2019-Apr-26_Cleaned

Move the Stand

CAUTION:

Obey these **cautions** to help prevent equipment damage:

- **Caution**—Do not apply force or pull the control unit when it is connected to the oxygen source.
- **Caution**—Do not pull the control unit using the breathing hose or circuit tubing. during transportation.

1. Disconnect the oxygen hose from the facility connection, and put the hose around the patient circuit hook.
2. Unlock the locking casters.
3. Move the stand to the applicable location.
4. Lock the casters.
5. Connect the oxygen hose to the facility connection.

Draft_H_2019-Apr-26_Cleaned

Install the Control Unit on a Medical Rail or IV pole

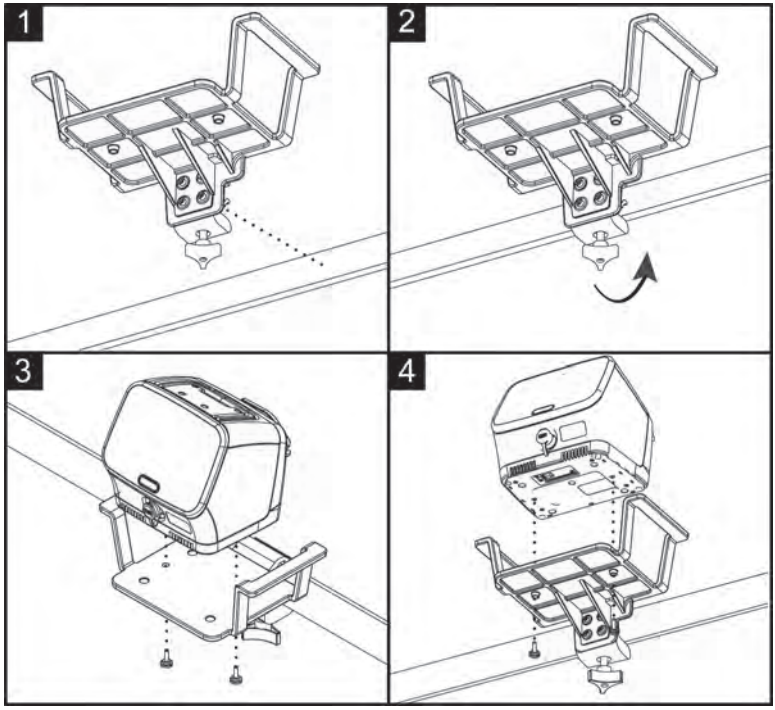
CAUTION:

To help prevent equipment damage, obey these **cautions** and make sure the mounting structure complies with these recommendations:

- **Caution**—Make sure the diameter of the pole for mounting the pole clamp assembly is between 16 to 35 mm.
- **Caution**—Make sure the dimension of the medical rail is 25 by 10 mm.
- **Caution**—Make sure the safe working load of the mounting structure (medical rail or IV pole system) is able to support the weight of the control unit and pole clamp assembly. See "Product Specifications" on page 121.

1. Find the preferred position to mount the pole clamp assembly.
2. Turn the knob on the pole clamp assembly clockwise to hold the tray in position.
3. Put the control unit on the tray. Make sure the screw holes on the bottom of the control unit are aligned with the screw holes on the tray.
4. Attach the control unit to the tray with the supplied thumb screws.

Draft_H_2019-Apr-26_Cleaned



Draft_H_2019-Apr-26_Cleaned

REPLACEMENT PARTS/KITS

Description	Part number
Adapter, in-line 22 mm x 22 mm	C10038
Adapter, in-line 22 mm/15F-15F	198096
Bio-filter	206680
Battery cover	194779
Breathing hose: 120 cm (47") long, 22 mm ID	206681
Face mask: 15 mm OD—infant	188339
Face mask: 22 mm ID—adult large	188343
Face mask: 22 mm ID—adult medium	188342
Face mask: 22 mm ID—adult small	188341
Face mask: 22 mm ID—child	188340
Face mask: 22 mm ID—adult, regular, inflatable	183158
Foam, air inlet filter	203923
Foam, nebulizer filter	202909
Foot switch (for custom configured systems only)	204405
Fuse, 4 A 250 V	207914
Handset with clear spontaneous breathing adapter	M08020
Mouthpiece	197068
Nebulizer kit	206705
Blue ventilator adapter with handset plug	M07937
Oxygen bleed-in adapter	206704
Patient circuit hook kit	203425S
Single patient use circuit for Synclara™ therapy	M08084
Stand assembly (for hospital use only)	M08088
Therapy port cap	196680
Flexible tracheostomy adapter	206707
Single patient use circuit for Volara™ therapy and in-line ventilator therapy	M08085

CLEANING AND DISINFECTING

WARNING:

When you clean and disinfect the system, obey these **warnings** to help prevent injury and/or equipment damage:

- **Warning**—The potential for electrical shock exists with electrical equipment. Failure to follow facility protocols may cause death or serious injury.
- **Warning**—Disconnect the control unit from its power source.
- **Warning**—Do not expose the control unit to excessive moisture.
- **Warning**—Do not reuse wiping material for multiple steps or on multiple products.
- **Warning**—Do not use harsh cleansers, solvents, or detergents. Harmful cleaning solutions may cause skin rash and/or irritation upon contact.
- **Warning**—Use cleaning and disinfectant products in accordance with the manufacturer's instructions.
- **Warning**—Fluid spills on to the unit electronics could cause a hazard. If such a spill occurs, unplug the unit and remove it from service. When fluid spills occur outside of what is seen in normal use, immediately do as follows:
  a. Unplug the control unit from its power source.
  b. Clean the fluid spill from the unit.
  c. Have maintenance examine the unit completely.
  d. Do not put the unit back into service until it is completely dry, tested, and found to be safe to operate.
- We recommend that you clean the unit with mild detergent and warm water. Do not use excessive liquid or harsh cleansers.

Draft_H_2019-Apr-26_Cleaned

CAUTION:

To help prevent equipment damage, obey these **cautions**:

- **Caution**—Do not use harsh cleansers/detergents, heavy duty grease removers, solvents such as toluene, xylene, or acetone, and do not use scouring pads (you may use a soft-bristle brush).
- **Caution**—Do not permit liquids, humidity, aerosols, or high pressure to contact internal components of the control unit or the foot switch.
- **Caution**—Do not use ethylene oxide gas or steam to sterilize the control unit or the foot switch.
- **Caution**—Do not steam clean or power wash the unit. Pressure and excessive moisture can damage the protective surfaces of the unit and its electrical components.
- **Caution**—Do not use bleach as your primary everyday cleaner/disinfectant.

The system has been tested for compatibility with the following cleaning and disinfecting solutions.

Compatible cleaning and disinfecting solutions

Chemical Class	Active Ingredient
Phenolic	Ortho-Phenylphenol Ortho-Benzyl-para-Chlorophenol
Alcohol	Isopropyl alcohol
Quaternary ammonium chloride	Didecyl dimethyl ammonium chloride Alkyl dimethyl benzyl ammonium chloride
Alcohol/ Quaternary ammonium chloride	Diisobutylphenoxyethoxyethyl Dimethyl Benzyl Ammonium Chloride Isopropanol

Clean the Control Unit, Stand with Cart, and Foot Switch

NOTES:

- Clean the control unit, stand, and foot switch between therapy sessions, when visibly soiled, or according to facility protocols.
- Do not spray the cleaner on to the control unit. It is recommended that the control unit, cart, and foot switch are cleaned with a soft cotton cleaning pad that is moistened with the cleaner.

Clean the control unit, mobile stand with cart, and foot switch, as follows:

1. Power off the control unit.
2. Disconnect the control unit from the power source.
3. Disconnect the patient circuit from the control unit. Put the therapy port cap over the therapy port.
4. Disconnect/detach any accessories attached to the control unit.
5. Thoroughly wipe down the control unit housing, stand with cart, and foot switch with a clean cloth dampened in a compatible bacterial cleaning solution or compatible disinfectant wipes. Do not use excessive liquid or harsh cleansers. See "Compatible cleaning and disinfecting solutions" on page 104.

Allow the unit to completely dry before use.

Clean the Pulse Oximeter

CAUTION:

To help prevent equipment damage, obey these **cautions** and cleaning instructions:

- **Caution**—Clean the pulse oximeter between patient to patient use, or when visibly soiled.
- **Caution**—Avoid using any alcohol-based solution to clean the display screen of the pulse oximeter. This can damage the screen and cause clouding.

1. Between patient use, clean the finger probe area of the pulse oximeter with a soft cloth dampened with isopropyl alcohol (concentration not exceeding 70%).
2. Use a soft, dry cloth to wipe the screen.

Clean the Single Patient Use Circuit

WARNING:

To help prevent cross-contamination and/or equipment damage, obey these **warnings** and cleaning instructions:

- **Warning**—Replace the patient circuit between patients. Failure to do so could cause infection.
- **Warning**—Replace the circuit if it is damaged or visibly soiled. Do **not** disinfect or sterilize the circuit for reuse by more than one patient.

Draft_H_2019-Apr-26_Cleaned

- **Warning**—Clean the patient circuit between each therapy session for the same patient.
- **Warning**—If the circuit and/or bio-filter are damaged or visibly soiled, replace them. See "Replacement Parts/Kits" on page 102.

NOTE:

Each patient circuit is for use by a single patient and intended for 30 days of treatment or a maximum of 90 treatment sessions.

These cleaning instructions are for multiple use of the circuit by a single patient. The circuit has been tested for compatibility with mild detergent and warm water for cleaning. The facility should follow their internal infection control policies on cleaning the nebulizer and circuit. If a policy is not in place, the following is a guideline for proper cleaning of the circuit:

1. Disconnect the circuit from the control unit.
2. If a nebulizer is used in the therapy, disconnect the nebulizer from the handset.
    a. Disconnect the nebulizer tubing from the medicine cup.
    b. Remove the lid from the medication cup.
    c. Discard any unused medication in accordance with facility protocol.
3. Disconnect the mouthpiece, face mask, adapters, handset, breathing hose, and bio-filter.
4. Examine the inside of the bio-filter for any damage and/or soilage. If there is soilage or damage, replace the bio-filter immediately. For examples of damaged bio-filters, see page 108.
5. Wipe down the outside of the bio-filter with a compatible bacterial cleaning solution. Do not use excessive liquid or harsh cleansers. See "Compatible cleaning and disinfecting solutions" on page 104.
6. Wash the mouthpiece or face mask, handset, and adapters with mild detergent and warm water.
7. Rinse the nebulizer cup and components with sterile water.
8. Let the handset, nebulizer cup, mouthpiece, and adapters air dry or dry them with a lint free cloth or paper towel.
9. Wipe down the outside of the circuit tubing with an approved alcohol-based cleaner.
10. After all parts are dry, assemble the circuit, and put it in a breathable bag with the patient's name on it for use later.

NOTE:

Before the next use of the system, follow these instructions:

- Examine the components of the circuit for cracks or other damage. If there is damage, replace the circuit. See "Replacement Parts/Kits" on page 102.
- For units with use of a nebulizer, assemble the nebulizer first. See page 26.

Draft_H_2019-Apr-26_Cleaned

Examples of Typical Damage of the Bio-filter

Each of the following three pictures show examples of possible damage. These pictures do not show all possible types of damage.

Soiled Filter:

Mucus or liquid is attached to the membrane.

Damaged Filter:

External casing of the filter has cracks or pieces missing.

Punctured Filter:

Membrane of the filter is broken.

DISINFECT

When there is visible soilage and also between patient use, we recommend that you disinfect the unit with an EPA registered (US only), tuberculocidal, disinfectant. Dilute and use the disinfectant as shown on the manufacturer's label.

MAINTENANCE

WARNING:

Warning—To prevent injury and/or equipment damage, do not do maintenance when the system is in use.

INLET FILTER

Examine the inlet filter every month, and clean it as necessary. Replace the inlet filter every twelve (12) months.

To clean the filter, do as follows:

1. Power off the control unit.
2. Remove the inlet filter from the back of the control unit.

   NOTE:

   If the filter is damaged, replace it. See "Replacement Parts/Kits" on page 102.
3. Wash the filter with mild detergent and warm water, and then rinse it with clean water.
4. Allow the filter dry completely, and then install it into the back of the control unit.

Draft_H_2019-Apr-26_Cleaned

Nebulizer Filter

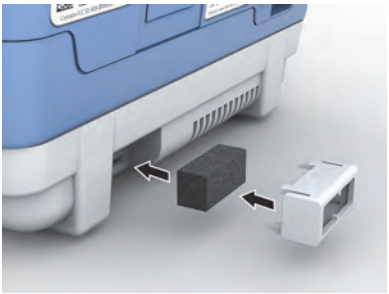
Examine the nebulizer filter every month, and clean it as necessary. Replace the inlet filter every twelve (12) months.

To clean the filter, do as follows:

1. Power off the control unit.
2. Remove the inlet filter from the back of the control unit.

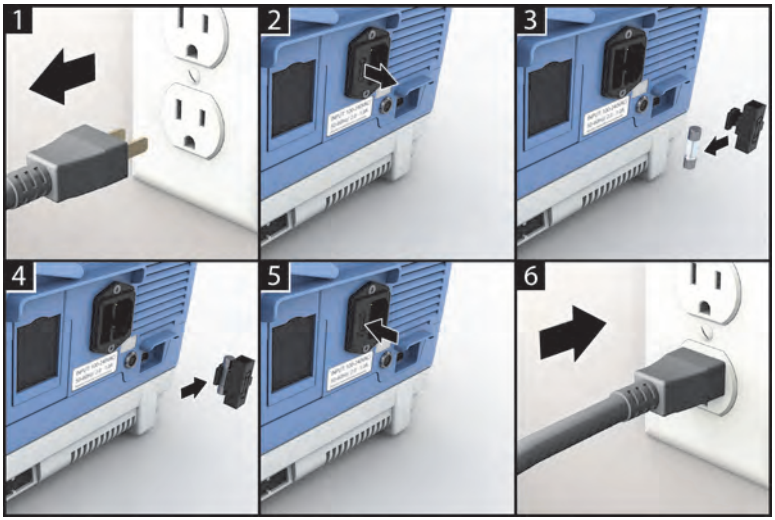
   NOTE:

   If the filter is damaged, replace it. See "Replacement Parts/Kits" on page 102.
3. Wash the filter with mild detergent and warm water, and then rinse it with clean water.
4. Allow the filter to dry completely, and then install it into the control unit.



Fuse

If a fuse needs to be replaced, do as follows:



EXPECTED LIFE

The expected service life for the control unit is five years from its date of purchase.

The expected service life of the single patient use circuit is 30 days of treatment or 90 treatment sessions.

The expected service life of the battery is one year from its date of purchase.

NOTE:

For proper disposal, make sure to follow your local, state, or country electronic and battery regulations to safely discard or recycle the Maximus™ System, parts, and batteries.

SERVICE CALLS

WARNING:

Warning—Only authorized persons should service the Maximus™ System. Service by unauthorized persons could cause personal injury or equipment damage.

If service is necessary, use this contact information:

- In the USA, call a Hill-Rom representative at: 800-426-4224.
- Outside the USA, contact your distributor or a local Hill-Rom representative or go to www.respiratorycare.hill-rom.com.

NOTE:

When contacting a Hill-Rom representative regarding the Maximus™ System, be prepared to provide the serial number from the product identification label. The label is on the back of the control unit.

When you provide the serial number, the Hill-Rom representative can identify your unit and give you the information you need more quickly.

Draft_H_2019-Apr-26_Cleaned

TROUBLESHOOTING

WARNING:

Warning—Only authorized persons should service the Maximus™ System. Service by unauthorized persons could cause personal injury or equipment damage.

NOTE:

Do not modify this system without the authorization of the manufacturer. To do so could cause personal injury or equipment damage.

Control Unit Does Not Power On

- If the control unit is powered by **AC power**:
  - Make sure the power cord is fully plugged into the electrical inlet on the back panel of the control unit. If necessary, disconnect the power cord from the control unit and then connect it again.
  - Make sure the power cord is fully plugged into an AC power.
  - Examine the fuse. If necessary, replace the fuse (see page 110).
  - If the problem continues, contact a Hill-Rom representative.
- If the control unit is powered by a **battery**:
  - Make sure the battery is correctly installed in the control unit. If necessary, remove and install it. See page 89.
  - Press the battery indicator button next to the LED indicator on the battery to see its remaining charge. If the battery is low (LED indicator is blinking), charge the battery or replace with freshly charged battery.
  - If the problem continues, contact a Hill-Rom representative.

On-screen Help

The Maximus™ System offers an in-built **Help** to assist you when you are using the system. To access **Help,** swipe the **Options** tab left, and press the **Options** menu control. Press the **Help** menu control.

Information Indicators

Information indicators provide the caregiver with audible indicators and visual indicators.

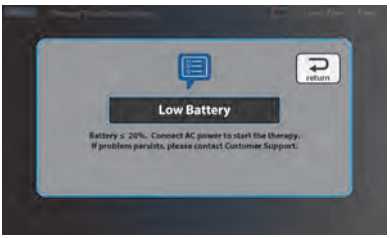
Audio Alerts

Beeps provide audible indications of the status of the system.

Alert Pattern	Status
One beep	Indicates that an activity is successful.
Three beeps	Indicates that attention is needed, and you should look at the touchscreen.
Three beeps, repeating every minute	Indicates that attention is needed. Read the Caution message shown on the touchscreen, and follow the on-screen instructions.
Three beeps followed by two beeps, repeating	Indicates that a critical fault has occurred. Read the Warning message shown on the touchscreen, and follow the on-screen instructions.

Notification Messages

Notification messages show on-screen to let you know the status of the system or guide you in the next action required. Follow the on-screen instructions.



Draft_H_2019-Apr-26_Cleaned

Warning Messages

Warning messages show on-screen to let you know that a critical issue has occurred. Follow the on-screen instructions to troubleshoot the issue. If an error code shows, see "Solutions for Warning Messages" on page 114.

Solutions for Warning Messages

Error Code	Do this:
001, 002, 003, 004, 005, 006, 008, 032	Power off the control unit, then power it on again.
009	1. Make sure only the Hill-Rom approved battery (194566S) is used. 2. Press **return** after reading the on-screen message. 3. Make sure the battery is correctly installed in the control unit. If necessary, remove the battery and install it. Remove the battery and install it. See "Install the Battery" on page 90.
010	1. Power off the control unit. 2. Make sure the nebulizer connected to the system is functioning properly. Change to a new nebulizer machine, if required. 3. Power on the control unit. 4. Start the therapy again.

Caution Messages

Caution messages show on-screen to let you know that an issue has occurred. Follow the on-screen instructions to troubleshoot the issue. If an error code shows, see "Solutions for Cautious Messages" on page 115.

Solutions for Cautious Messages

Error Code	Do this:
007, 013, 020	1. Press **return** after you read the on-screen message. 2. Power off the control unit, and then power it on.
011	1. Make sure the power cord is fully plugged into the electrical inlet on the back of the control unit. If necessary, disconnect the power cord from the control unit, and then connect it. 2. Make sure the power cord is securely plugged into an AC power. 3. Press **return** after you read the on-screen message.
012	1. Make sure the foot switch buttons are not pressed down or stuck. 2. Press **return** after you read the on-screen message.
014	1. Make sure the correct patient circuit is set up for the required therapy. For details, see "Assemble and Connect the Patient Circuit" on page 19. 2. Press **return** after you read the on-screen message.

Draft_H_2019-Apr-26_Cleaned

Error Code	Do this:
015, 016, 017, 018	1. Press **return** after you read the on-screen message. 2. Power off the control unit and let it cool down for at least 5 minutes. Power on the control unit. 3. If the same message shows, power off the control unit and let it cool down for at least 30 minutes. Power on the control unit.
019	1. Make sure only the Hill-Rom approved battery (194566S) is used. 2. Press **return** after you read the on-screen message. 3. Make sure the battery is correctly installed in the control unit. If necessary, remove the battery and install it. Remove the battery and install it. See "Install the Battery" on page 90.
021	1. Press **return** after you read the on-screen message. 2. If a foot switch is connected, make sure the foot switch buttons are not pressed down or stuck. 3. Make sure the **Inhale**/**Exhale** control on the touchscreen is not pressed and held for more than 10 seconds during a manual therapy session.

Error Code	Do this:
022	1. Make sure the correct patient circuit is set up for the required therapy. See page 19. 2. Make sure a tight seal is maintained on the face mask or mouthpiece. 3. Examine the connections between the patient circuit components, tubings, and the control unit for any source of leakage. If necessary, disassemble the patient circuit and assemble it again. If you see cracks on the patient circuit components, replace the parts. See "Replacement Parts/Kits" on page 102. 4. Press **return** after you read the on-screen message.
023	1. Make sure only the Hill-Rom approved bio-filter (206680) is used. For instructions on how to connect the filter correctly, see page 19. 2. Press **return** after you read the on-screen message.
024	1. Make sure a tight seal is maintained on the face mask or mouthpiece. 2. Examine the connections between the patient circuit components, tubings, and the control unit for any source of leakage. If necessary, disassemble the patient circuit and assemble it again. If you see cracks on the patient circuit components, replace the parts. See "Replacement Parts/Kits" on page 102. 3. Press **return** after you read the on-screen message.
025	1. Make sure there are no other bio-filters near the control unit, other than the one that is connected to the control unit. 2. Press **return** after you read the on-screen message.

Draft_H_2019-Apr-26_Cleaned

Error Code	Do this:
026	1. Replace the current bio-filter with a new one. See "Replacement Parts/Kits" on page 102. 2. Press **return** after you read the on-screen message.
029	1. Press **return** after you read the on-screen message. 2. Power off the control unit and leave the system to warm up in a warmer environment for at least 5 minutes. Power on the system again. (For the recommended operating ambient temperature, see page 28). 3. If the same message shows, power off the control unit and leave it in a warmer environment for at least 30 minutes. 4. Power on the control unit.
030	1. Press **return** after you read the on-screen message. The Real Time Clock (RTC) battery in the control unit needs to be replaced. 2. For the replacement of the RTC battery, contact Hill-Rom.

NOTE:

In most instances, you may have to restart the system. If the problem continues, contact Hill-Rom:

- In the USA, call Hill-Rom at 800-426-4224.
- Outside of the USA, contact your distributor or local Hill-Rom representative, or go to www.respiratorycare.hill-rom.com.

STORAGE AND HANDLING

To store or transport the Maximus™ System, do the following:

1. Put the therapy port cap over the therapy port.

2. Put the control unit in the carrying case.
3. Put the patient circuit components into a clean plastic bag.
4. Pack the power cord, replaceable battery, patient circuit, and other accessories into the compartments of the carry case.
5. Close the carry case to secure the product inside.
6. Store the system in a safe location within the recommended environmental conditions. See “Environmental Conditions for Transport and Storage” on page 123.

NOTE:

For long term storage, make sure that the replaceable battery is recharged fully once every five months.

Draft_H_2019-Apr-26_Cleaned

Shipping and Packaging

WARNING:

To help prevent injury and/or equipment damage, obey these **warnings**:

- **Warning**—Do not ship the battery with over a 30% charge.
- **Warning**—Do not store the battery at temperatures above 140°F (60°C), such as inside of a car on a hot day or in direct sunlight.

CAUTION:

Caution—If shipping is required, the original packing material provides the best protection for the system. Keep the original packing material. Failure to do so could cause equipment damage.

If shipping is required, ship the unit in its original packing material. When the system has reached the end of its useful life, discard the system in accordance with local and federal standards.

Shipping for Repair

When the control unit is shipped for repair, follow these shipping and packaging instructions:

- Request and get a return material authorization (RMA) number from Hill-Rom.

You will get a return kit in the mail.

1. Clean and disinfect the unit. Make sure it is dry before you pack it. See "Clean the Control Unit, Stand with Cart, and Foot Switch" on page 104.
2. Follow the instructions in the return kit to pack the unit.
3. Close and seal the box, and apply the applicable labels on the outside of the box.
4. During shipment, the unit should be kept dry and kept at temperatures of -4° F to 140° F (-20° C to 60° C).

SPECIFICATIONS

PRODUCT IDENTIFICATION

Product Number	Description
POPT1	Maximus™ System, Model POPT1

PRODUCT SPECIFICATIONS

Feature	Description
When used for Synclara™ therapy:	
Inhale Pressure	0 to 70 cmH2O
Exhale Pressure	-70 to 0 cmH2O
PAP Pressure	0 to 30 cmH2O
Sigh Pressure	0 to 30 cmH2O
Per Stage Duration	0 - 5 seconds
Flutter Pressure	1 to 10 cmH2O
Flutter Frequency	5 to 20 Hz
Pressure Accuracy	± 5 cmH2O
Flutter Frequency Accuracy	± 1 Hz
When used for Volara™ therapy:	
CPEP	5 to 25 cmH2O
CHFO	5 to 70 cmH2O
Nebulizer	5 cmH2O
Per Stage Duration	1 sec to 5 minutes
CHFO Frequencies	Low, medium and, high
Pressure Accuracy	± 5 cmH2O
CHFO Frequency Accuracy	± 1 Hz

Draft_H_2019-Apr-26_Cleaned

DIMENSIONS

Control Unit	
Depth	8.8" (22.3 cm)
Width	9.2" (23.3 cm)
Height	10.6" (27 cm)
Weight	11 lb (5 kg)
Stand (Optional)	
Height, to top of pole	39.4" (100 cm)
Pole diameter (Top pole)	1.3" (3.2 cm)
Pole diameter (Bottom pole)	1.5" (3.9 cm)
Pole total length	
Base height	5.6" (14.2 cm)
Base width	22" (56 cm)
Weight	26.9 lb (12.2 kg)

POWER REQUIREMENTS

Condition	**Range**
Line voltage	100 - 240 V AC
Supply frequency	50 - 60 Hz
Supply current	2.0 - 1.0 A
Mode of operation	Non-continuous: 5 minutes ON/ 20 minutes OFF at **CHFO** pressure setting of 65 cmH2O and above.
Fuse rating	Fuse, 4 A H 250 V

Replaceable Battery (Optional)

Feature	**Description**
Lithium-ion Battery	A new and fully charged battery can support 6 sessions of typical Volara™ therapy or 9 sessions of typical Synclara™ therapy.
Output:	24 V DC +/- 1.5 V DC
Capacity	2700 mAh

Environmental Conditions for Use

Condition	Range
Temperature	41°F to 95°F (5°C to 35°C) ambient temperature
Relative humidity	10% to 90% non-condensing
Pressure	70 kPa to 106 kPa

Environmental Conditions for Transport and Storage

Condition	Range
Temperature	-4°F to 140°F (-20° to 60°C)
Relative humidity	10% to 90%
Pressure	50 kPa to 106 kPa

System Cool Down

CAUTION:

Caution—Failure to follow the system cool down guidelines below could cause equipment damage.

Condition	Cool Down Period
System operates continuously for 5 minutes, at **CHFO** pressure setting of 65 cmH2O and above.	At least 20 minutes

Draft_H_2019-Apr-26_Cleaned

Wireless Communication

The Maximus™ System, Model POPT1 features an optional Bluetooth® interface to connect to a pulse oximeter or barcode reader to retrieve patient information. The Maximus™ System, Model POPT1 also features an optional WiFi module to export system use data in both acute care and home care environments.

Feature	Dimension
Bluetooth® Specification (Optional Configuration)	
Bluetooth® compliance	Bluetooth® V4.0 (BT Classic)
Frequency	2.40 to 2.48 GHz
Transmit Power	+8 dBm (max) + 0.5 dBm
Receive Sensitivity	-90 dBm (typical)
Modulation	Frequency shift keying Frequency hopping spectrum
WiFi (Optional Configuration)	
WLAN	IEEE 802.11a, 802.11b, 802.11g, 802.11n
Frequency	2412 MHz - 2462 MHz 5180 MHz - 5240 MHz 5745 MHz - 5825 MHz
Transmit Power (+/- 2 dBm)	17.5 dBm for 802.11b DSSS 17.5 dBm for 802.11g/n OFDM 12 dBm for 802.11a/g/n OFDM
Receive Sensitivity (+/- 2 dBm)	1 Mbps - 95.5 dBm (<10% PER) 54 Mbps - 74.5 dBm (<10% PER) MCS7 (20 MHz) - 71.5 dBm (<10% PER) MCS7 (40MHz) - 68 dBm (<10% PER)
Security Authentication/ Encryption	WPA/WPA2-Personal, WEP 64/128 bits

Classification and Standards

Classification	Standards
Safety Standards	ANSI/AAMI ES60601-1: 2005 + C1: 09 + A2: 10 + A1: 12 ANSI/AAMI HA60601-1-11:2015 CAN/CSA-C22.2 No. 60601-1: 14 CAN/CSA-C22.2 No. 60601-1-11:15 IEC 60601-1: 2005 + A1: 2012 EN 60601-1: 2006 + A12:2014 IEC 60601-1:1988 + A1:1991 + A2:1995 IEC 60601-1-11: 2015-01 EN 60601-1-11: 2015 IEC 60601-1-6: 2010 + A1:2013 EN 60601-1-6: 2010 + A1:2015 IEC 62366-1: 2015-02 EN 62366-1: 2015
EMC Standards	FCC Part 15 Subpart B EN 301 489-1 V 1.9.2:2011 EN 301 489-17 V 2.2.1:2011 IEC 60601-1-2: 2014 EN 60601-1-2: 2015 RTCA DO-160G Section 21
Radio Standards	FCC Part 15 Subpart C (2.4 GHz) FCC Part 15 Subpart E (5.0 GHz) ETSI EN 300 330
Bio-compatibility	ISO 10993-1: 2009 ISO 18562-1: 2017

Essential Performance

The essential performance of the Maximus™ System, Model POPT1 is defined as:

- Therapy air pressure not to exceed 120 cmH2O.

Draft_H_2019-Apr-26_Cleaned

Federal Communications Commission (FCC) Compliance Statement

<This section is pending further updates from C&S. To be updated in Phase 3 after certification submission.>

NOTES:

- This system may not cause harmful interference,
- This system must accept any interference received, including interference that may cause undesired operation.

FCC Caution

- Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.
- This equipment should be installed and operated with the minimum distance 20 cm between the radiator & your body.

Part 15B compliance statements for digital devices:

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on.

The user is encouraged to try to correct the interference by one or more of the following measures:

- Re-orientate or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

To see the FCC ID of this system—

1. Swipe the **Options** tab left, and press the **Device Settings** menu control.

   The device information screen shows.

2. Find the FCC ID in the system information.

Draft_H_2019-Apr-26_Cleaned

ELECTROMAGNETIC COMPATIBILITY GUIDANCE

The Maximus™ System, Model POPT1 is suitable for the electromagnetic environment settings specified in the tables that follow.

WARNING:

Warning—The Maximus™ System, Model POPT1 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Maximus™ System should be observed to verify normal operation. If operation is not normal, the Maximus™ System or any other equipment should be moved.

Use of accessories, transducers, and cables, other than those specified or provided by the manufacturer of this equipment, could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The Maximus™ System, Model POPT1 is intended for use in the electromagnetic environment specified below. The customer or user of the Maximus™ System, Model POPT1 should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF Emissions CISPR 11	Group 1	The Maximus™ System uses RF energy only for its internal functions. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Maximus™ System is suitable for use in all establishments, including domestic establishments, 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	

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The Maximus™ System, Model POPT1 is intended for use in the electromagnetic environment specified below. The customer or user of the Maximus™ System, Model POPT1 should make sure 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 ± 15 kV air	± 8 kV contact ± 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%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle at: 0^o, 45^o, 90^o, 135^o, 180^o, 225^o, 270^o, and 315^o 0% U_T for 1 cycle 70% U_T; 25/30 cycles, single phase at 0^o 0% U_T for 250/300 cycles	0% U_T for 0.5 cycle at: 0^o, 45^o, 90^o, 135^o, 180^o, 225^o, 270^o, and 315^o 0% U_T for 1 cycle 70% U_T; 25/30 cycles, single phase at 0^o 0% U_T for 250/300 cycle	Mains power quality should be of a typical home healthcare environment. If it is necessary for the user to have continued operation of the Maximus™ System during power mains interruptions, it is recommended that the Maximus™ System 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 home healthcare environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Draft_H_2019-Apr-26_Cleaned

Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The Maximus™ System, Model POPT1 is intended for use in the electromagnetic environment specified below. The customer or user of the Maximus™ System, Model POPT1 should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Maximus™ System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	150 kHz to 80 MHz $d = \left[\frac{3.5}{3}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	80 MHz to 800 MHz $d = \left[\frac{3.5}{10}\right]\sqrt{P}$ 800 MHz to 2.7 GHz $d = \left[\frac{7}{10}\right]\sqrt{P}$ 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 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. 

NOTES:

- At 80 MHz and 800 MHz, the higher the frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
- Electromagnetic immunity was examined under normal operation at the time of testing. Normal operation was the essential performance used. Electromagnetic immunity was verified at settings of 4 for intensity and 12 Hz for frequency.

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 can not be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, the electromagnetic site used should be considered. If the measured field strength in the location in which the Maximus™ System, Model POPT1 is used is more than the applicable RF compliance level above, the Maximus™ System, Model POPT1 should be monitored to make sure it operates correctly. If it operates incorrectly, additional measures may be necessary, such as a change in the Maximus™ System, Model POPT1s position or location.
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 Maximus™ System, Model POPT1

The Maximus™ System, Model POPT1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Maximus™ System, Model POPT1 prevents electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system 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 $d = \left[\frac{3.5}{3}\right]\sqrt{P}$	80 MHz to800 MHz $d = \left[\frac{3.5}{10}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{10}\right]\sqrt{P}$
0.01 W	0.12 m	0.04 m	0.07 m
0.1 W	0.37 m	0.11 m	0.22 m
1 W	1.17 m	0.35 m	0.70 m
10 W	3.69 m	1.11 m	2.21 m
100 W	11.67 m	3.50 m	7.00 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in metres (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.
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.

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Draft_H_2019-Apr-26_Cleaned

ELECTROMAGNETIC IMMUNITY TO WIRELESS COMMUNICATIONS

The Maximus™ System, Model POPT1 is intended for use in the electromagnetic environment specified below. The customer or user of the Maximus™ System, Model POPT1 should make sure it is used in such an environment.

Sides Tested	Frequency (MHz)	Test Severity Level	Test Distance (m)
Front, back, left, right	385	27 V/m, 50% PM 18 Hz	0.3
Front, back, left, right	450	28 V/m, FM ± 5 kHz,1 kHz	0.3
Front, back, left, right	710	9 V/m, 50% PM 217 Hz	0.3
Front, back, left, right	745	9 V/m, 50% PM 217 Hz	0.3
Front, back, left, right	780	9 V/m, 50% PM 217 Hz	0.3
Front, back, left, right	810	28 V/m, 50% PM 18 Hz	0.3
Front, back, left, right	870	28 V/m, 50% PM 18 Hz	0.3
Front, back, left, right	930	28 V/m, 50% PM 18 Hz	0.3
Front, back, left, right	1720	28 V/m, 50% PM 217 Hz	0.3
Front, back, left, right	1845	28 V/m, 50% PM 217 Hz	0.3
Front, back, left, right	1970	28 V/m, 50% PM 217 Hz	0.3
Front, back, left, right	2450	28 V/m, 50% PM 217 Hz	0.3
Front, back, left, right	5240	9 V/m, 50% PM 217 Hz	0.3
Front, back, left, right	5500	9 V/m, 50% PM 217 Hz	0.3
Front, back, left, right	5785	9 V/m, 50% PM 217 Hz	0.3


Hill-Rom