GE Healthcare

CARESCAPE™ V100 Vital Signs Monitor
Service Manual

CARESCAPE V100 Vital Signs Monitor
English
2037106-001 B (paper)

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NOTE: The information in this manual also applies to CARESCAPE V100 Vital Signs Monitor software version RAA. There are no user-apparent differences among these software versions. Due to continuing product innovation, specifications in this manual are subject to change without notice.

NOTE: For technical documentation purposes, the abbreviation GE is used for the legal entity name, GE Medical Systems *Information Technologies*.

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1 Introduction

For your notes

Revision History

Each page of this manual has a revision letter located at the bottom of the page. This letter identifies the revision level of the entire manual. This may be important if you have different manuals and you do not know which is the most current.

For the initial release, all pages have the revision letter A. For the second update, all pages receive the revision letter B. The latest letter of the alphabet added to the table below corresponds to the most current revision.

Revision	Comment
A	Release of new manual
B	Updated CE marking information.

Manual Purpose

This manual supplies technical information for service representatives and technical personnel so they can maintain the equipment to the assembly level. Use it as a guide for maintenance and electrical repairs considered field repairable. Where necessary the manual identifies additional sources of relevant information and technical assistance. See the operator's manual for the instructions necessary to operate the equipment safely in accordance with its function and intended use.

Ordering Manuals

A paper copy of this manual will be provided upon request. Contact your local GE representative and request the part number on the first page of the manual.

Safety Information

The information presented in this section is important for the safety of both the patient and operator. This chapter describes how the terms Danger, Warning, Caution, Important, and Note are used throughout the manual. In addition, standard equipment symbols are defined.

Responsibility of the Manufacturer

GE is responsible for the effects on safety, reliability, and performance only if:

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by GE;
- the electrical installation of the relevant room complies with the requirements of appropriate regulations; and
- the monitor is used in accordance with the instructions of use.

General

This device is intended for use under the direct supervision of a licensed health care practitioner.

This device is not intended for home use. Federal law restricts this device to be sold by or on the order of a physician.

Contact GE for information before connecting any devices to the equipment that are not recommended in this manual.

Parts and accessories used must meet the requirements of the applicable IEC/EN 60601 series safety standards, and/or the system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard.

Periodically, and whenever the integrity of the device is in doubt, test all functions.

The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the PATIENT VICINITY; and
- evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard.

If the installation of the equipment, in the USA, will use 240V rather than 120V, the source must be a center-tapped, 240V, single-phase circuit.

References to Persons, Places, and Institutions

References to persons, places, and institutions used within this manual are solely intended to facilitate user comprehension of the V100 Monitor's use and functions. Extreme care has been taken to use fictitious names and related information in the examples and illustrations provided herein. Any similarity of this data to persons either living or dead and to either current or previously existing medical institutions should be regarded as coincidental.

Warnings, Cautions, and Notes

The terms danger, warning, and caution are used throughout this manual to point out hazards and to designate a degree or level or seriousness. Familiarize yourself with their definitions and significance. Hazard is defined as a source of potential injury to a person.

WARNING indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.

CAUTION indicates a potential hazard or unsafe practice which, if not avoided, could result in minor personal injury or product/property damage.

NOTE provides application tips or other useful information to assure that you get the most from your equipment.

Product Specific Hazards

WARNINGS

Do not use the CARESCAPE V100 Vital Signs Monitor in the presence of magnetic resonance imaging (MRI) devices. There have been reports of sensors causing patient burns when operating in an MRI environment.

Do not use the Monitor in the presence of flammable anesthetics.

The use of approved accessories will provide protection from burns during HF surgery. To help prevent unintended current return paths with the use of high frequency (HF) surgical equipment, ensure that the HF surgical neutral electrode is properly connected.

To avoid personal injury, do not perform any servicing unless qualified to do so.

These Monitors should not be used on patients who are connected to cardiopulmonary bypass machines.

If powering the Monitor from an external power adapter or converter, use only GE Medical Systems *Information Technologies*-approved power adapters and converters.

The Monitor does not include any user-replaceable fuses. Refer servicing to qualified service personnel.

To reduce the risk of electric shock, do not remove the cover or the back. Refer servicing to a qualified service person.

If the accuracy of any determination reading is questionable, first check the patient's vital signs by alternate means and then check the V100 Monitor for proper functioning.

Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

WARNINGS

The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

CAUTIONS

Do not use replacement batteries other than the type supplied with the Monitor. Replacement batteries are available from GE Medical Systems - *Accessories and Supplies*.

The V100 Monitor is designed to conform to Electromagnetic Compatibility (EMC) standard IEC 60601-1-2 and will operate accurately in conjunction with other medical equipment which also meets this requirement. To avoid interference problems affecting the Monitor, do not use the Monitor in the presence of equipment which does not conform to these specifications.

Place the V100 Monitor on a rigid, secure surface. Monitor must only be used with mounting hardware, poles, and stands recommended by GE Medical Systems *Information Technologies*.

The weight of the accessory basket contents should not exceed 5 lb (2.7kg).

Arrange the external AC/DC power converter, air hoses, and all cables carefully so they do not constitute a hazard.

Verify calibration of NIBP parameter (temperature and pulse oximeter do not require calibration). Ensure that the display is functioning properly before operating the V100 Monitor.

Do not immerse the Monitor in water. If the Monitor is splashed with water or becomes wet, wipe it immediately with a dry cloth.

Do not gas sterilize or autoclave.

Caution should be taken to not set ALARM LIMITS to extreme values, as this can render the ALARM SYSTEM useless.

The V100 Monitor, when used with GE Medical Systems Information Technologies-approved applied parts and accessories, is protected against defibrillator damage.

NOTE: The electromagnetic compatibility profile of the V100 Monitor may change if accessories other than those specified for use with the V100 Monitor are used.

Equipment Symbols

The following symbols are associated with the V100 Vital Signs Monitor.

NOTE: The model of the monitor determines which symbols appear on it.


Attention, consult accompanying documents


Silence


Alarms


+ / - Increase / decrease adjustable settings


Menu


Inflate/Stop


Cycle


History


Print


On/Off


External communications port connector


Battery Power


Charging

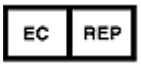
External DC power input


Class II equipment according to IEC 60536

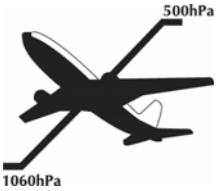

Defibrillator-proof type BF equipment

Manufacturer: This symbol is accompanied by the name and the address of the manufacturer.

Manufacturing Date: This symbol is accompanied by the date of the manufacturing.



European authorized representative.



Packaging label depicting the transportation and storage atmospheric pressure range of 500 to 1060 hPa.

WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE): This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

IPX1

The CARESCAPE V100 Vital Signs Monitor is protected against vertically falling drops of water and conforms with the IEC 529 standard at level of IPX1. Vertically falling drops shall have no harmful effects to the Monitor.

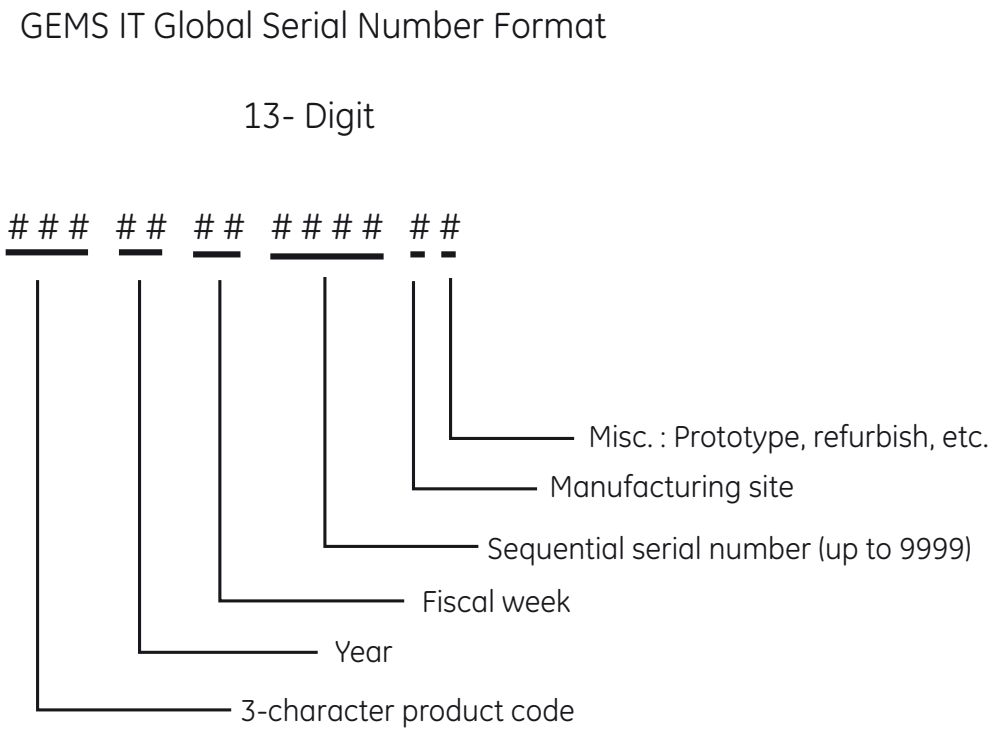
Service Requirements

Follow the service requirements listed below.

- Refer equipment servicing to GE Medical Systems *Information Technologies* authorized service personnel only.
- Any unauthorized attempt to repair equipment under warranty voids that warranty.
- It is the user's responsibility to report the need for service to GE Medical Systems *Information Technologies* or to one of GE's authorized agents.
- Failure on the part of the responsible individual, hospital or institution using this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
- Regular maintenance, irrespective of usage, is essential to ensure that the equipment will always be functional when required.

Equipment ID

The following graphic illustrates the components of the monitor's serial number.



Intended Audience

This manual is intended for service representatives and technical personnel who maintain, troubleshoot, or repair this equipment.

Intended Use

General Use

- The V100 Monitor is intended to monitor one patient at a time in a clinical setting.
- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- To ensure patient safety, use only parts and accessories manufactured or recommended by GE Medical Systems *Information Technologies*. Parts and accessories used shall meet the requirements of EN60601.1.1.
- Disposable devices are intended for single use only. They should not be reused.
- Periodically, and whenever the integrity of the monitor is in doubt, test all functions.

Related Manuals

Manual	Title
2036991-001	CARESCAPE V100 Vital Signs Monitor Operator's Manual

Service Policy

The warranty for this product is enclosed with the product in the shipper carton. All repairs on products under warranty must be performed or approved by Product Service personnel. Unauthorized repairs will void the warranty. Only qualified electronics service personnel should repair products not covered by warranty.

Service Contracts

Extended warranties can be purchased on most products. Contact your Sales Representative for details and pricing.

Assistance

If the product fails to function properly, or if assistance, service or spare parts are required, contact Customer Support. Before contacting Customer Support, it is helpful to attempt to duplicate the problem and to check all accessories to ensure that they are not the cause of the problem. If you are unable to resolve the problem after checking these items, contact GE Medical Systems *Information Technologies*. Prior to calling, please be prepared to provide:

- product name, model number, and serial number
- a complete description of the problem

If repair parts or service are necessary, you will also be asked to provide:

- the product serial number
- the facility's complete name, address, and account number
- a purchase order number if the product is to need of repair or when you order spare parts
- the facility's GE Medical Systems *Information Technologies* account number, if possible
- the appropriate part number for spare or replacement parts

Service

If your product requires warranty, extended warranty or non-warranty repair service, call Customer Support and a representative will assist you. To facilitate prompt service in cases where the product has external chassis or case damage, please advise the Customer Support representative when you call.

The Customer Support representative will record all necessary information and will provide you with a Return Merchandise Authorization Number (RMA). Prior to returning any product for repair, you must have a RMA number. Contact GE Medical Systems I*nformation Technologies*.

Packing Instructions

Follow these recommended packing instructions.

- Remove all hoses, cables, sensors, and power cords from the monitor before packing.
- Pack only the accessories you are requested to return; place them in a separate bag and insert the bag and the product inside the shipping carton.
- Use the original shipping carton and packing materials, if available.

If the original shipping carton is not available:

- Place the product in a plastic bag and tie or tape the bag to prevent loose particles or materials from entering openings such as hose ports.
- Use a sturdy corrugated container to ship the product; tape securely to seal the container for shipping.
- Pack with 4 to 6 in. of padding on all sides of the product.

Insurance

Insurance is at the customer's discretion. The shipper must initiate claims for damage to the product.

Service No Charge Rental

A no charge rental unit is provided at no charge during the warranty period of the product when we perform the repair service.

- GE Medical Systems *Information Technologies* pays the shipping charges for a loaner sent to the customer for product repairs under the warranty.
- Rental units are available in non-warranty situations.
- The customer pays the shipping charges to return a rental.

All loaners provided to customers must be returned within the specified time stated on the loaner agreement or a rental fee will be incurred.

Repair Parts

Repair parts can be ordered from GE Medical Systems *Information Technologies:*

Via phone: 1-800-558-7044, or

Via FAX: 1-800-421-6841

Exchange replacement assemblies such as Circuit Board Assemblies also are available; ask the Customer Support representative for details.

Please allow one working day for confirmation of your order. All orders must include the following information.

- Facility's complete name, address, and phone number
- FAX number
- Your purchase order number
- Your GE Medical Systems *Information Technologies* account number

Disposal of Product Waste

As you use the V100 Monitor, you will accumulate solid wastes that require proper disposal or recycling. These include batteries, patient applied parts, and packaging material.

Batteries

CAUTION
Do not incinerate batteries.

The sealed, rechargeable backup battery contains lead and can be recycled. The rechargeable memory battery is of the Sealed Lead Acid form. Discharge this battery prior to disposal. Place the battery in packaging which electrically isolates its contents. Do not puncture or place the battery in a trash compactor. Do not incinerate the battery or expose it to fire or high temperatures. Dispose in accordance with regional body controlled guideline.

Patient Applied Parts

Certain patient applied parts, such as those with adhesive (disposable SpO_2 sensors), are intended for single use and should be disposed of properly as medical waste in accordance with regional body controlled guideline.

Other patient applied parts, such as blood pressure cuffs, should be cleaned according to instructions. Inspect reusable applied parts for wear, replace as necessary, and dispose of used product as medical waste in accordance with regional body controlled guideline.

Packaging Material

Retain original packaging materials for future use in storing or shipping the Monitor and accessories. This recommendation includes corrugated shippers and inserts.

Whenever possible recycle the packaging of accessories and patient applied parts.

Monitor

At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of the product, please contact GE Medical Systems *Information Technologies* or its representatives.

2 Equipment Overview

For your notes

Equipment Description

The CARESCAPE V100 Vital Signs Monitor provides a small, portable, easy-to-use monitoring alternative for sub-acute hospital and non-hospital settings. The V100 is for use on adult, pediatric, or neonatal patients—one at a time. The battery-operated monitor offers noninvasive determination of systolic blood pressure, diastolic blood pressure, mean arterial pressure, pulse rate, oxygen saturation, and temperature. Monitors are available with or without integrated printers as well as the following parameters and technologies.

- NIBP, Pulse: SuperSTAT, Auscultatory, Classic
- SpO_2: Ohmeda TruSignal, Nellcor, or Masimo
- Temperature: Alaris Turbo Temp

The model of the monitor determines which parameters are in your monitor. Please refer to applicable sections.

Using the V100 Monitor, a clinician can measure, display, and record patient vital sign data that is derived from each parameter. The monitor is also capable of alerting the clinician to changes in the patient's condition or when it is unable to effectively monitor the patient's condition. All of the main operations of the V100 Monitor are easy-to-use and only a button-touch away. Please review the factory default settings and, where applicable, enter settings appropriate for your use.

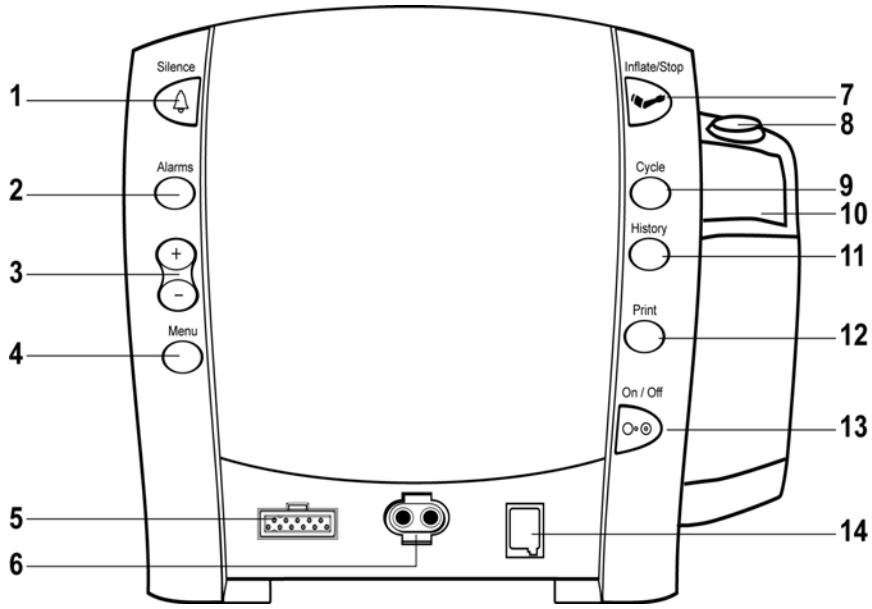
Product Configurations

Each CARESCAPE V100 Monitor is supplied with an accessory pack. The contents of the pack vary according to model. Unpack the items carefully, and check them against the checklists enclosed within the accessory boxes. If an accessory is missing or if an item is in a nonworking condition, contact GE Medical Systems *Information Technologies* Customer Service immediately.

It is recommended that all the packaging be retained, in case the V100 Monitor must be returned for service in the future.

Basic Components

Buttons

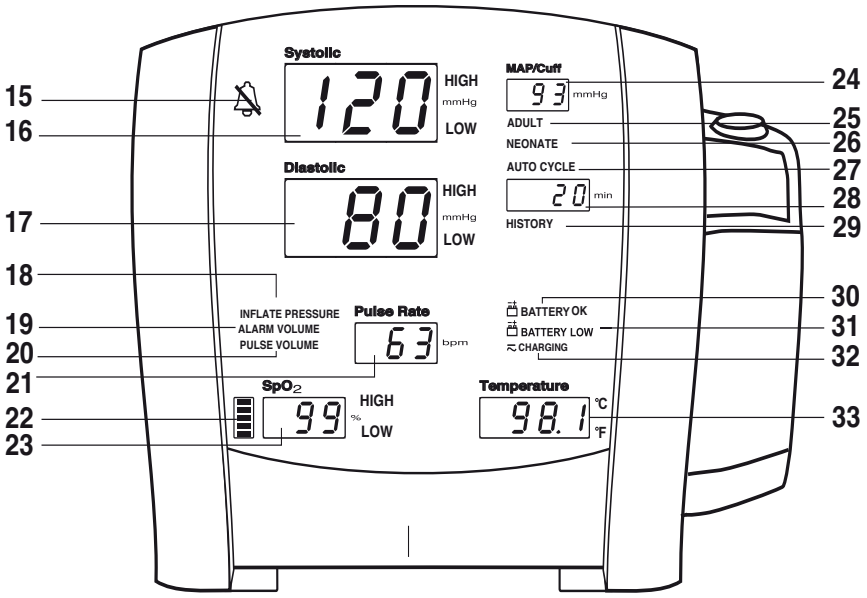


1. **Silence** button: mutes audible alarms. Any other active alarm that can be acknowledged is also removed whenever this key is pressed. When pressed, the silence icon (bell) lights red to indicate that audible alarms have been silenced for 2 minutes. Alarm silence can be cancelled by pressing the **Silence** button again.
2. **Alarms** button: used to view or adjust parameter alarm limit settings.
3. **+/-** buttons (Plus/Minus): used when you are in the following modes: limit, menu, cycle, and history. When you are in limit or menu setting, pressing the **+/-** button increases and decreases an adjustable setting. When you are in cycle or history mode, pressing the **+/-** buttons displays the next or previous cycle selection or entry in the history list, respectively. When you reach the beginning or ending of a list, a negative key-click sounds.
4. **Menu** button: accesses menu settings that can be adjusted: **INFLATE PRESSURE (ADULT** and **NEONATE), ALARM VOLUME,** and **PULSE VOLUME.** (Refer to *Operating Modes* in this section for a description of clinical mode.)

   NOTE: ADULT indicator encompasses both adult and pediatric patients.
5. SpO_2 sensor connector: attach SpO_2 cables here.
6. NIBP connector: attach NIBP cuff hoses here.
7. **Inflate/Stop** button: starts a manual NIBP determination or stop any NIBP determination.
8. Temperature probe holster: stores temperature probe.
9. **Cycle** button: used to select NIBP mode of manual, auto cycle, or Stat mode.
10. Temperature probe cover storage: stores probe covers.

11. **History** button: activates the history mode to view stored patient data. The most recent entries are displayed first. Press and hold the button for 2 seconds to clear all entries stored; the adaptive inflate pressure setting returns to the configured setting. Refer to the "*History*" Section of this manual for more information.
12. **Print** button: prints currently displayed values or all stored entries when in history mode.
13. **On/Off** button: controls on/off state of monitor; push for power on and push again for power off.
14. Temperature probe connector: attach temperature probe cable here.

Front Panel



15. **Silence** icon: silences audible alarms for 2 minutes; silence icon (bell) lights.
16. **Systolic** window: indicates measured systolic NIBP in mmHg.
17. **Diastolic** window: indicates measured diastolic NIBP in mmHg.
18. **INFLATE PRESSURE** indicator: flashes to indicate you are making a change to the inflation pressure. Adjustable for adult/ped and neonate patients.
19. **ALARM VOLUME** indicator: flashes to indicate you are making a change to the alarm volume.
20. **PULSE VOLUME** indicator: flashes to indicate you are making a change to the pulse volume.
21. **Pulse Rate** window: shows pulse rate in beats per minute.
22. SpO_2 pulse indicator: flashing red LED bar indicates that pulses are being derived from SpO_2 signals.
23. **SpO_2** window: indicates oxygen saturation in %.
24. **MAP/Cuff** window: indicates measured mean arterial pressure (MAP) in mmHg and shows cuff pressure during NIBP determination.

25. **ADULT** indicator: lights to indicate you are making a change to adult/ped NIBP limits or inflation pressure settings.
26. **NEONATE** indicator: lights to indicate you are making a change to neonate NIBP limits or inflation pressure settings.
27. **AUTO CYCLE** indicator: lights green to indicate auto mode is the chosen NIBP mode; flashes to indicate you are making a change to the auto mode.
28. **Min** window: displays the NIBP mode if manual or Stat as well as the cycle time when taking auto NIBP determinations.
29. **HISTORY** indicator: flashes to indicate you are in history mode.
30. **BATTERY OK** indicator: lights green to indicate the monitor is operating on battery power and that the battery is sufficiently charged.
31. **BATTERY LOW** indicator: lights amber to indicate low charge for the battery (45 min or less when solid; 5 min or less when flashing).
32. **CHARGING** indicator: lights green to indicate presence of external power source and battery charging.
33. **Temperature** window: lights 4-digit red LED to indicate measured temperature.

Product Compliance

The CARESCAPE V100 Monitor is classified in the following categories for compliance with IEC 60601-1:

- Internally powered or Class II when powered from external supply
- Transportable
- For continuous operation
- Not suitable for use in the presence of flammable anesthetics
- Not for use in the presence of an oxygen-enriched atmosphere (oxygen tent)
- Type BF applied parts
- IPX1, degree of protection against ingress of water
- Sterilization/Disinfection, see Appendix C *"Maintenance"*
- Software is developed in accordance with IEC 60601-1-4.
- This equipment is suitable for connection to public mains via power adaptors as defined in CISPR 11.
- The SpO_2 parameter complies to ISO 9919:2005.
- Defibrillation protected. When used with the recommended accessories, the monitor is protected against the effects of defibrillator discharge. If monitoring is disrupted by the defibrillation, the monitor will recover.

CARESCAPE V100 Monitor Classified with respect to electric shock, fire, and mechanical and other specified hazards only in accordance with CAN/CSA C22.2 No. 60601.1. Also evaluated to IEC-60601-2-30.

This product conforms with the essential requirements of the Medical Device Directive 93/42. Accessories without the CE mark are not guaranteed to meet the Essential Requirements of the Medical Device Directive.

IPX1

The CARESCAPE V100 Monitor is protected against vertically falling drops of water and conforms with the IEC 529 standard at level of IPX1. No harmful effects will come of vertically falling drops of water making contact with the monitor.

Theory of Operation

Introduction

This section provides overall theory of operation and functional description of the V100 Monitor. Monitors are available with or without integrated printers as well as the following parameters and technologies.

- NIBP, Pulse: DINAMAP SuperSTAT, Auscultatory, Classic
- SpO_2: Ohmeda TruSignal, Nellcor, or Masimo
- Temperature: Alaris Turbo Temp

The model of the monitor determines which parameters are in your monitor. Please refer to applicable sections.

Using the V100 Monitor, a clinician can measure, display, and record patient vital sign data that is derived from each parameter. The monitor is also capable of alerting the clinician to changes in the patient's condition or when it is unable to effectively monitor the patient's condition. All of the main operations of the V100 Monitor are easy-to-use and only a button-touch away. Please review the factory default settings and, where applicable, enter settings appropriate for your use.

Overall Principles of Operation

The V100 Monitor is a portable unit that receives power from an internal rechargeable Lead Acid Battery.

When the ON/OFF button is pressed, the Main Board is brought out of a sleep mode and turns on the power regulators. The power regulators provide conditioned power from the Lead Acid Battery. The external DC source is used only to charge the Lead Acid Battery. Once the V100 Monitor is energized, a self-test is performed. The self-test automatically tests the main functions of the V100 Monitor. Failure of the self-test will set the V100 Monitor into a fail-safe mode with an audio alarm.

Under normal operating conditions, the V100 Monitor is ready to record the patient vital signs using three external attachments: the temperature probe, SpO_2 sensor, and cuff. Interface with a central station or other device is accomplished through the host communication port on the back of the V100 Monitor.

NOTES

- Prior to each use, inspect the power supply cord to ensure proper connection and condition.
- Be sure to unplug the Monitor before transport.

SpO_2

The SpO_2 probe has a built-in sensor. When the SpO_2 sensor is attached to the SpO_2 connector and patient, the probe senses both heart rate and oxygen saturation. The analog signals are routed to the SpO_2 PWA (Ohmeda, Nellcor, or Masimo). The analog signals are analyzed on the SpO_2 PWA. The results are digitized and sent to the Main Board via opto couplers. The couplers provide patient isolation as well as serial data interface. The Main Board temporarily stores the data and routes it to the UI Board for display and/or printer.

A reset signal to the SpO_2 PWA is also provided so that power up sequencing is correct. If the SpO_2 circuit quits communicating to the Main Board, the Main Board will attempt to reset the SpO_2 PWA.

Cuff Blood Pressure (NIBP) and Pulse

The NIBP parameter in the V100 Monitor is available with three types of DINAMAP NIBP technologies: two calibrated to intra-arterial pressure (Classic and SuperSTAT) and one calibrated to the auscultatory method (Auscultatory). Specific technologies are available in select markets. All user interface options, instructions for use, and alarms will be the same for all technologies. The NIBP parameter is included in all models. Blood pressure is monitored noninvasively in the V100 Monitor by oscillometric method.

NOTE: For neonatal populations, the reference is always the intra-arterial pressure monitoring method.

When the cuff and hose are attached to the V100 Monitor and a Non-Invasive Blood Pressure (NIBP) determination is initiated, the pump inflates the cuff. Pressure transducers PT1 and PT2 monitor pressure information. The pneumatic manifold has one valve, which is used to deflate the cuff. Valve control is through the Main Board. Once determinations are made for the systolic NIBP and diastolic NIBP, the Main Board calculates the pulse rate/ Mean Arterial Pressure (MAP). The results are then displayed on the UI Board and sent to the printer (if the user presses the **Print** button).

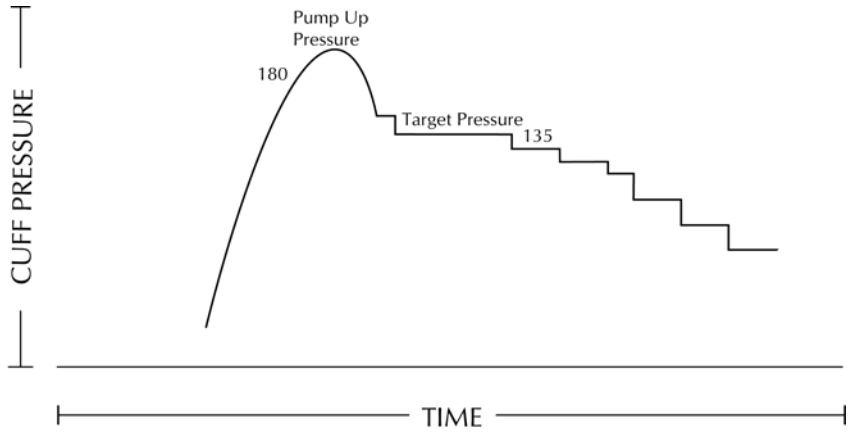
The Pneumatics are controlled by the NIBP processor. The NIBP processor monitors pressure information from PT2. If an over-inflation condition occurs, the OVERPRESSURE signal is routed to the Pneumatics to release the air pressure. The Main Board also generates an alarm condition with the speaker sounding and error code message on the UI Board.

DINAMAP SuperSTAT Algorithm

The oscillometric method of determining NIBP is accomplished by a sensitive transducer which measures cuff pressure and pressure oscillations within the cuff. For the first determination taken on a patient, the algorithm stores the pattern of the patient's oscillation size as a function of the pressure steps. For subsequent manual, auto, or Stat determinations taken within 2 minutes of a previous determination of the same patient, as few as four pressure steps may be necessary to complete the determination process. In auto mode the data is stored for up to 16 minutes. When employing fewer pressure steps, the system uses the stored information from the previous blood pressure determination to decide the best pressure steps to take. The algorithm measures the consistency of pulse size to tell if the oscillations taken at a step are good and if more steps are needed.

The first determination settles at an initial target pressure of 135 mmHg (adult mode) and 100 mmHg (neonate mode), depending on initial target pressure preset. To allow for rapid settling of cuff pressure, the monitor will momentarily inflate to a higher pressure then immediately deflate to the target pressure. After inflating the cuff, the NIBP parameter begins to deflate. The oscillations versus cuff pressure are measured to determine the mean pressure and calculate the systolic and diastolic pressures.

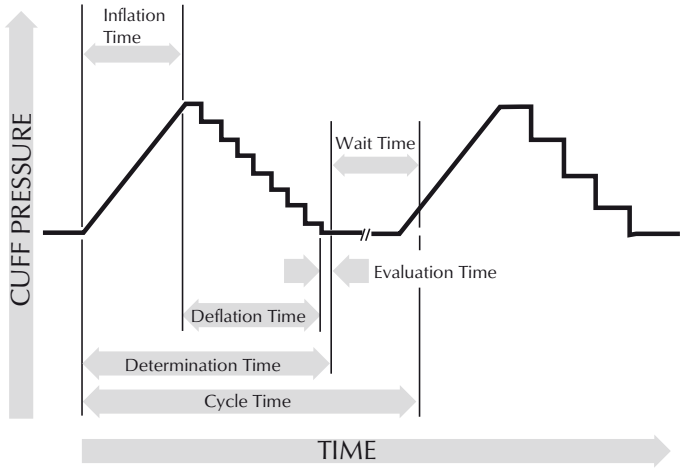
During an NIBP determination, the parameter deflates the cuff one step each time it detects two pulsations of relatively equal amplitude. The time between deflation steps depends on the frequency of these matched pulses (pulse rate of the patient). However, if the monitor is unable to find any pulse within several seconds, it will deflate to the next step. The process of finding two matched pulses at each step provides artifact rejection due to patient movement and greatly enhances the accuracy of the monitor. The figure shows a full determination sequence for an adult patient. In Stat mode, some steps may require only one pulse.



Full NIBP determination sequence for adult

At each step the microprocessor stores cuff pressure, the matched pulse amplitude, and the time between successive pulses. The stepped deflation and matched pulse detection continues until diastolic pressure is determined or total cuff pressure falls below 8 mmHg. The parameter then deflates the cuff (to zero detected pressure), analyzes the stored data, and updates the screen.

The operating cycle is composed of four parts: inflation time, deflation time, evaluation time, and wait time. Wait time, which varies from mode to mode, is affected by the cycle time (auto mode) or operator intervention (manual mode). The figure shows the basic operating cycle for an NIBP determination.



SuperSTAT NIBP - auto mode

Systolic Search

If systolic pressure is not found, the SuperSTAT algorithm can search at cuff pressures higher than the initial target pressure. The algorithm will inflate above the initial target pressure to obtain more data in the systolic region. The pressure is limited to the maximum allowed for the selected patient type.

The SuperSTAT algorithm evaluates the data obtained during the determination, and the prior determination if it is available, to determine if additional data is needed to complete the determination. It can then selectively pump to a single cuff pressure to obtain the data it needs and then return to the existing deflation sequence. This search process makes SuperSTAT more efficient.

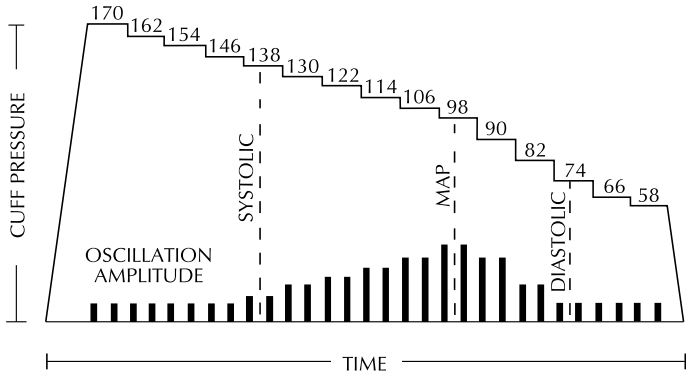
Accuracy of the DINAMAP NIBP measurements was validated against the intra-arterial method. Do not use the auscultatory method to verify the accuracy of the SuperSTAT NIBP parameter. The auscultatory method (using the cuff and stethoscope) determines the systolic and diastolic pressures from sounds that occur during cuff deflation. Mean arterial pressure cannot be determined by this method. The oscillometric method used with all DINAMAP technologies determines systolic, mean and diastolic pressures for the oscillations that occur in the cuff during deflation.

WARNING
Arrhythmias will increase the time required by the NIBP parameter to determine a blood pressure.

DINAMAP Classic and Auscultatory Reference Algorithm

The oscillometric method of determining NIBP is accomplished by a sensitive transducer, which measures cuff pressure and minute pressure oscillations within the cuff. The first determination sequence initially pumps up to a cuff pressure of about 160 mmHg for adult/pediatric patients or 110 mmHg for neonates depending on initial target pressure preset. After inflating the cuff, the monitor begins to deflate it and measures systolic pressure, mean arterial pressure, and diastolic pressure. When the diastolic pressure has been determined, the monitor finishes deflating the cuff and updates the screen.

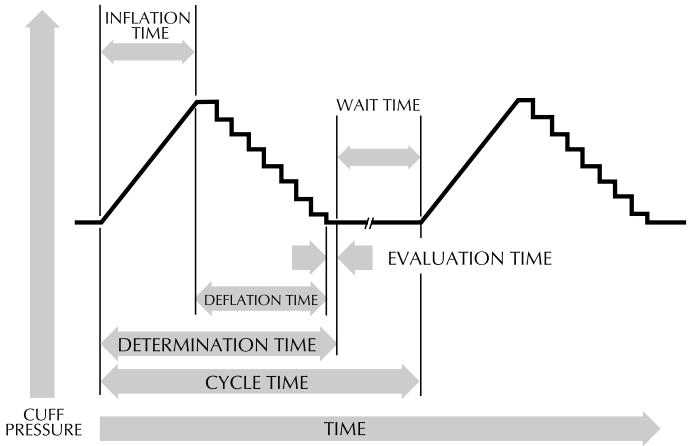
The monitor deflates the cuff one step each time it detects two pulsations of relatively equal amplitude. The time between deflation steps depends on the frequency of these matched pulses (pulse rate of the patient). However, if the monitor is unable to find any pulse within several seconds, it will deflate to the next step. The process of finding two matched pulses at each step provides artifact rejection due to patient movement and greatly enhances the accuracy of the monitor. The figure shows the NIBP determination sequence.



NIBP determination sequence

At each step the microprocessor stores cuff pressure, the matched pulse amplitude, and the time between successive pulses. The stepped deflation and matched pulse detection continues until diastolic pressure is determined or total cuff pressure falls below 7 mmHg. The monitor then deflates the cuff (to zero detected pressure), analyzes the stored data, and updates the screen.

The operating cycle is composed of four parts: inflation time, deflation time, evaluation time, and wait time. Wait time, which varies from mode to mode, is affected by the cycle time (auto mode) or operator intervention (manual mode). The figure shows the basic operating cycle.



NIBP operating cycle

Systolic Search

If systolic pressure is not found, the NIBP parameter can search at cuff pressures higher than the initial target pressure. The parameter will inflate the cuff above the initial target pressure to get more data in the systolic region. The pressure is limited to the maximum allowed for the selected patient type.

In any operating mode, if a patient's systolic pressure exceeds the inflation pressure of the monitor, the monitor will begin normal deflation sequence, detect the absence of a systolic value, stop deflation, reinflate to a higher (than initial) inflation pressure, and resume normal deflation sequence.

In manual mode, if a previous valid systolic pressure is displayed and less than 2 minutes old, and the new systolic pressure oscillations are compared with the previous valid determination and the monitor "thinks" that the systolic was not obtained, the monitor will inflate the cuff to a pressure above the immediately preceding inflation.

Reference Used to Determine NIBP Accuracy

To establish accuracy of an NIBP device, manufacturers have used several different types of references. The reference blood pressures may be obtained by invasive pressure monitoring at the central aortic region or at the radial sites. The reference blood pressures may also be obtained by noninvasive methods like auscultatory method (using cuff and stethoscope).

NOTE: For neonatal mode, the reference is always the intra-arterial pressure monitoring method.

CARESCAPE V100 Monitors With Intra-Arterial Reference (DINAMAP SuperSTAT and Classic Technology)

For these monitors, the NIBP is referenced to the invasive blood pressure obtained at the central aortic region.

CARESCAPE V100 Monitors With Auscultatory Reference (DINAMAP Auscultatory Reference Technology)

In these monitors, the reference blood pressure is the auscultatory method for adult and pediatric populations. For neonatal populations, the reference is the invasive blood pressure obtained at the central aortic region.

NOTE: For neonatal determinations the SuperSTAT algorithm is always used.

Temperature

The V100 Monitor uses Alaris Turbo Temp technology to measure patient temperature. The Turbo Temp probe contains a heating element that preheats the probe to reduce determination time. The heating function is controlled by the Main Board. The Turbo Temp probe also contains a thermistor that indicates the temperature. When the probe is attached to the temperature connector and patient, the signal generated by the thermistor is routed to the Main Board. The Main Board converts the thermistor signal along with status information (i.e., ORAL or RECTAL probe indicators) to a DIGITAL signal. The Main Board then processes the DIGITAL signal and displays the patient temperature on the UI Board and printer in Celsius or Fahrenheit.

Host Communication Port

The Host Comm Port is used to interface the V100 Monitor with other electronic devices (a central nurse's station or remote alarm device.) Signals can be sent to the V100 Monitor to initiate blood pressure determinations and other functions. Patient data can also be retrieved through this port. For further information, reference the Host Communication manual.

Functional Description

The following paragraphs provide the functional interface relationship. The V100 Monitor contains a number of electrical & electro-mechanical assemblies. These assemblies are:

- Main Board PWA
- User Interface (UI) Board PWA
- SPO_2 PWA (optional)
- Printer (optional)
- Pneumatic Valve/Manifold (PVM)
- Optical Switch (optional)

Main Board PWA

The V100 Main Board is based on the NXD LPC2366 integrated microprocessor. The microprocessor integrates Flash ROM, RAM, A/D converter with input multiplexer, SPI interface, and timers into one chip. This microprocessor is the primary processor for the V100 Monitor. It services and controls the Patient Parameter Interface (PPI) devices, printer, UI Board, Real Time Clock, audio circuit, and host communication. There are three TI MSP430 secondary processors that control Power, NIBP and Temperature. The Power Processor controls the watchdog, primary processor reset, and power supply control. The Power processor is powered at all times.

The NIBP processor controls pneumatic safety interlock, timing check, and NIBP control. The temperature processor controls the temperature parameter.

Independent software in the primary and secondary processor periodically communicate when the software systems are operating properly. When either system stops processing or detects an error, it stops communicating with the other. Either system, upon detecting a failure, can assert a safe state (herein called FAILSAFE) of the hardware.

Upon entering a FAILSAFE condition, the Main Board will perform the following tasks:

- Parameter monitoring disabled
- Alarm tone sounding from speaker
- Pneumatic FAILSAFE (deflate the cuff, pump off)
- Normal communications interface disabled
- Remote alarm is in alarm state
- Hard keys except ON/OFF key inactive

The ON/OFF key can reset the Monitor and end the FAILSAFE condition. The FAILSAFE condition will terminate automatically after 5 minutes to preserve battery power.

All regulated DC power, isolated and non-isolated is generated on the Main Board from Battery supply. The external DC input is used to charge the battery via charging circuitry on the Main Board.

User Interface (UI) Board PWA

The UI Board is used as a message center. It displays patient vital signs, alarms status, monitor set-up, limit violation, NIBP cycle and the time the data was received. The primary processor on the Main Board controls the UI Board. When the primary processor reads the parameter signals, it decodes the signals and routes the display information to the UI Board.

The UI assembly also provides hardkey switches for the V100 Main Board. The primary processor asserts a HIGH on the 16 outputs of the 1-of-16 decoder/ demultiplexer one at a time and then reads at the signal on SW_MUX. A LOW on SW_MUX indicates that the switch is asserted.

SpO_2 PWA

The V100 Monitor can be configured for use with either a Ohmeda, Nellcor, or Masimo SpO_2 PWA. The SpO_2 PWA provides continuous readings of oxygen saturation and pulse rate. Additional circuitry on the Main Board provides power, data communications, and isolation between SpO_2 PWA and primary processor.

Patient data received from the finger sensor is filtered, amplified, and analyzed on the SpO_2 PWA. The information is sent to the Main Board via the optically coupled electrically isolated serial connection. The primary processor receives the data and routes it to the UI board for display. The data is also sent to the printer if specified

Printer

The printer receives power from the Main Board and communicates with the primary processor. Printer presence and print head temperature is indicated by PR_TH signal to the primary processor. When a print command is sent to the printer from the primary processor, the following will occur:

- PR_CLK signal - transfer the data into print head
- PR_DI signal - serial dot to be printed
- PR_LAT signal - latch the data stream into the head
- PR_ST1-6 - cause the head to print various sections
- PR_M1-4 signals - control power sequentially to the two stepper motor windings

Together these signals (CONTROL DATA) cause the printer to print a graphic hardcopy of the patient vital sign values and trend data. It also causes the printer to print a hardcopy of error logging and service record data.

The printer has a built-in sensor to monitor the printer paper presence. When the printer is out of paper, it sends a PAPER OUT signal to the primary processor.

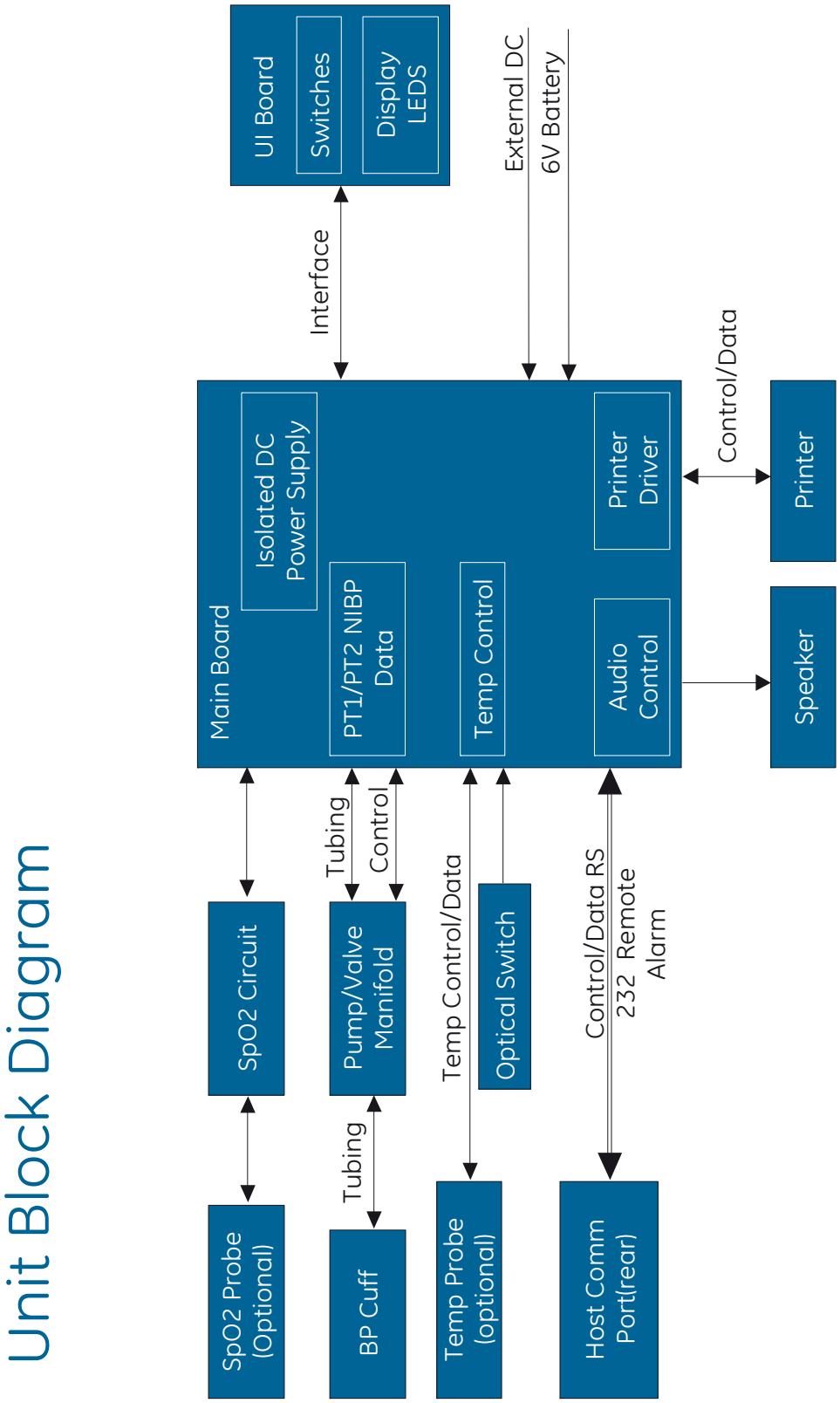
Pneumatics

The pneumatics consists of a pump, a deflate valve, and a dump valve. The pneumatics inflates/deflates the cuff during NIBP determinations. During normal operation the pneumatics are controlled by the primary processor. If a failsafe mode or overpressure condition occurs, the NIBP processor provides the appropriate control signals to insure a safe condition, where the cuff vents to ambient atmosphere pressure.

Optical Switch

The optical switch indicates whether the temperature probe is inserted in the probe holder or not. The Main Board powers the switch.

Unit Block Diagram

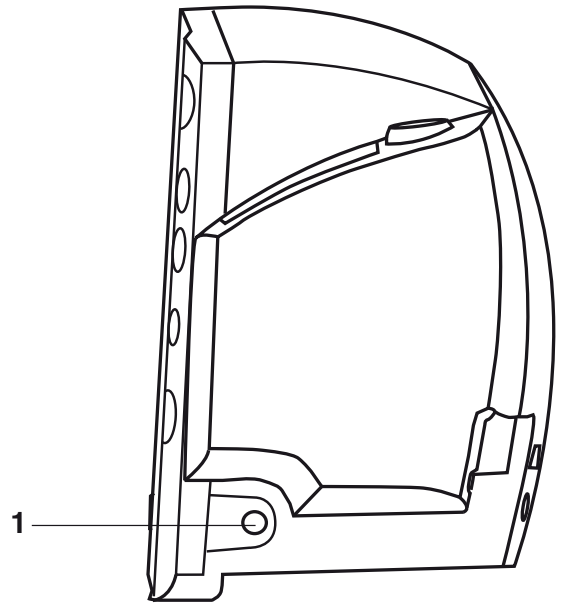


3 Installation

For your notes

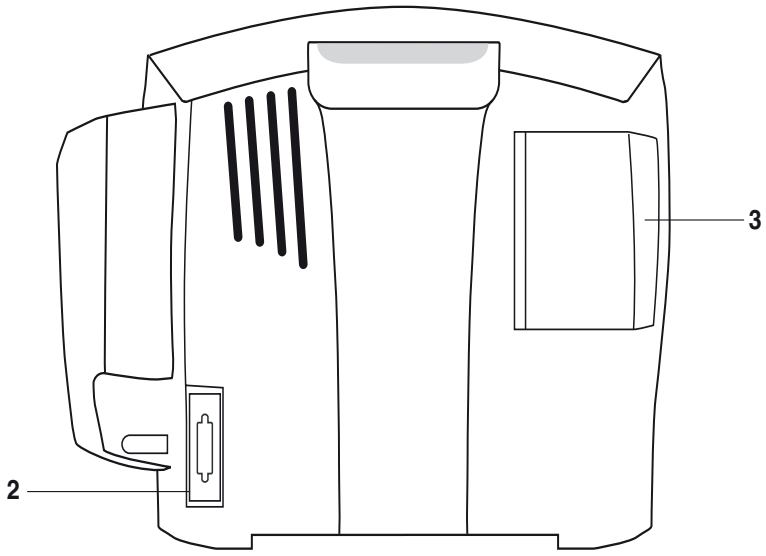
Connections

Right-Side Panel



1. External DC power socket: used with approved GE Medical Systems *Information Technologies* AC-DC power converter ONLY.

Rear Panel



2. Data interface connector: host communications port (15 pin D-type RS-232 serial port) for use only with equipment conforming to IEC 60601-1, configured to comply with IEC 60601-1-1.
3. Printer door.

Powering the Monitor

Power Sources

The V100 Monitor is designed to operate from an internal lead-acid battery.

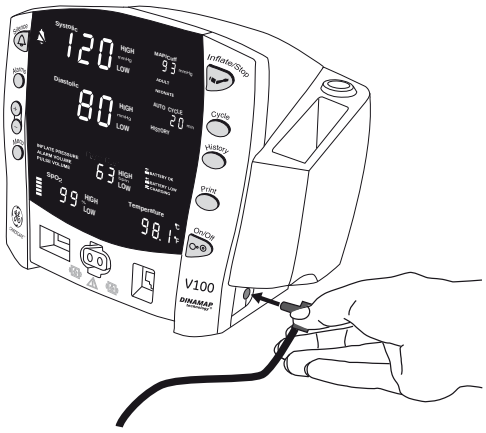
NOTE: The V100 Monitor is not designed to operate without a functional internal battery.

Battery Charging

Prior to each use, inspect the power supply cord to ensure proper connection and condition.

With external DC power connected, the green **CHARGING** indicator will light to indicate that the battery is charging. This indicator remains active whether the unit is on or off. An audible "two beep" sounds whenever the DC charger is connected/disconnected.

Battery charging will take place as long as the monitor remains connected to an external DC power source.



- Charge battery pack for 12 hours before first use or after prolonged periods of storage.
- If the monitor is idle for extended periods, it should be fully charged at least once a month to ensure optimum performance.
- The battery pack should be charged before use, because a charged battery loses charge when left in storage. Sealed lead acid batteries can discharge to less than 80% of charge within 60 days of storage. Charging is done automatically by the monitor when the external DC power is connected.
- The battery pack should be charged at room temperature (59°F to 86°F; 16°C to 30°C).
- You can charge or top-off the battery pack at any time. Do not have to wait until battery is fully discharged.
- To prolong the life of the battery, keep the monitor connected to a DC power supply whenever possible. Do not allow the battery to become completely discharged.
- A fully charged battery will power the monitor for approximately 8-11 hours, depending upon configuration and usage.
- To ensure full charge cycles, replace only with a the specified battery.
- If the monitor is to be stored for some time, first charge the battery and then remove it and store it separately from the monitor.

BATTERY OK

When the Monitor is operating on battery power and the BATTERY LOW alarm is not active, the BATTERY OK indicator is backlit green.

Battery Alarms

When about 45 minutes of battery charge remains:

The low-priority **BATTERY LOW** alarm is issued.

- The **BATTERY LOW** indicator illuminates.
- This alarm can be silenced by pressing the **Silence** button.
- The **BATTERY LOW** alarm will re-alarm every 10 minutes after it's been silenced.
- If the alarm is not silenced, the alarm is re-issued every 8 seconds.
- The monitor continues to operate normally.

When about 5 minutes of battery charge remains:

The low-priority **BATTERY LOW** alarm escalates to a high-priority **BATTERY LOW** alarm.

- The **BATTERY LOW** indicator flashes.
- Any NIBP determination in progress at the time of the alarm escalation is allowed to finish.
- Any Stat mode cycle that was initiated before the alarm escalation is allowed to finish.
- The user is not able to initiate:
  - any new NIBP determinations of any type
  - any printouts

NOTE: At this time, it is highly recommended to plug the monitor into external DC power.

When 5 minutes of battery charge expires:

After 5 minutes of high-priority **BATTERY LOW** alarm, the monitor enters a battery low shutdown.

- No error code is displayed.
- The **BATTERY LOW** indicator flashes.
- The monitor alarms for 2.5 minutes then shuts down completely.

CAUTION
You must plug the monitor into DC power before resuming monitoring.

After plugging the monitor into DC power:

- The **BATTERY LOW** indicator (when the monitor is on) and **CHARGING** indicator illuminate.
- The **BATTERY LOW** indicator turns off when the battery level reaches a sufficient charge level to operate without the **BATTERY LOW** alarm active.

E13 Battery Low

At any time while the high-priority **BATTERY LOW** alarm is active, certain actions can trigger the **E13 BATTERY LOW** alarm: any attempt to start an NIBP determination or a printout. This alarm is giving you additional warning that the battery charge is critically low.

NOTE: At this time, it is highly recommended to plug the monitor into external DC power.

- The **E13** error code appears in the **min** window.
- The **BATTERY LOW** indicator flashes.
- This alarm can be silenced by pressing the **Silence** button.
- The user is not able to initiate:
  - any new NIBP determinations of any type
  - any printouts

Unpacking and Preparation for Installation

1. Unpack and identify the contents of all shipping materials.
2. Remove the V100 Monitor.
3. Unpack the AC cord.
4. Plug the AC cord into the AC Mains input on the external power supply, and plug the supply DC output into the back of the Monitor.
5. Plug the AC cord into a Hospital Grounded AC receptacle. The word CHARGING will illuminate green on the front of the Monitor indicating that an AC source is available.

Prior to usage it is necessary to charge the Monitor for 12 hours. This charge calibrates the battery charging circuitry with the charge status of the battery.

Configuring Your V100 Monitor

Operating Modes

The V100 Monitor can operate in one of four modes: clinical, configuration, advanced configuration, and service.

Clinical Mode

Clinical mode is the Monitor's normal operating mode. While this mode is active, alarm limits and a few other commonly used settings are adjustable. All parameters are available for monitoring in this mode.

Configuration Mode

Configuration and advanced configuration modes display the software revision and allow you to configure defaults for some settings that are available in clinical mode, as well as some less commonly used settings that are only adjustable in these modes. A fatal error history is also available in the advanced configuration mode. No parameters are operable in these modes, therefore, patient monitoring is suspended.

Configuration Mode Settings

Monitor settings such as HIGH/LOW alarm settings changed in the Clinical Mode will not be retained after the monitor is powered off. To retain alarm and parameter settings, the changes must be done in the configuration mode. Date/Time settings are also entered in the configuration mode.

To enter the configuration mode: with the Monitor off, press and hold the **Menu** button at the same time as pressing and holding the **On/Off** button for 3 seconds. The Monitor enters the configuration mode.

For a few seconds immediately after power up in this mode, the Systolic and Diastolic windows display the major and minor version codes. The version codes are numbers that represent the letters of the English alphabet, which are designated to the currently loaded version of the monitor firmware (e.g., 1 indicates A, 2 indicates B, etc.).

At the same time, the NIBP Algorithm selected in the monitor is displayed in the "min" (minutes display) window as follows:

- AUSC if the monitor is configured with auscultatory NIBP Algorithm
- STAT if the monitor is configured with DINAMAP SuperSTAT Algorithm
- CLAS if the monitor is configured with DINAMAP Classic Algorithm

Display	Window
Major software revision	Systolic
Minor software revision	Diastolic
Type of NIBP technology	min

These displays appear only during the first part of the power up sequence and are not selectable and cannot be changed. After a moment, this version information is cleared, and the monitor displays the 1st page of configuration mode which simply displays **CFG** in the Systolic window.

Pressing the **Menu** button cycles through all the configuration option pages. After all options pages have been displayed, the display returns to the 1st configuration mode page (displaying **CFG**). You can use the **+** and **-** buttons to make changes to settings. After making changes, simply cycle the power to return to normal operation (clinical) mode. Changes are automatically retained.

The Menu selections appear in the following order. Refer the each manual section for settings options.

NOTE: Menu selections for SpO_2 settings are different depending upon the SpO_2 technology your monitor contains.

Setting	Window	LED Display	Pulse Rate Window Display	Comment
Inflate pressure (adult/ped)	Systolic	XXX (numeric)	XXX (numeric)	ADULT indicator illuminated, INFLATE PRESSURE indicator flashing
Inflate pressure (neonate)	Systolic	XXX (numeric)	XXX (numeric)	NEONATE indicator illuminated, INFLATE PRESSURE indicator flashing
Line frequency mode (Ohmeda TruSignal only)	SpO_2	50 or 60	LF	AC line frequency
SpO_2 mode (Nellcor only)	SpO_2	1 or 2	MOd	User selects the averaging technique* 1=Normal Response, 2= Fast Response
SpO_2 sat (Nellcor only)	SpO_2	0, 10, 25, 50, 100	SAt	User selects the SMART Sat tolerance level *
SpO_2 mode (Masimo only)	SpO_2	4, 6, 8, 10, 12, 14, 16	MOd	User selects the number of seconds over which data is averaged 4 to 16*
SpO_2 sat (Masimo only)	SpO_2	0 or 1	SAt	Fast Sat Mode 0=Off, 1=On*
SpO_2 sensitivity (Masimo only)	SpO_2	1, 2, 3	SEn	1= Low Perfusion-Maximized, 2= Low Perfusion-Default, 3= for engaging Adaptive Probe Off Technology algorithm*
Temperature	Temperature	blank	Unt	C or F indicator illuminated

Setting	Window	LED Display	Pulse Rate Window Display	Comment
Year	Systolic	XXX (numeric)	YR	use + & - keys to change
Month	MAP/Cuff	XXX (numeric)	MTH	use + & - keys to change
Day	Diastolic	XXX (numeric)	DAY	use + & - keys to change
Hour	min	XXX (numeric)	HR	use + & - keys to change
Minute	min	XXX (numeric)	MIN	use + & - keys to change
Mode (when main screen is active)	Systolic	blank	CFG	indicates configuration mode
NOTE: Refer to the "SpO_2" Section of Operators Manual for detailed descriptions of the different user selectable SpO_2 settings.				

Setting the Date and Time – To set the date and time on the V100 Monitor, you must access the configuration mode. Press **Menu** to skip the default settings that do not require changes. Refer to the table above.

NOTE: While in configuration mode, all entries stored in the clinical history are erased when the time and/or date is changed.

Procedures

1. Press the **Menu** button to move from one setting to another. Use the **+/-** buttons to increment or decrement the setting.

   NOTE: For the date and time to be saved, you must advance the menu through the minute setting.

2. To exit the configuration mode, press the **On/Off** button.
3. To continue with other changes, press the **Menu** button. **CFG** will appear in the Systolic window. To change parameter settings, press the **Menu** button and select the parameter function. To change alarm settings, press the **Alarms** button.

Inflation Pressure Default Setting –

Procedures

1. Enter the configuration mode: with the Monitor off, press and hold the **Menu** button at the same time as pressing and holding the **On/Off** button for 3 seconds.
2. Use the **+/-** buttons to increment or decrement the inflate pressure default setting.
3. To exit the configuration mode, turn the unit off. To continue with additional configuration settings, press **Menu**.

Alarm Default Settings –

Procedures

1. Enter the configuration mode: with the Monitor off, press and hold the **Menu** button at the same time as pressing and holding the **On/Off** button for 3 seconds. After the unit enters the configuration mode, press **Alarms**. At any point in the configuration mode menu, Alarms default can be selected.
2. To set or change the default setting, press the Alarms button to select alarm setting. Use the **+/-** buttons to increment or decrement the individual settings.

   NOTE: For the Alarms default setting to be saved, you must advance the menu through the SpO_2 settings.
3. To exit the configuration mode, turn the unit off. To continue with additional configuration settings, press **Menu**.

SpO_2 Configuration Settings –

Procedure for units with Ohmeda TruSignal Technology

1. With the monitor off, press and hold the **Menu** button at the same time as pressing the **On/Off** button until the display test completes.
2. Press the **Menu** button until **LF** appears in the **Pulse Rate** window.
3. Use the **+/-** buttons to select the option.
4. To exit the configuration mode, turn the unit off. To continue with additional configuration settings, press the **Menu** button.

CAUTIONS

The LF mode must be set according to each country's electrical power utilities implementation. The LF mode must be checked and reset any time the monitor is set to or reverts to factory default settings.

If the LF mode is set incorrectly, the susceptibility to ambient light is increased and low perfusion performance may be effected resulting in inaccurate readings.

Procedure for units with Nellcor Technology

1. With the monitor off, press and hold the **Menu** button at the same time as pressing the **On/Off** button until the display test completes.
2. Press the **Menu** button until **n0d** (response mode) appears in the **Pulse Rate** window.
3. Use the **+/-** buttons to select the option.
4. Press the **Menu** button once. **SAt** (*SatSeconds*) appears in the **Pulse Rate** window.
5. Use the **+/-** buttons to select the option.

6. To exit the configuration mode, turn the unit off. To continue with additional configuration settings, press the **Menu** button.

Procedure for units with Masimo Technology

1. With the monitor off, press and hold the **Menu** button at the same time as pressing the **On/Off** button until the display test completes.
2. Press the **Menu** button until **n0d** (averaging time) appears in the **Pulse Rate** window.
3. Use the **+/-** buttons to select the option.
4. Press the **Menu** button once. **SAt** (FastSAT) appears in the **Pulse Rate** window.
5. Use the **+/-** buttons to select the option.
6. Press the **Menu** button once. **SEn** (sensitivity mode) appears in the **Pulse Rate** window.
7. Use the **+/-** buttons to select the option.
8. To exit the configuration mode, turn the unit off. To continue with additional configuration settings, press the **Menu** button.

Advanced Configuration Mode

Advanced Configuration mode is entered by holding the **Menu** button and the **-** button simultaneously while powering on with the **On/Off** button.

For a couple of seconds immediately after power up in this mode the Systolic and Diastolic display windows will display the major and minor version codes. The version codes are numbers that represent the letters of the English alphabet which are designated to the currently loaded version of the monitor firmware (e.g., 1 indicates A, 2 indicates B, etc.).

After a moment, this version information is cleared, and the monitor displays the 1st page of configuration mode which simply displays **ACF** in the Systolic display window indicating that the monitor is in advanced configuration mode.

You can then press the **Menu** button to cycle through all the advanced configuration mode option pages. After all options pages have been displayed, the display will return to the 1st advanced configuration mode page (displaying **ACF**). You can use the **+** and **-** buttons to make changes to settings. After making changes, simply cycle the power to return to normal operation mode. Changes are automatically be retained.

The advanced configuration mode option pages are as follows:

Displayed on Monitor	Function
ACF	Advanced Configuration Mode announcement (No settings are entered on this page.)
rEn	Remote mode 0 : Remote mode is disabled 1 : Remote mode is enabled (default)
Adr	Host Comm unit address 32 : This is the default value: 126 max.
br	Host Comm bit rate (bits per sec) 0 : 300 bps 1 : 600 bps 2 : 1200 bps 3 : 2400 bps 4 : 4800 bps 5 : 9600 bps (default) 6 : 19200 bps
nod	Host Comm mode 0 : Host Comm Command mode (default) 1 : 1846 Compatibility mode (1846 mode requires user to also select 600 bps.)

Service Mode

Service mode is entered by holding the **Cycle** button while powering on with the **On/Off** button. You can press the **Cycle** button to advance through the available service mode pages.

NOTES

- Only transducer calibration pages are available until calibration is valid.
- Calibration and other service mode setting changes will not be retained unless the “Save Settings” operation is executed (on the final Service Mode options page).

After all options pages have been displayed, the display will return to the 1st service mode page (initial calibration page). To save service mode settings the Service Mode option pages are as follows:

Displayed on Monitor	Function
0 (in "min" window)	Refer to calibration section for functions.
1 (in "min" window)	Refer to calibration section for functions.
2 (in "min" window)	Refer to calibration section for functions.
3 (in "min" window)	NIBP Algorithm Type loaded (Displayed in MAP/Cuff display window) 1: DINAMAP Classic NIBP 2: DINAMAP Auscultatory NIBP 3: DINAMAP SuperSTAT NIBP (Warning: Changing setting effects NIBP performance.)
4 (in "min" window)	SpO_2 Type loaded (Displayed in SpO_2% display window) 0: No SpO_2 1: Nellcor 2: Masimo 3: Ohmeda (Warning: Incorrect setting will cause fatal 930 alarm during operation.)
5 (in "min" window)	Temperature loaded (Displayed in Temperature display window) 0: No Temp 1: Turbo Temp

Displayed on Monitor	Function
6 (in "min" window)	Language The number displayed in Pulse Rate display window indicates the language setting. These range from 0 to 20. For example, 0 indicates English. The language setting is used in printed reports. Russian, Greek, Korean, Chinese, and Japanese are printed in English only. 0 English 1 Chinese 2 Czech 3 Danish 4 Dutch 5 Finnish 6 French 7 German 8 Greek 9 Hungarian 10 Italian 11 Japanese 12 Korean 13 Norwegian 14 Polish 15 Portuguese Brazilian 16 Portuguese Continental 17 Russian 18 Slovak 19 Spanish 20 Swedish
In "MAP/Cuff" window: # of remaining saves possible	In order to save any changes made in config mode, press and hold the menu button until a tone sounds
Warning: The number displayed in the "MAP/Cuff" window will decrease each time the "Save Settings" operation is done. If it reaches zero, a fatal 975 alarm (calibration space exhausted) results and the unit will have to be serviced before operation will be possible again.	

Host Communications Connector

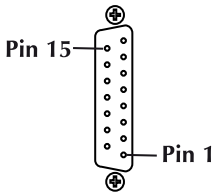
All host port signals are NON-ISOLATED and should be connected to equipment conforming to IEC 60601-1-1 ONLY. Where isolation of data communication is required, the isolated level converter should be used. If external alarm control is required, p/n 487208CR (Isolated Remote Alarm Cable Assembly) should ALWAYS be used. Please refer to the Information Sheet included with the isolated remote alarm cable for operational details.

NOTE: When using remote alarm, the V100 Monitor should be considered the primary alarm source. The secondary alarm is used for secondary purposes only.

DB15 Connector Pin Assignments

Connection Details

Host Port Connector (rear panel)



WARNING! Auxiliary equipment connected to the V100 Monitor will result in the formation of an electromedical system and thus, must comply with the requirements of EN 60601-1-1/ IEC 60601-1. All host port signals are NON-ISOLATED and should be connected to equipment conforming to IEC-60601-1, configured to comply with IEC 60601-1-1 ONLY. Where isolation of data communication is required, GE Medical Systems *Information Technologies* part number ILC1926 should be used. If external alarm control is required, GE Medical Systems *Information Technologies* part number 487208CR (Isolated Remote Alarm Cable. When a high-priority alarm condition is displayed on the Monitor, the remote alarm signal becomes active within 0.5 seconds. The active state of the alarm signal is an open circuit. In the inactive state the alarm signal is connected to ground. Please refer to the Information Sheet included with the isolated remote alarm cable for operational details.

NOTE: When using remote alarm, the V100 Monitor should be considered the primary alarm source. The secondary alarm is used for secondary purposes only.

Pin #	Function
1	Common
2	Inverted TTL Transmit Data
3	Inverted TTL Receive Data
4	+5 volts
5	No connection
6	No connection
7	Common
8	Remote Alarm
9	No connection
10	No connection
11	RS232 Transmit Data (TxD)
12	No connection
13	RS232 Receive Data (RxD)
14	No connection
15	No connection

4 Maintenance

For your notes

Preventative Maintenance

WARNING
Failure on the part of all responsible individuals, hospitals or institutions, employing the use of this device, to implement the recommended maintenance schedule may cause equipment failure and possible health hazards. The manufacturer does not, in any manner, assume the responsibility for performing the recommended maintenance schedule, unless an Equipment Maintenance Agreement exists. The sole responsibility rests with the individuals, hospitals, or institutions utilizing the device.

General

Preventative maintenance tasks include cleaning the V100 Monitor, checking pressure calibration, pneumatic leakage, pneumatic system overpressure point, temperature calibration (200 and 400), and verification of the SpO_2 system (300 and 400). Perform the following maintenance procedures as required.

Integrity of Hoses and Cuffs

When the pneumatic integrity of any NIBP cuff and hose is in doubt, replace the cuff and hose, and discard the questionable accessories.

Visual Inspection

The monitor and its components should be carefully inspected prior to installation, once every 12 months thereafter and each time the equipment is serviced.

- Carefully inspect the equipment for physical damage to the case, the display screen, and the keypad. Do not use the monitor if damage is determined. Refer damaged equipment to qualified service personnel.
- Inspect all external connections for loose connectors or frayed cables.
- Have any damaged connectors or cables replaced by qualified service personnel.
- Inspect the display face for marks, scratches, or other damage.
- Physical damage to a flat panel display glass may pose an implosion hazard. Have the flat panel display replaced by qualified service personnel if necessary.
- Safety labels and inscription on the device are clearly legible.

Cleaning

Cleaning the Monitor

CAUTIONS

Never pour or spray water or any cleaning solution on the equipment or permit fluids to run behind switches, into connectors, into the recorder, or into any ventilation openings in the equipment.

Do not let fluid "pool" around connection pins.

Never immerse monitor or accessories in any liquid.

Do not attach the monitor or accessories to a patient until it is thoroughly dry.

Failure to follow these cleaning recommendations may melt, distort, or dull the finish of displays and cases; blur lettering on labels; embrittle cases and lead to cracks and breakage; or cause equipment failures. Use of non-approved cleaning agents is not considered normal wear and repair or replacement of parts is not covered under warranty.

Monitor Exterior

Disconnect the monitor from AC power before cleaning or disinfecting its surface. The exterior surfaces of CARESCAPE Monitors may be cleaned with a dampened, lint-free cloth. Wipe off all cleaning solutions with a clean, dry cloth and let air dry for at least 15 minutes. Use one of the following approved solutions:

- Mild soap (diluted)
- Commercial diluted bleach solution or bleach wipe
- Commercial diluted ammonia solution
- 10% solution of household bleach (5.25% sodium hypochlorite) in distilled water

Never use the following cleaning agents: –

- Abrasive cleaners or solvents of any kind
- Acetone
- Ketone
- Betadine
- Alcohol- or petroleum-based cleaning agents
- Any type of solution that contains ammonium chloride, conductive solutions, wax or wax compounds
- Sodium salts

NOTE: Never autoclave or steam clean the monitor, cuffs, or accessories.

Monitor Display

To clean the display screen, use a soft, clean cloth dampened with a glass cleaner. Never spray the glass cleaner directly onto the display, and never use alcohol- or petroleum-based products.

Cuffs

General

The cuff must be thoroughly cleaned with the specified detergent before reuse. The additional use of household bleach as described below provides at least intermediate-level disinfection.

- Apply cuff hose plugs before cleaning.
- The following cleansing procedure was repeated 20 times on DURA-CUF® Blood Pressure Cuffs and once on SOFT-CUF® Blood Pressure Cuffs without affecting the performance of the cuff.
- While this procedure is adequate for cleaning/disinfection, it may not remove all stains.
- Do *not* immerse hoses.
- Do *not* immerse cuffs without prior application of cuff hose caps.

Materials

- Enzymatic detergent such as ENZOL* enzymatic detergent (US) or Cidezyme* enzymatic detergent (UK)
- Distilled water
- 10% solution of household bleach (5.25% sodium hypochlorite) in distilled water
- Soft cloths and soft-bristled brushes
- Spray bottles

Procedure

1. Prepare the enzymatic detergent according to the manufacturer's instructions and the 10% bleach solution, in separate spray bottles.
2. Spray the detergent liberally on device. If the material is dried on, allow the cuff to sit for 1 minute. For soil on the soft part of the closure or the cuff itself, wipe the material off with a soft cloth. For persistent contamination on the soft part of the closure, use a soft-bristled brush to loosen particles. Rinse with copious amounts of distilled water. Repeat until no visible contamination remains. For soil on the hook part of the closure, use a soft-bristled brush to remove the material, and rinse with copious amounts of distilled water. Repeat until no visible contamination remains.
3. Spray the 10% bleach solution on the affected area until the area is saturated. Allow the cuff to sit for 5 minutes.
4. Wipe away any excess solution and rinse the cuff again with distilled water. Allow 2 hours for drying.

NOTE: The user has the responsibility to validate any deviations from the recommended method of cleaning and disinfection.

For additional information on infection control procedures, contact GE Medical Systems *Information Technologies* Technical Support.

Temperature Devices

Do not immerse predictive temperature probes. The probe may be cleaned with a solution of 10% bleach in water. Use a cloth or sponge—just damp, not wet—and avoid getting any liquid into the interior of the probe.

SpO_2 Sensors

Adhesive sensors are sterile and for single use only. Reusable sensors should be cleaned before reuse with a 70% alcohol solution. If low-level disinfection is required, use a 1:10 bleach solution. Do not use undiluted bleach (5% - 5.25% sodium chlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor could occur. Do not sterilize the sensor by irradiation, steam, or ethylene oxide. If disposable sensors or their packaging are damaged, they must be disposed of as advised in this appendix.

To clean or disinfect the sensor:

1. Saturate a clean, dry gauze pad with the cleaning solution. Wipe all surfaces of the sensor and cable with this gauze pad.
2. Saturate another clean, dry gauze pad with sterile or distilled water. Wipe all surfaces of the sensor and cable with this gauze pad.
3. Dry the sensor and cable by wiping all surfaces with a clean, dry gauze pad.

Long-Term Storage

If it becomes necessary to store the Monitor for an extended period of time, remove all attached accessories. Attach the original packing inserts, and place the Monitor into the original shipping container.

Battery life is significantly reduced if the battery is left in a discharged state. For long-term storage, fully charge the battery, then remove the battery from the unit and periodically charge the battery. For more information, refer to the “Storage and Battery Care” section below.

Long-term storage at high temperatures can lead to deterioration of seals and separators and should be avoided.

Battery Care

If it becomes necessary to store the Monitor for an extended period of time, first fully charge, then remove the battery. Then store the Monitor and the battery in the original packaging materials.

Batteries should always be fully charged before being placed in storage. Batteries should not be left in storage more than 6 months without removal and full recharge. A fully charged battery in good condition will provide sufficient power to operate a Monitor for approximately 8-11 hours, depending upon configuration and use.

It is best to keep the battery charged as fully as practical and never store the Monitor with the battery in a discharged condition. When the battery will no longer hold a charge, remove and replace it. Failure to replace the battery with the same GE Medical Systems *Information Technologies* part number may result in shorter battery life. Battery charging will take place as long as the Monitor remains connected to an external DC power source.

NOTE: After replacing batteries, an E00 error code is normal. The user settings and date/time revert to the factory default setting.

CAUTIONS

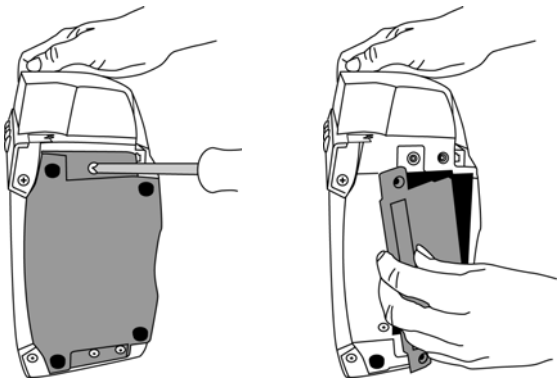
To ensure that the battery will be ready for portable operation, keep the Monitor connected to a mains supply whenever possible.

Repeated failure to fully charge the battery will result in a significant reduction in battery life.

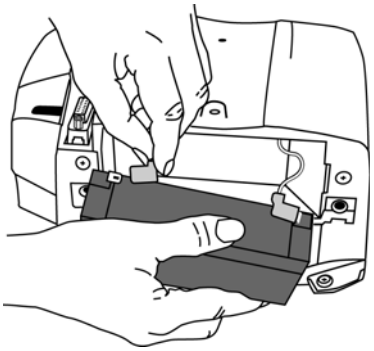
The expected lifetime of the battery largely depends on the way in which the Monitor is used. Never fully discharge the battery. To prolong battery life, connect the Monitor to AC power source when not in use.

Replacing the Battery

1. Unplug the Monitor from the DC power source.
2. Looking at the bottom of the V100 Monitor, remove the battery compartment cover by removing the four screws that secure the cover and help card tray.
3. Remove the help card tray and battery door cover.



4. Remove the old battery and disconnect the wires. Attach the battery wires to the new battery, ensuring the red terminal (+) is connected to the red wire and the black terminal (-) is connected to the black wire.
5. When reconnecting battery power, the monitor enters fatal mode. To clear the alarm press the **On/Off** button.
6. Insert the battery into the compartment.



7. Then replace the cover, help card tray, and screws. Insert the external DC power converter plug into the external DC power socket and plug into an AC outlet.

NOTES:

- Error code **E00** appears (MEMORY LOST) alerting you that the user settings (including alarm limits and inflation pressure) and date/time will go back to default values.
- Configured settings and time/date will NOT be lost when reset due to pressing and holding the **On/Off** button regardless of whether the DC charger is attached.
- Configured settings and time/date will NOT be lost when the battery is

disconnected while the DC charger is attached (i.e., monitor is plugged in).

- Configured settings and time/date WILL be lost if the battery is disconnected while the DC charger is not attached (i.e., monitor is not plugged in).

8. Reset the date/time and applicable user settings.

CAUTION
Do not touch either the pin of the DC input connector or the terminals within the battery compartment and the patient at the same time.

Replacement batteries can be obtained from GE Medical Systems *Information Technologies*.

Fuses

The monitor contains three fuses. The fuses are mounted within the monitor. The fuses protect the low voltage DC input, the battery, and the remote alarm output. The +5 V output on the host port connector is regulated by internal supply. Fuses are not replaceable.

Parameter Level Functional Testing

After the initial configuration is complete, perform functional testing of each of the parameters, using the accessories supplied with the V100 Monitor.

Refer to the operation manual for more detailed parameter-specific instructions.

NIBP

Perform a blood pressure by connecting the supplied hose and cuff together, then attaching to the front of the V100 Monitor. Press the **Start** button on the front to begin the NIBP cycle.

Temperature

Connect the supplied temperature probe to the corresponding connection. A predictive temperature will begin once the probe is removed from its holster. Place the probe in the holster after completion of the Temp cycle.

Ohmeda, Nellcor, and Masimo SpO_2 Technologies

The SpO_2 sensor is an assembly consisting of two parts: the sensor and the extender cable. Connect the cables prior to attaching to the Monitor. An SpO_2 reading will be displayed within moments of attaching the sensor to either a simulator or to your finger.

Calibration Procedures and Tests

NOTE: All devices are tested and calibrated during manufacturing and are certified for operation at installation.

- To adequately test the safety and integrity of the V100 Monitor, the following test equipment is recommended:
- 12VDC power supply
- IEC 60601-1 approved leakage tester
- Digital manometer (with range to 350 mmHg)
- Stopwatch/timer (capable of measuring seconds)
- Adult NIBP cuff, Neonate NIBP cuff, hose, inflation bulb, and associated tubing
- Calibration kit (p/n 320246, available through GE Medical Systems
- SpO_2 cable (for appropriate SpO_2 type, if SpO_2 is installed)
- TE 1811 Temperature Probe Simulator (if TEMP is installed) available from Cardinal Health, Inc.
- Printer paper (if PRINTER is installed)
- 3" diameter rigid cylinder (mandrel)
- SPO_2 connector with all leads shorted
- Temperature connector with all leads shorted
- DC input connector with both wires shorted

CAUTION
Calibration equipment should always be kept dry and free of particulate matter. Moisture or foreign substances introduced to the pneumatic system will likely cause damage to the Monitor and/or the accessories.

Annual Procedures

Perform the following test procedures every 12 months, or whenever the accuracy of any reading is in doubt.

Parameter Test Procedures

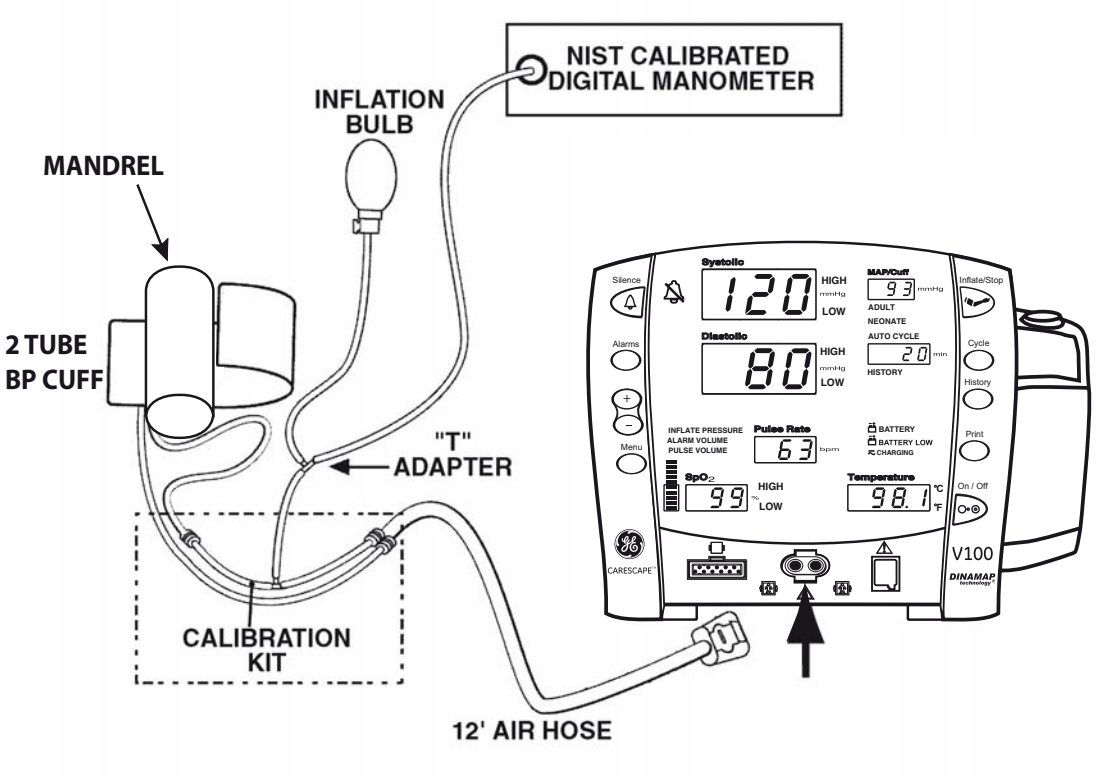
Complete the Test Record at the end of this section as tests are performed.

NOTES

- This test is written so that a knowledgeable technician who is familiar with the V100 Monitor and the test equipment and will be able to follow the test procedure.
- To enter Service Mode press and hold **Cycle** button while pressing the **On/ Off** button.

Setup

1. Connect manometer to unit as shown.
2. 'T' an inflation bulb into the pneumatic setup.
3. Consult the following diagram for pneumatic setup guidelines.



Pneumatic Leakage Testing

NOTE: To enter Service Mode press and hold the **Cycle** button while pressing the **On/Off** button.

1. Turn unit on and enter Service Mode.
2. Press **Cycle** button and **1** should appear in the **min** window.
3. Close the valve on the inflation bulb.
4. Using the inflation bulb, inflate the system to 210 mmHg.
5. Allow the system to stabilize for 5 seconds (it is normal to see some decrease in pressure at this point).
6. Start the stopwatch and record the pressure value.
7. After 60 seconds record the pressure value.
8. The leakage rate is the difference between the first and second readings.
9. Record and verify the leakage rate.
10. Turn the V100 Monitor off.

Pressure Transducer Verification

NOTE: To enter Service Mode press and hold the **Cycle** button while pressing the **On/Off** button.

1. Turn unit on and enter Service Mode.
2. The **min** window should display **0**.
3. Open the valve on the inflation bulb and remove all pressure from the system (manometer reads zero).
4. Press **Cycle** button and **1** should appear in the **min** window.
5. Use the inflation bulb to inflate the cuff, hose and pressure indicator setup to 200 mmHg.
6. Record and verify the pressure reading that appears in the **Systolic** window.
7. Record and verify the pressure reading that appears in the **Diastolic** window.
8. Use the valve on the bulb to reduce pressure to 150 mmHg.
9. Record and verify the pressure reading that appears in the **Systolic** window.
10. Record and verify the pressure reading that appears in the **Diastolic** window.
11. Use the valve on the bulb to reduce pressure to 100 mmHg.
12. Record and verify the pressure reading that appears in the **Systolic** window.
13. Record and verify the pressure reading that appears in the **Diastolic** window.
14. Use the valve on the bulb to reduce pressure to 50 mmHg.
15. Record and verify the pressure reading that appears in the **Systolic** window.
16. Record and verify the pressure reading that appears in the **Diastolic** window.

Pressure Transducer Calibration

Perform only if Pressure Transducer Verification is out of tolerance as specified in Test Results Table at the end of this section.

NOTE: To enter service mode press and hold **Cycle** button while pressing the **On/Off** button.

1. Turn the V100 Monitor on and enter Service Mode.
2. The **min** window should display **0**.
3. Open valve on bulb to open pressure system to atmosphere.
4. Verify the manometer reads zero.
5. Press **Cycle** button and **1** should appear in the **min** window.
6. Close valve on bulb and slowly inflate pressure to 200 mmHg (using the manometer as reference).
7. Press **Menu** button when pressure reads exactly 200 mmHg to set calibration value.
8. To save the calibration setting, press the **Cycle** button until **6** appears in the **min** window.
9. Press and hold **Menu** button until monitor beeps and the number in the MAP/Cuff window decrements by 1, which acknowledges that data was saved.
10. Turn the Monitor off.

Overpressure Verification

NOTE: : To enter service mode press and hold **Cycle** button while pressing the **On/Off** button.

1. Wait a few seconds after entering service mode. Press **Cycle** button so that the min window changes from **0** to **1**.
2. Use the inflation bulb to inflate close to 300 mmHg. Slowly inflate (1 to 2 mmHg/sec) until valve opens and pressure is released.
3. Record and verify pressure at which valve opens.
4. Press **Cycle** button and **2** should appear in the **min** window.
5. Use the inflation bulb to inflate close to 150 mmHg. Slowly inflate (1 to 2 mmHg/sec) until valve opens and pressure is released.
6. Record and verify pressure at which valve opens.
7. Turn unit off.

Button Testing

1. Disconnect the cuff/hose assembly and power on the unit.
2. Press **Inflate/Stop** button.
3. Verify a NIBP determination has been initiated.
4. Block pump port and verify **E80** alarm.
5. Verify flashing red indicator of **Silence** button.
6. Press **Silence** button, verify alarm has been removed.
7. Press **Alarm** button several times, verify unit cycles through all alarm settings (i.e., SYS, DIA, SpO_2).
8. Turn unit off.

LED Tests

1. Power on the Monitor.
2. During the power-up self-test verify all 7 segment LED display segments and all discrete LEDs illuminate.
3. Repeat power up cycle until all LEDs are checked.

External DC Verification

1. Plug the power supply into the Monitor.
2. Verify that the CHARGING indicator is illuminated.

NIBP Determination

NOTE: For best results, it is important to be seated and not moving, talking, eating, and/or smoking, etc. while taking your blood pressure. If you are uncertain as to the proper technique, consult the operation manual.

1. Remove the calibration set up and attach an adult cuff and hose (be sure to select the correct cuff size).
2. Press **Start/Stop** button on monitor to begin a determination.
3. Record **Systolic**, **Diastolic**, map and heart rate from the Monitor display.
4. Wait 1 minute, then press **Cycle** button to initiate a determination in Auto NIBP mode.
5. Record **Systolic**, **Diastolic**, map and heart rate from the Monitor display.
6. Wait 1 minute, then press **Cycle** button until **stat** is displayed in the **min** window to initiate a determination in STAT mode.
7. Record **Systolic**, **Diastolic**, map and heart rate from the Monitor display.
8. Press **Start/Stop** button, end STAT mode.

NIBP Overpressure Verification

1. Remove the cuff/hose from the monitor, restrict airflow from cuff hose port.
2. Press **Start/Stop** to begin NIBP determination.
3. Verify **E80** is displayed on the **Systolic** window and audible alarm sounds.
4. Remove the air restriction.
5. Press **Start/Stop** and verify that the pump does not start.
6. Press the **Silence** button.
7. Press the **Silence** button again.
8. Verify the alarm condition is cleared from the **Systolic** window.

Temperature (Perform if equipped with Temp module)

The Alaris Turbo Temp probes cannot be calibrated. These probes must be discarded after 2 years from the date of manufacture stamped into the RJ45 connector (first two digits=year, second two digits=week). Refer to the illustration example (0520=fw20 in 2005).

NOTE: It is the responsibility of the user to maintain proper records.

Alaris Turbo Temp Probe Date Code

1. Turn Monitor off. Make sure the temp probe is properly stored in the probe well.
2. Disconnect the temp probe cable from the monitor.
3. Connect Temp simulator; set to 80.2°F.
4. Turn the Monitor on.
5. Put the Monitor into temp monitor mode:
   a. partially remove the probe from the well (stop when you hear the Monitor beep).

b. Quickly re-insert the probe and remove again (you should hear two beeps of a different tone).
c. A temperature value should appear quickly, if not, repeat Step 5b.

6. Record and verify the reading in the temp display is 80.2°F ±0.2°F.
7. Set the simulator to 98.6°F.
8. Record and verify the reading in the temp display is 98.6°F ±0.2°F.
9. Set the simulator to 107.8°F.
10. Record and verify the reading in the temp display is 107.8°F ±0.2°F.
11. Calibration is complete. If the monitor does no pass the calibration verification then contact Technical Support.

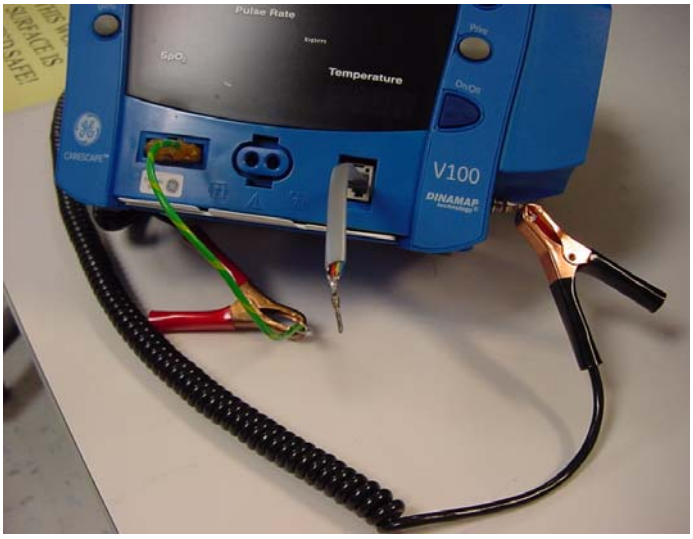
SpO_2 (Perform only if equipped with SpO_2 module)

1. Connect the appropriate SpO_2 probe and cable to the SpO_2 connector. Place the probe on your finger.
2. Verify the unit displays a:
   - Pulse value
   - Saturation value
   - Signal Strength Bar Graph
3. Remove the sensor from your finger to generate a **---** (SpO_2 SENSOR OFF FINGER) alarm and to sound the speaker.
4. Press the **Silence** button.
5. Verify the sound has stopped and the **---** (SpO_2 SENSOR OFF FINGER) error is cleared.
6. Re-apply the SpO_2 sensor to your finger.
7. Verify the unit displays a:
   - Pulse Value
   - Saturation value
   - Signal Strength bar Graph

Printer Output Test

1. Load Paper into the print mechanism.
2. Press **Print** button.
3. Verify the printer outputs a record and print quality is good.

Safety Testing



1. Connect leakage tester to unit as shown above.

NOTE: Connection to SpO_2 connector shown, switch red lead to temperature connector to test temperature circuit.

SpO_2 Circuit Leakage Test

1. Setup an IEC 60601-1 approved leakage tester to apply 240 VAC to the isolated SpO_2 circuit.
2. Plug SpO_2 adapter into the SpO_2 connector on the front of the unit.
3. Activate the Leakage Tester, verify and record the temp circuit leakage current.

Temp Circuit Leakage Test

1. Setup an IEC 60601-1 approved leakage tester to apply 240 VAC to the isolated temperature circuit.
2. Plug temp probe adapter into the temp jack.
3. Activate the Leakage Tester, verify and record the temp circuit leakage current.

Test Results Form

Description	Min	Max	Actual	Pass-Fail-N/A
LEAKAGE				
Pneumatic Leakage Result (mmHg)	0	6		
PRESSURE TRANSDUCER VERIFICATION				
Pressure reading at 200mmHg, top display - Systolic	197	203		
Pressure reading at 200mmHg, bottom display - Diastolic	197	203		
Pressure reading at 150mmHg, top display - Systolic	147	153		
Pressure reading at 150mmHg, bottom display - Diastolic	147	153		
Pressure reading at 100mmHg, top display - Systolic	97	103		
Pressure reading at 100mmHg, bottom display - Diastolic	97	103		
Pressure reading at 50mmHg, top display - Systolic	47	53		
Pressure reading at 50mmHg, bottom display - Diastolic	47	53		
OVERPRESSURE VERIFICATION				
Overpressure threshold, Adult (mmHg)	305	325		
Overpressure threshold, Neonate (mmHg)	150	165		
BUTTONS				
NIBP Determination Initiated				
"E80" displayed on SYSTOLIC display				
Audible alarm can be silenced				
"Silenced" LEDs flash				
Overpressure alarm can be cleared				
Alarm button is functioning				
DISPLAY				
All 7-Segment LEDs Light Correct Color				
All Discrete LEDs Light, Correct Color				
EXTERNAL DC DETECTION				
Charging indicator LED illuminated				

Description	Min	Max	Actual	Pass-Fail-N/A
NIBP DETERMINATION				
Systolic reading (mmHg)				
Diastolic reading (mmHg)				
MAP reading (mmHg)				
Heart rate reading (bpm)				
Systolic reading (mmHg)				
Diastolic reading (mmHg)				
MAP reading (mmHg)				
Heart rate reading (bpm)				
Systolic reading (mmHg)				
Diastolic reading (mmHg)				
MAP reading (mmHg)				
Heart rate reading (bpm)				
NIBP OVERPRESSURE				
"E80" displayed on SYSTOLIC display				
Pump will not start				
Overpressure alarm can be cleared				
TEMPERATURE TEST				
Temperature reading at 80.2° F	79.9° F	80.5° F		
Temperature reading at 98.6° F	98.4° F	98.8° F		
Temperature reading at 107.8° F	107.5° F	108.1° F		
SpO_2				
Pulse Value Displayed				
Saturation Value Displayed				
Signal Strength Bar				
"---" displayed on SpO_2 display				
Alarm is silenced, error display remains				
Pulse Value				
Saturation Value Displayed				
Signal Strength Bar				
PRINTER TEST				
Printout is generated cleanly				
Temp Circuit Leakage Current (µA)		300		
SpO_2 Circuit Leakage Current (µA)		300		

5 Troubleshooting

For your notes

Alarm Code Interpretation

If any other alarms appear that are not listed in the paragraphs that follow, record the error message and report the failure to Customer Support. Refer to the operation manual for information about patient alarms and general procedural alarms.

System Failures

When a system failure is encountered, the error code is displayed on the screen for > 5 seconds and the system enters failsafe mode. The error code is logged in the history log.

Pressing and holding the **On/Off** button for between 10 and 20 seconds, results in a fatal alarm. The same fatal alarm occurs when reconnecting the battery (refer to "*Maintenance*" Section for more detailed information on replacing batteries).

General system error codes are listed below. If any other system or similar code appears, report it to Customer Support.

Alarm Conditions and Error Codes

When responding to a monitor alarm, always CHECK THE PATIENT FIRST and then check the Monitor, cuff, hose and sensors. Press SILENCE to reset patient alarm conditions.

Error Log

You can view and print an error log that stores up to 40 error code entries. The log is a "rolling" list that—once 40 entries are stored—deletes the oldest entry in order to add the most recent entry. The error log is saved until the monitor experiences a memory loss, then all entries are deleted.

Procedure to View and Print Error Code History Log:

1. Enter the Advanced Configuration Mode (ACF) by holding down the **Minus** (-) and **Menu** buttons while powering up the monitor (pressing the **On/Off** button).
2. The monitor briefly displays the software revision, then displays ACF in the **Systolic** window.
3. The monitor is now in Advanced Configuration Mode
4. To view the error log use the **History** button to step through the log in reverse order of when the error occurred (oldest appears first).
5. The **Systolic** window shows the Year the error occurred.
6. The **Diastolic** window shows the Day the error occurred.
7. The **MAP** window shows the Month the error occurred.

8. The **SpO_2** window shows the Time the error occurred.
9. The **Pulse Rate** window shows the error code that occurred at the recorded time.
10. To print the error log, press the **Print** button while viewing the log.

Error Codes

Error Code or Problem	Source	Definition	Can be Silenced?*	Probable Source
Display blank, high pitch alarm	System	Failsafe error	No	Mains PWA issue
891	System	Hostcomm command forced safe state	No	Check comms cable connections
892	System	Hostcomm buffer full	No	Check comms cable connections
920	NIBP	Comm timeout between main processor and nibp subprocessor	No	Mains PWA issue
921	NIBP	Startup communication failure with NIBP processor	No	Mains PWA issue
922	NIBP	NIBP processor reports communication timeout	No	Mains PWA issue
923	NIBP	Determination time too long	No	Mains PWA issue
930	SpO_2	No status from module for 60 ±10 sec. Fatal error reported by module	No	Verify SpO_2 configuration is correct type Parameter turned on - no hardware installed in unit
940	Temp	TEMP data samples less than 45 in 5 sec while idle	No	Mains PWA issue
950	NIBP	NIBP pump on during idle or over current detected	No	Pneumatic assembly failure
951	NIBP	NIBP valve stuck closed during cuff typing	No	Pneumatic assembly failure
952	NIBP	NIBP PT2 higher than 150 for greater than 15 seconds while idle	No	Pneumatic assembly failure
970	Printer	Time base failure	No	Mains PWA issue
971	System	RAM test failure	No	Mains PWA issue
972	System	ROM checksum failure	No	Mains PWA issue
973	System	Secondary 12C communication error during initialization	No	Mains PWA issue
974	System	Calibration data invalid on initialization or unit never calibrated	No	Calibrate unit Mains PWA issue
975	System	Could not save calibration data	No	Mains PWA issue
976	System	Power supply voltage has peaked above 18 Volts (incorrect power supply)	No	External power brick issue
979	System	Unknown power processor mode received on power-up	No	Mains PWA issue

Error Code or Problem	Source	Definition	Can be Silenced?*	Probable Source
980	System	Heap memory exhausted	No	Mains PWA issue
984	System	Unused vector called	No	Return unit for evaluation
985	System	RTK 400hz timer re-entry	No	Return unit for evaluation
986	System	RTK 50hz timer re-entry	No	Mains PWA issue
989	System	RTK overrun	No	Mains PWA issue
994	System	Stack overflow	No	Mains PWA issue
999	System	Background task stalled	No	Mains PWA issue
E10	Printer	Printer no paper	Yes	No paper in printer Printer problem
E11	Printer	Printer too hot	Yes	Printer problem
E13	Battery	Battery low	Yes	Battery too low to operate the unit Charge battery External DC source failed Replace battery
BATTERY LOW	Battery	Battery is running low	Yes	Plug monitor in to recharge
E00	Battery	Memory lost	Yes	Usually noted after changing batteries. User settings and date/time revert to default settings.
---	SpO_2	SpO_2 Sensor off finger	Yes	Reposition SpO_2 sensor
E20	SpO_2	SpO_2 sensor disconnected	Yes	Sensor disconnected
E21	SpO_2	SpO_2 replace sensor	Yes	Replace SpO_2 sensor
E25	SpO_2	SpO_2 lost pulse	Yes	Reposition SpO_2 sensor
E61	Temp	Temp probe broken	No	Replace temperature probe
E63	Temp	Temp disconnected	Yes	Check for correct probe
E66	Temp	Temperature probe too hot	Yes	Replace probe
E80	NIBP	Overpressure	Yes	Check for pinched or occluded internal tubing
E82	NIBP	Excess air in cuff	Yes	Wrong cuff type Failed valve on pneumatics assembly

Error Code or Problem	Source	Definition	Can be Silenced?*	Probable Source
E83	NIBP	NIBP pump timeout	Yes	Leak in cuff or o-ring in hose Internal leak in tubing or pneumatic valve Pump not turning on
E84	NIBP	NIBP total timeout	Yes	Pneumatic assembly failure
E85	NIBP	NIBP level timeout	Yes	Cuff placement on patient Minor leak in cuff Pneumatic assembly failure
E89	NIBP	NIBP no determination	Yes	Cuff placement on patient

*****Acknowledging an alarm by pressing the Silence button, cancels the alarm.

6 Parts List, Drawings, and Replacement

For your notes

Ordering Parts

This section of the manual provides parts lists for the V100 Monitor. Parts lists should be used in conjunction with the other chapters of this manual.

GE makes every effort possible to provide the most up-to-date reference documentation for your equipment. However, in special cases involving field-installed upgrades, the revision level of a diagram or parts list in this manual may not reflect the revision level of your unit's subassemblies. When discrepancies are found, contact your GE Medical Systems *Information Technologies* Service Representative.

NOTE: Fab drawings are not contained in this manual.

Service Parts

Compatible Parts

Part	Part description	Part number
NIBP		
NIBP, Adult, 12ft	Air hose adult/ped 12 ft, gray	107365
NIBP, Neonate, 12ft	Air hose, neonatal 12 ft, light blue	107368
NIBP, Adult, 24ft	Air hose adult/ped 24 ft, gray	107366
NIBP, Cuff, Classic Cuff, Neonate	Classic-Cuf, assortment pack, neonatal, 2-tube, M slip	2693
NIBP, Cuff, Classic Cuff, Various	Classic-Cuf, assortment pack, various, 2-tube, screw	2692
NIBP, Cuff, Soft Cuff, Various	Soft-Cuf, assortment pack, various, 2-tube, screw	2695
NIBP, Cuff, Soft Cuff, Neonate	Soft-Cuf, assortment pack, neonatal, 2-tube, M slip	2694
NIBP, Cuff, Dura Cuff, Adult	Dura-Cuf, assortment pack, adult, 2-tube, screw	2698
NIBP, Cuff, Dura Cuff, Child	Dura-Cuf, assortment pack, child, 2-tube, screw	2697
NIBP, Cuff, Dura Cuff, Various	Dura-Cuf, assortment pack, various, 2-tube screw	2699
SpO_2 - Ohmeda		
SpO_2 - Cable Assy - 3M	OxyTip+ Interconnect cable, Ohmeda, 3 m	OXY-ES3
SpO_2 - Sensor	Finger Sensor with UN connector, 1 m	OXY-F-UN
SpO_2 - Sensor	Wrap Sensor with UN connector, 1 m	OXY-W-UN
SpO_2 - Sensor	Ear Sensor with UN connector, 1 m	OXY-E-UN
SpO_2 - Sensor	Sensitive Skin Sensor with UN connector, 4 m	OXY-SE-3
SpO_2 - Sensor	Adult/Pediatric Adhesive Sensor - 25/box	OXY-AP-25

Part	Part description	Part number
SpO_2 - Sensor	Adult/Pediatric Adhesive Sensor - 10/box	OXY-AP-10
SpO_2 - Sensor	AllFit Adhesive Sensor, 0.9 m - 10/box	OXY-AF-10
SpO_2 - Sensor	Integrated finger sensor, 4 m	OXY-F4-GE
SpO_2 - Sensor	Integrated ear sensor	OXY-E4-GE
SpO_2 - Sensor	OxyTip+ Integrated Finger Care connector 2 m	OXY-F2-GE
SpO_2 - Sensor	OxyTip+ Integrated Ear Care connector 2 m	OXY-E2-GE
SpO_2 - Accessory	OxyTip+ wide replacement tape, adhesive	OXY-RTW
SpO_2 - Accessory	Foam wrap replacement, large, weight range $\geq$ 3 kg	OXY-RWL
SpO_2 - Accessory	Foam wrap replacement, medium, weight range $\geq$ 3 kg	OXY-RWM
SpO_2 - Accessory	Foam wrap replacement, small, weight range < 3 kg	OXY-RWS
SpO_2 - Accessory	OxyTip+ replacement tape, AllFit Sensor, Bears - 100/box	OXY-RTB
SpO_2 - Accessory	OxyTip+ replacement tape, AllFit Sensor, Blue - 100/box	OXY-RT
SpO_2 - Accessory	Infant Foam Sandal, use with OxyTip+ Sensitive Skin sensor - 3/box	OXY-SND
SpO_2 - Nellcor		
SpO_2 Cable Assy 3M	Cable Assy SpO_2 Nellcor OxiMax 3 m - Smart	2021406-001
SpO_2 Cable Assy 3M	Cable Assy SpO_2 Nellcor OxiMax 1.2 m - Smart	2021406-002
SpO_2 - Sensor	Max -A Adult Finger Adhesive Sensor - 24/box	70124027
SpO_2 - Sensor	Max -AL Adult Long Finger Adhesive Sensor - 24/box	2028117-001
SpO_2 - Sensor	Max-P Pediatric Finger Adhesive Sensor - 24/box	70124022
SpO_2 - Sensor	Max-N Neonate Foot Adhesive Sensor - 24/box	70124032
SpO_2 - Sensor	Max-I Infant, Adhesive, Sensor - 24/box	70124026
SpO_2 - Sensor	Max-R, Adhesive, Nasal - 24/box	407705-005
SpO_2 - Sensor	OXIBAND (OXI-P/I) Pediatric/Infant Sensor	414248-001
SpO_2 - Sensor	OXIBAND (OXI-A/N) Adult/Neonate Sensor	414248-002
SpO_2 - Sensor	OXIBAND (OXI-A/N) Adult/Neonate Sensor	70124035 (EMEA)
SpO_2 - Sensor	Nellcor Multisite Sensor D-YS Reusable	70124033
SpO_2 - Sensor	Nellcor DuraSensor DS-100A	70124021
SpO_2 - Sensor	Nellcor DuraSensor DS-100A	407705-006 (US)

Part	Part description	Part number
SpO_2 - Accessory	Nellcor Ear-Clip D-YSE Sensor for 70124033	70124034
SpO_2 - Accessory	Nellcor Tape ADH-A/N, use with 70124035	2016130-001
SpO_2 - Accessory	Nellcor Tape ADH-P/I, use with Oxi-P/I Sensors	2016131-001
SpO_2 - Masimo		
SpO_2 - Sensor	Masimo LNOP Disposable Adhesive Sensor, LNOP Adt. Adult - 20/box	2010458-001
SpO_2 - Sensor	Masimo LNOP Disposable Adhesive Sensor, LNOP Pdt. Pediatric - 20/box	2010459-001
SpO_2 - Sensor	Masimo LNOP Disposable Adhesive Sensor, LNOP NeoPT. Neonatal - 20/box	2010461-001
SpO_2 - Sensor	Masimo LNOP Disposable Adhesive Sensor Bridge, LNOP Neo. Neonatal - 20/box	2010460-001
SpO_2 - Sensor	Masimo LNOP Disposable Adhesive Sensor, LNOP-Neo-L. Neonatal - 20/box	2017089-001
SpO_2 - Sensor	Masimo LNOP Disposable Adhesive Sensor, LNOP NeoPT-L. Neonatal - 20/box	2017090-001
SpO_2 - Sensor	Masimo LNOP Adtx Disposable Adhesive Sensor Transparent Tape LNOP, Adult - 20/box	2027269-001
SpO_2 - Sensor	Masimo LNOP Pdtx Disposable Adhesive Sensor Transparent Tape LNOP, Pediatric - 20/box	2027270-001
SpO_2 - Sensor	Masimo LNOP Disposable LNOP Disposable LNOP Hi Fi Sensor Neonatal/Adult - 20/box	2027272-001
SpO_2 - Sensor	Masimo LNOP Disposable LNOP Disposable LNOP Hi Fi Sensor Infant/Pediatric - 20/box	2027271-001
SpO_2 - Sensor	Masimo LNOP Disposable LNOP Disposable LNOP Blue Infant Thumb/Toe Sensor - 20/box	2027273-001
SpO_2 - Sensor	Masimo LNOP Reusable Finger Sensor LNOP/DCIP Pediatric	2002799-001
SpO_2 - Sensor	Masimo LNOP Reusable Finger Sensor LNOP/DCI Adult, LNOP/DCI	2002800-001
SpO_2 - Sensor	Masimo LNOP Reusable Multisite Sensor LNOP-YI	2010463-001
SpO_2 - Sensor	Masimo LNOP Reusable Tip-Clip Ear Sensor LKNOP TC-I	2027274-001
SpO_2 - Sensor	Masimo LNOP Reusable Finger Sensor Adult DC-195	2009745-001
SpO_2 - Sensor	Masimo LNCS DCI Reusable Adult Sensor	2027258-001
SpO_2 - Sensor	Masimo LNCS DCIP Reusable Pediatric Sensor	2027259-001
SpO_2 - Sensor	Masimo LNCS TC-I TipClip Reusable Ear Sensor	2027261-001

Part	Part description	Part number
SpO_2 - Sensor	Masimo LNCS Adult, Transparent Adhesive Sensor - 20/box	2027253-001
SpO_2 - Sensor	Masimo LNCS Pdtx Pediatric Adhesive Sensor - 20/box	2027254-001
SpO_2 - Sensor	Masimo LNCS Inf-L Infant Adhesive Sensor - 20/box	2027255-001
SpO_2 - Sensor	Masimo LNCS Neo-L Neonatal Adhesive Sensor - 20/box	2027256-001
SpO_2 - Sensor	Masimo LNCS NeoPt-L Neonatal PT Adhesive Sensor - 20/box	2027257-001
SpO_2 - Cable Assy - 2.4M	Masimo LNOP, SpO_2 2.4 m	2017002-003
SpO_2 - Cable Assy - 3.6M	Masimo LNOP, SpO_2 3.6 m	2017002-001
SpO_2 - Cable Assy - 3M	Masimo LNC-10, SpO_2 3 m	2027263-002
SpO_2 - Accessory	Masimo Replacement Posey Wrap, LNOP-NeoPt-L, Neonatal - 12/box	2010466-001
SpO_2 - Accessory	Masimo Tape Bag for LNOP-NEO - 100/box	2010467-001
SpO_2 - Accessory	Masimo Tape Cleanshield Multisite, LNOP-YI - 100/box	2010468-001
SpO_2 - Accessory	Masimo Disposable Standard Multisite Wrap, Adult/Ped/ Neonatal Adhesive Attachment Wraps, use with LNOP-YI Multisite Reusable Sensor - 100/box	2010469-001
SpO_2 - Accessory	Masimo Tape Standard Petite Wrap, LNOP-YI - 100/box	2010470-001
SpO_2 - Accessory	Masimo Adhesive Tape for LNOP-YI - 12/box	2010471-001
Temperature		
Alaris Temperature, Oral Probe	Sensor Turbo Temperature Long, White Cord	2008774-001
Alaris Temperature, Rectal Probe	Sensor Turbo Temperature Long Rectal, White Cord	2008775-001
Alaris Probe Covers	Probe covers - 20/box	615118
Power		
Battery	Battery, Lead-Acid, 6-V, 3.0Ah	633178CR
12W Power Supply	Power supply, Universal, 12W, 100-250VAC, 12VA	2018859-001
Printer		
Replacement Paper	Printer paper roll - 10/box	089100
Mounting Options		
Roll Stand	Rollstand, CARESCAPE, GCX Version	2033297-001
Pole Mount	Pole Mount	2009762-001
Power Supply Mounting Bracket	12W Power supply roll stand bracket	2016929-001

Part	Part description	Part number
Connectivity		
ILC1931	DINALINK ApexPro Adapter	001931
ILC1926	Isolated Level Convertor	001926
ILC1931	DINALINK ApexPro FH adapter	001932
Cable Assy, use with 001932	Cable assembly to use with 001932	394119-008
Cable Assy, use with 001931	Cable assembly telemetry interface DINALINK	418497-002
Cable Assy, use with 001926, 001931, 001932	Cable assembly, DINAMAP to ILC	683235
Patient ID	Patient ID IR Cable (used with IR adaptor kit)	2024500-001
Patient ID Kit	IR adaptor kit with bracket	2026273-002
Remote Alarm	Remote Alarm Cable	487208CR
Manuals		
Operation Manual - Paper	CARESCAPE V100 Operator's Manual, Hard Copy	2036991-001
Service Manual - Paper	CARESCAPE V100 Service Manual, Hard Copy	2037106-001
Service Manual - CD	CARESCAPE V100 Service Manual, CD	2037107-001

Field-Replaceable Units (FRUs)

WARNING
REPAIR TO THE FRU LEVEL - Field repairs are recommended to the field replaceable unit (FRU) only. Attempting a field repair on a PCB or a factory sealed component or assembly could jeopardize the safe and effective operation of the monitor.

FRU List

The following table offers details of each of the corresponding bubble numbers that appear on the exploded engineering-assembly drawing (drawing is located after this table). Photos of each FRU follows.

NOTE: FRU numbers are subject to change.

Bubble Number	Part Number	Description
2	2037103-002	FRU CARESCAPE Plastic Kit No PRTR
3	2037103-003	FRU CARESCAPE Plastic Kit W/ PRTR
4	2037103-004	FRU CARESCAPE V100 TEMPERATURE KIT
5	2037103-005	FRU CARESCAPE V100 Printer Assembly
6[a]	2037103-006	FRU CARESCAPE V100 BZL, (BP ONLY)
7	2037103-007	FRU CARESCAPE V100 Inner chassis kit
8	2037103-008	FRU CARESCAPE V100 PRTR DOORX1/ROLLERS X5
10[b]	2037103-010	FRU CARESCAPE V100 Main Board
12[c]	2037103-012	FRU CARESCAPE V100 UI Board
13	2037103-013	FRU CARESCAPE V100 SpO_2 NELLCOR
15[d]	2037103-015	FRU CARESCAPE V100 Pneumatic Kit
16[e]	2037103-016	FRU CARESCAPE V100 BATTERY (X1 BATT)
16[e]	633178CR	BATTERY, LEAD-ACID, 6-VOLT, 3.0 AH
17	2037103-017	FRU CARESCAPE V100 Speaker
18	2037103-018	FRU CARESCAPE V100 Cable kit
19[f]	2037103-019	FRU CARESCAPE V100 Fascia Kit - EN

Bubble Number	Part Number	Description
22	2037103-022	FRU CARESCAPE V100 ALL HARDWARE KIT
23	2037103-023	FRU CARESCAPE V100 SpO_2 MASIMO
24	2037103-024	FRU CARESCAPE V100 SpO_2 OHMEDA
25[f]	2037103-025	FRU CARESCAPE V100 Fascia Kit - GER
26[f]	NA	NA
27[f]	2037103-027	FRU CARESCAPE V100 Fascia Kit - CZ
28[f]	2037103-028	FRU CARESCAPE V100 Fascia Kit - DA
29[f]	2037103-029	FRU CARESCAPE V100 Fascia Kit - DU
30[f]	2037103-030	FRU CARESCAPE V100 Fascia Kit - FIN
31[f]	2037103-031	FRU CARESCAPE V100 Fascia Kit - FRE
32[f]	2037103-032	FRU CARESCAPE V100 Fascia Kit - GR
33[f]	2037103-033	FRU CARESCAPE V100 Fascia Kit - HU
34[f]	2037103-034	FRU CARESCAPE V100 Fascia Kit - IT
35[f]	2037103-035	FRU CARESCAPE V100 Fascia Kit - JA
36[f]	2037103-036	FRU CARESCAPE V100 Fascia Kit - KOR
37[f]	2037103-037	FRU CARESCAPE V100 Fascia Kit - NO
38[f]	2037103-038	FRU CARESCAPE V100 Fascia Kit - PO
39[f]	2037103-039	FRU CARESCAPE V100 Fascia Kit - PORT
40[f]	2037103-040	FRU CARESCAPE V100 Fascia Kit - RU
41[f]	2037103-041	FRU CARESCAPE V100 Fascia Kit - SLO
42[f]	2037103-042	FRU CARESCAPE V100 Fascia Kit - SP
43[f]	2037103-043	FRU CARESCAPE V100 Fascia Kit - SW
44[g]	2037103-044	FRU CARESCAPE V100 Keypad Kit
52[a]	2037103-052	FRU CARESCAPE V100 BZL, (BP & TEMP)
53[a]	2037103-053	FRU CARESCAPE V100 BZL, (BP & SpO_2)

Bubble Number	Part Number	Description
54[a]	2037103-054	FRU CARESCAPE V100 BZL, (BP & SpO_2 & TEMP)
56[e]	2037103-056	FRU CARESCAPE V100 BATTERY (X5 BATTS)

[a] All SpO_2 technology labels included. Select applicable label per monitor configuration.

[b] Main boards configured with SuperSTAT NIBP algorithm, Nellcor SpO_2, and Temperature enabled. Reconfigure as applicable per monitor configuration. Refer to *"Installation"* Section 3 for more details.

[c] All UI board LEDs installed. Cover LEDs with applicable fascia per monitor configuration.

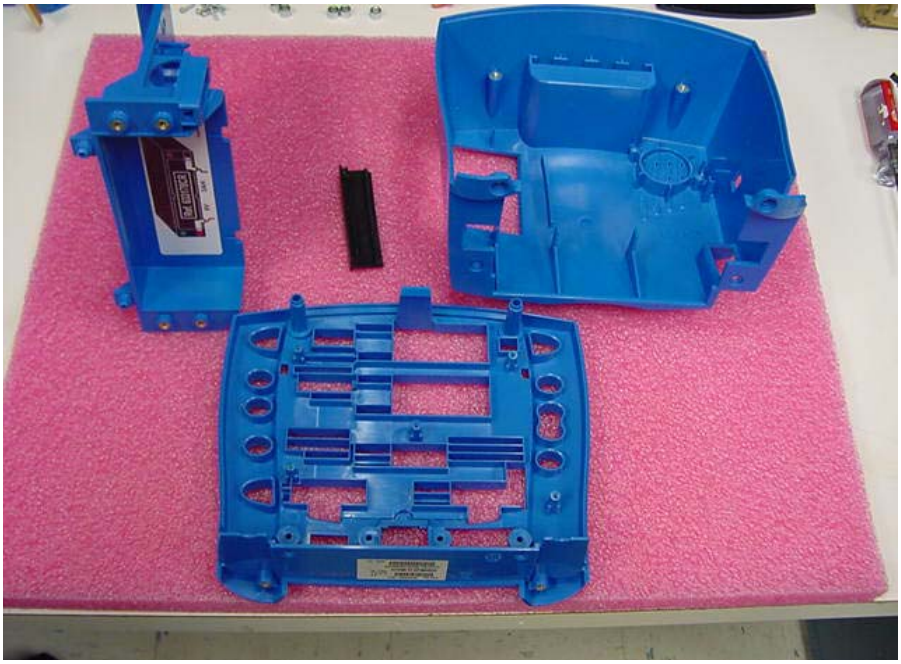
[d] Check valve has directional arrow indicating correct orientation for assembly.

[e] Fully charge battery before initial use. Refer to *"Installation"* Section 3 for more details.

[f] Kit includes all versions of fascia and display covers. Install per monitor configuration.

[g] Remove Print button for non-printer versions of monitor. Refer to following assembly drawings.

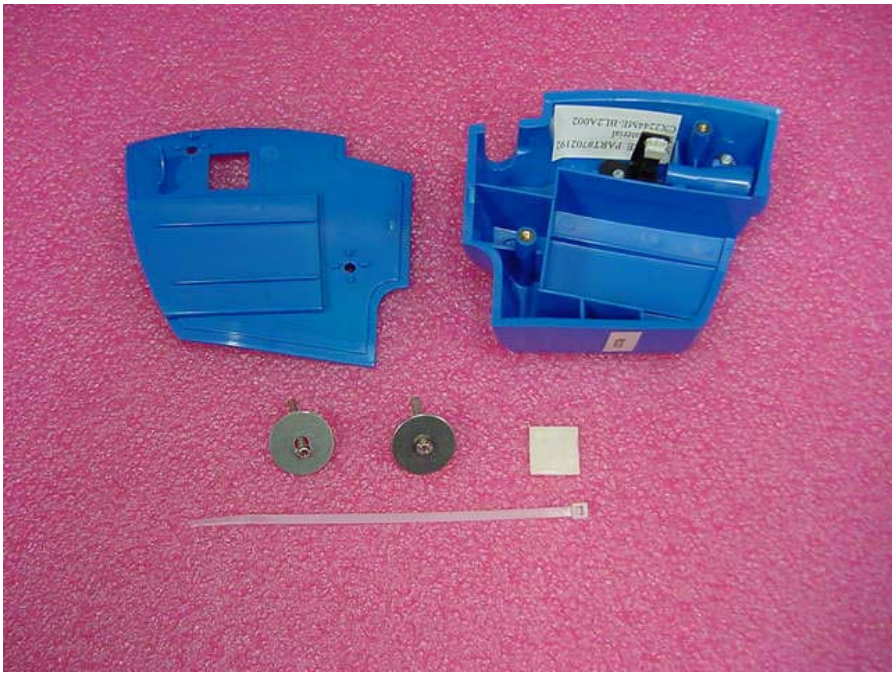
FRU Photos



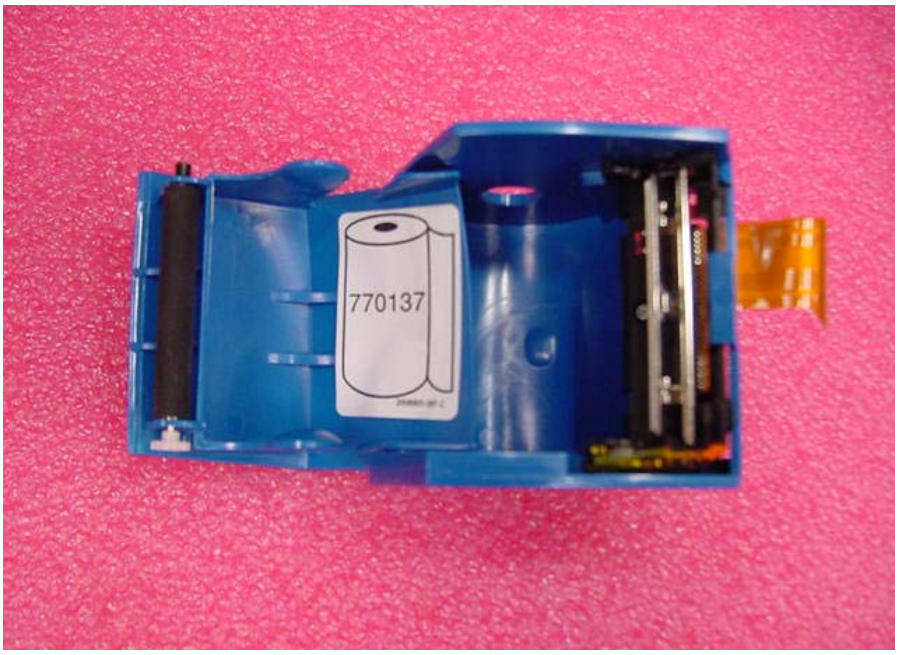
FRU 2037103-002: CARESCAPE Plastic Kit No Printer

FRU 2037103-003: CARESCAPE Plastic Kit W/ Printer

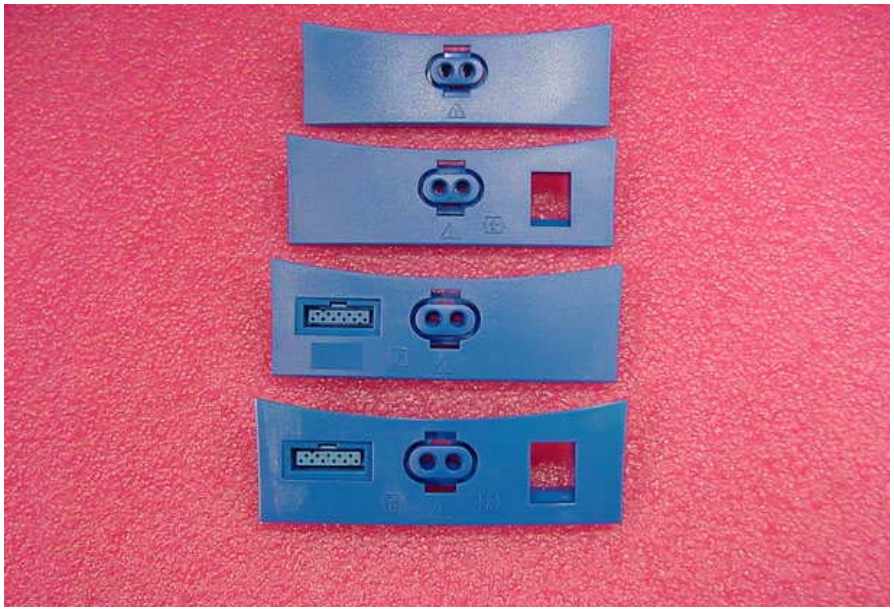
NOTE: Rear case with printer shown.



FRU 2037103-004: CARESCAPE V100 Temperature Kit



FRU 2037103-005: CARESCAPE V100 Printer Assembly



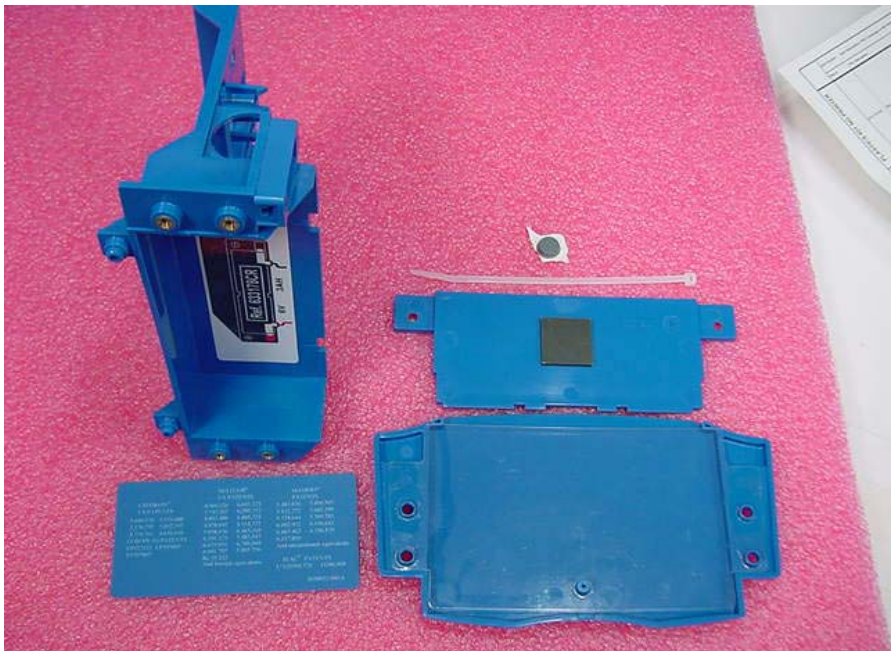
FRU 2037103-006: CARESCAPE V100 BZL, (BP ONLY)

FRU 2037103-052: CARESCAPE V100 BZL, (BP & TEMP)

FRU 2037103-053: CARESCAPE V100 BZL, (BP & SpO_2)

FRU 2037103-054: CARESCAPE V100 BZL, (BP & SpO_2 & TEMP)

NOTE: Kit includes only 1 bezel.



FRU 2037103-007: CARESCAPE V100 Inner Chassis Kit

NOTE: Kit includes 4 adhesive-backed feet.

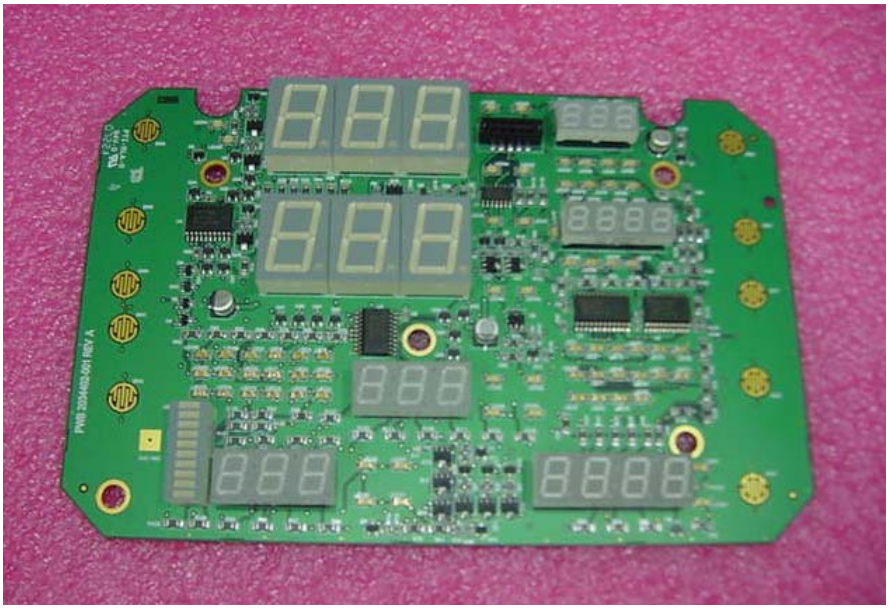
FRU 2037103-008: CARESCAPE V100 PRTR Door X1/Rollers X5

NOTE: Kit includes 1 printer door with label and 5 printer rollers.

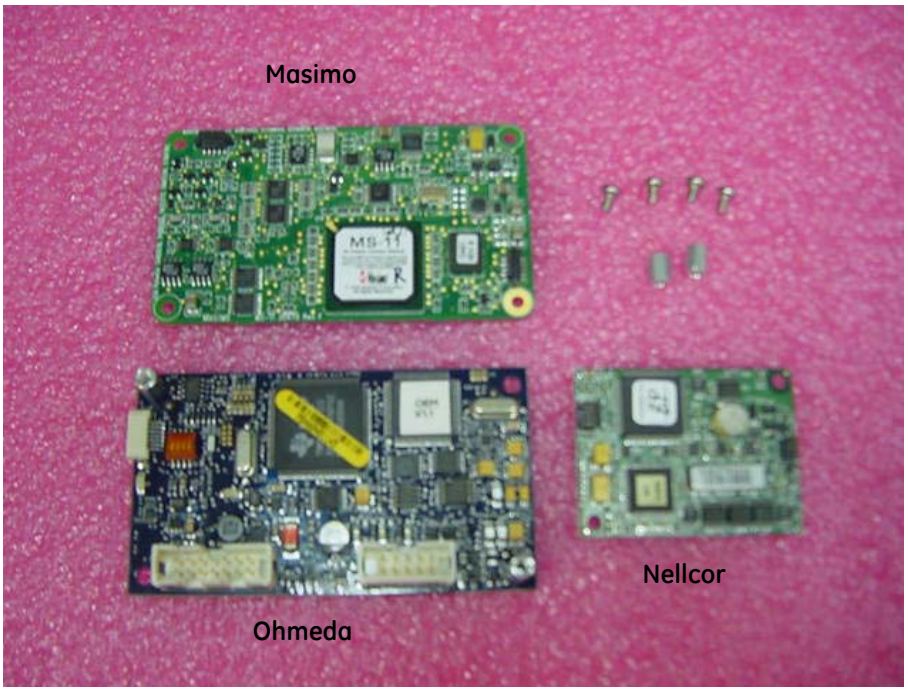
FRU 2037103-010: CARESCAPE V100 Main Board

NOTE 1: Each main board comes with all parameters installed. For monitors that do not include specific options (Printer, SpO_2, Temperature), these options must be turned off while the monitor is in configuration mode.

NOTE 2: Each main board comes configured with the SuperSTAT NIBP algorithm. If your monitor was originally configured with the Auscultatory or Classic NIBP Algorithm, the algorithm must be changed while the monitor is in configuration mode.



FRU 2037103-012: CARESCAPE V100 UI Board



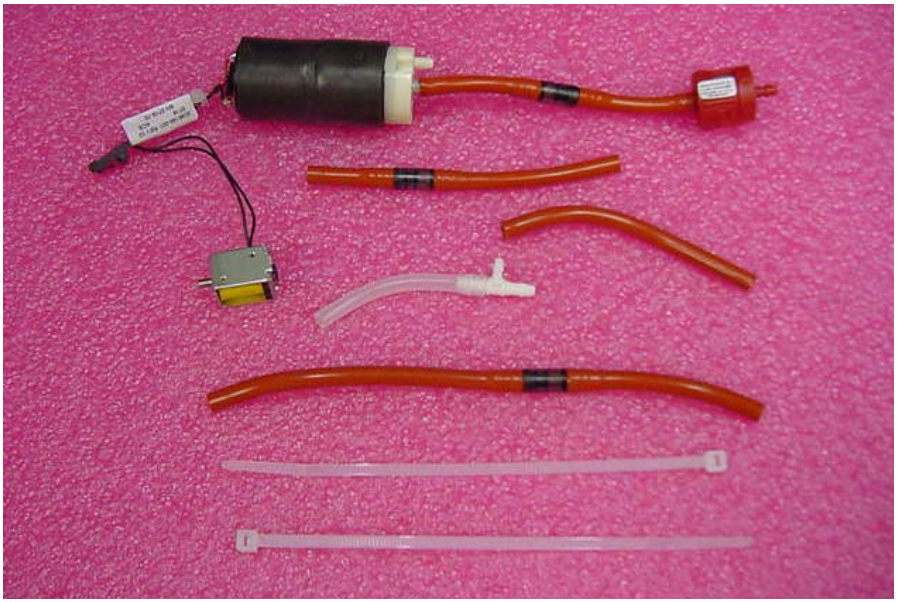
FRU 2037103-013: CARESCAPE V100 SpO_2 Nellcor

FRU 2037103-023: CARESCAPE V100 SpO_2 Masimo

FRU 2037103-024: CARESCAPE V100 SpO_2 Ohmeda

NOTE 1: All 3 SpO_2 boards shown. Kit includes only one.

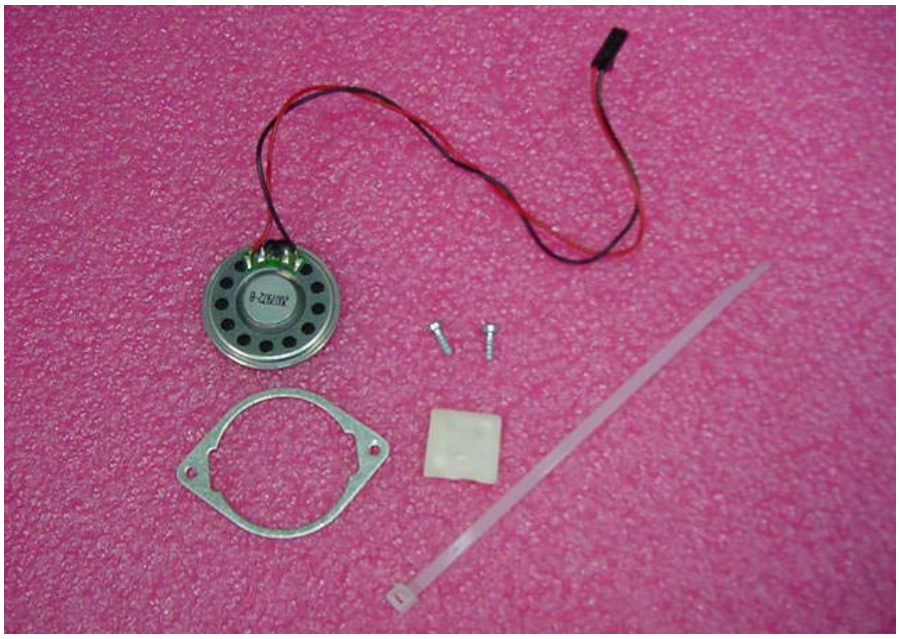
NOTE 2: Nellcor hardware shown. Kit includes matching hardware.



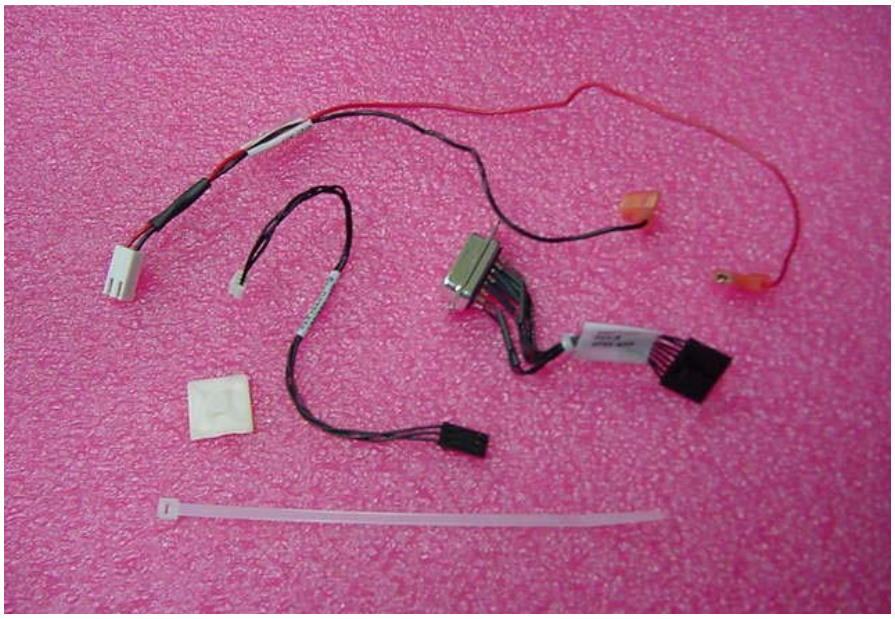
FRU 2037103-015: CARESCAPE V100 Pneumatic Kit

FRU 2037103-016: CARESCAPE V100 Battery (X1 BATT)

FRU 2037103-056: CARESCAPE V100 Battery (X5 BATTS)



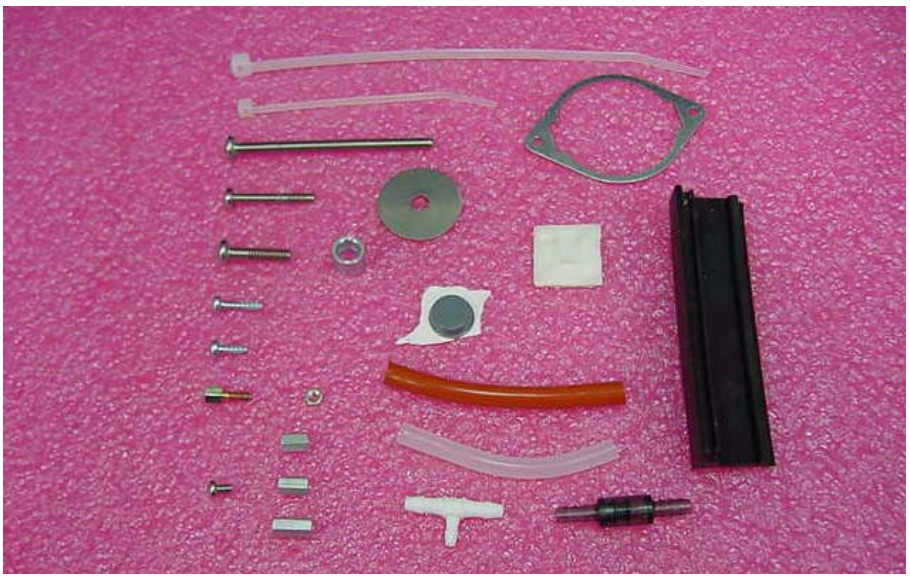
FRU 2037103-017: CARESCAPE V100 Speaker



FRU 2037103-018: CARESCAPE V100 Cable Kit

FRU Number	Description	Language
FRU 2037103-019	CARESCAPE V100 Fascia Kit	EN
FRU 2037103-025	CARESCAPE V100 Fascia Kit	GER
FRU 2037103-026	CARESCAPE V100 Fascia Kit	CH
FRU 2037103-027	CARESCAPE V100 Fascia Kit	CZ

FRU Number	Description	Language
FRU 2037103-028	CARESCAPE V100 Fascia Kit	DA
FRU 2037103-029	CARESCAPE V100 Fascia Kit	DU
FRU 2037103-030	CARESCAPE V100 Fascia Kit	FIN
FRU 2037103-031	CARESCAPE V100 Fascia Kit	GRE
FRU 2037103-032	CARESCAPE V100 Fascia Kit	GRE
FRU 2037103-033	CARESCAPE V100 Fascia Kit	HU
FRU 2037103-034	CARESCAPE V100 Fascia Kit	IT
FRU 2037103-035	CARESCAPE V100 Fascia Kit	JA
FRU 2037103-036	CARESCAPE V100 Fascia Kit	KOR
FRU 2037103-037	CARESCAPE V100 Fascia Kit	NOR
FRU 2037103-038	CARESCAPE V100 Fascia Kit	POL
FRU 2037103-039	CARESCAPE V100 Fascia Kit	POR (CONT.)
FRU 2037103-040	CARESCAPE V100 Fascia Kit	RU
FRU 2037103-041	CARESCAPE V100 Fascia Kit	SLO
FRU 2037103-042	CARESCAPE V100 Fascia Kit	SP
FRU 2037103-043	CARESCAPE V100 Fascia Kit	SWE

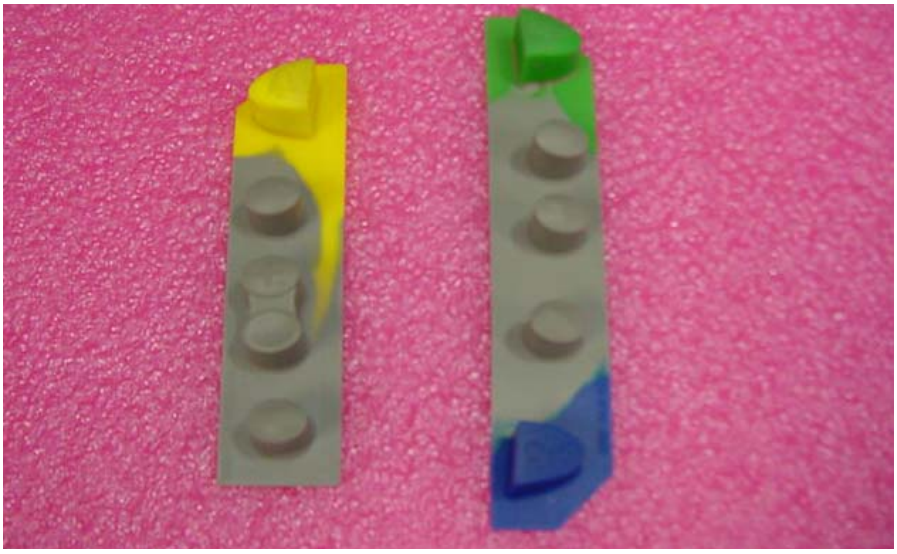


FRU 2037103-022: CARESCAPE V100 All Hardware Kit

NOTE: Each Hardware kit includes the following:

Description	QTY
ADHESIVE BACKED CABLE TIE MOUNT,.75X.75	5
CABLE TIE, LOCKING, NYLON 6.6,3.1"X0.09”	5
CABLE TYE WRAP	10
CONN PLASTIC TEE	4
EXTRUSION GROMMET,HANDLE	3
FILTER 40 MICRON	10
FOOT,RND,12.7 DIA X 3.5H SELF ADHSV	20
KIT,SCREWLOCK FEMALE WITH THREAD-LOCK	3
SCREW, M3X12, SELF-TAP, TORX	20
SCREW, MACH PNHD 832X2-1/2 SS VIBRATITE	6
SCREW, MACH PNHD PHIL 440X3/16 SS VIBRATITE	20
SCREW, NO6, TORX PAN, 1.0 INCH VIB	4
SCREW, SELF TAP, TORX, ZINC	20
SCREW, SELF TAP,TORX, ZINC	3
SCREW, NO8, POZI-PAN .75IN VIB	20
SPACER, STEEL ZINC	20
SPEAKER CLAMP RING	3

Description	QTY
STANDOFF MASIMO SpO_2	4
STANDOFF NELLCOR SpO_2	4
STANDOFF OHMEDA SpO_2	4
TUBING SILICONE 1/8ID X 1/4OD	1 foot
TUBING SILICONE CLEAR 3/32" ID 7/32" OD	1 foot
WSHR,#10 FENDER WASHER 1.00" OD STAINLE	4

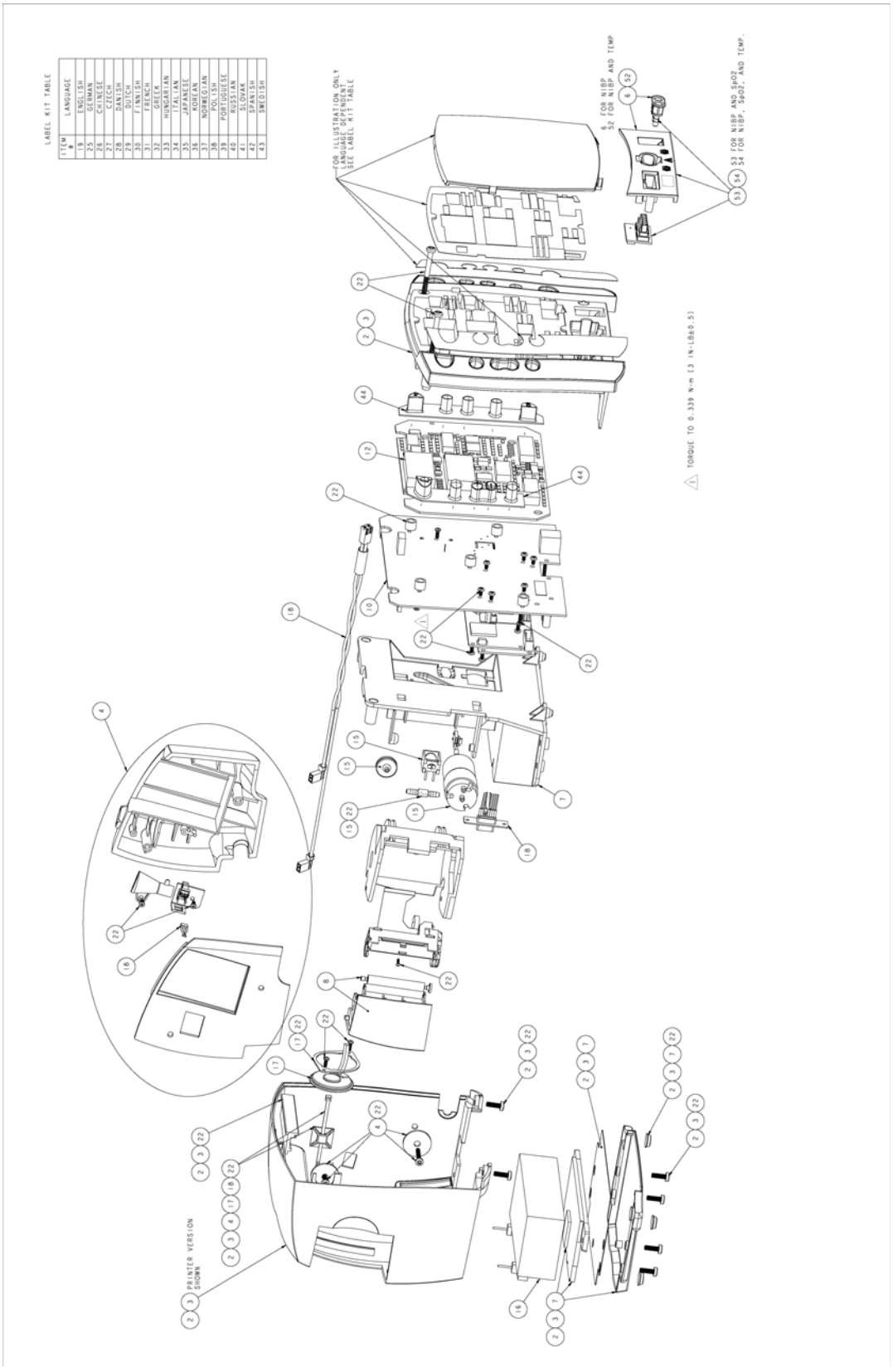


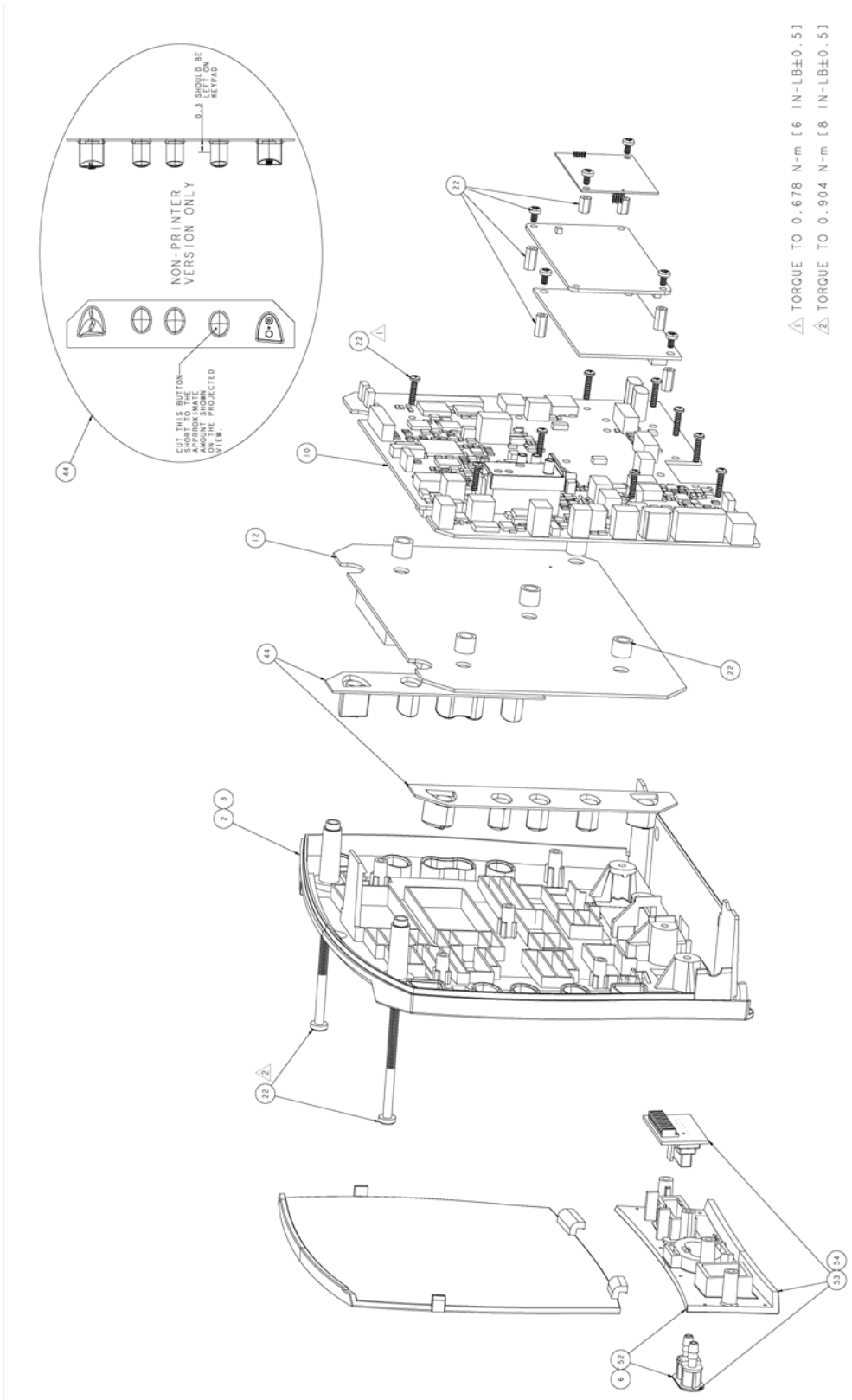
FRU 2037103-022: CARESCAPE V100 Keypad Kit

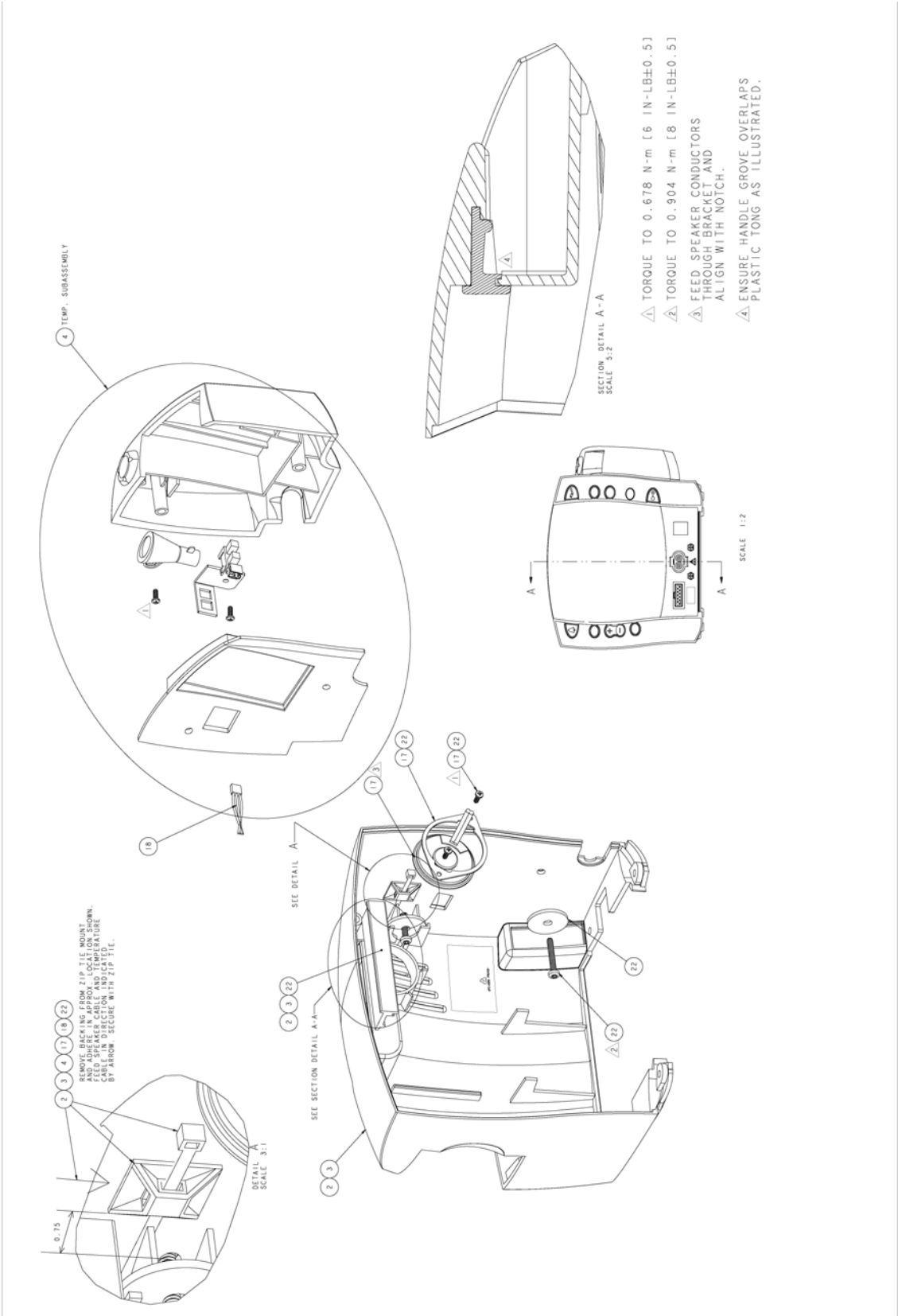
NOTE: Printer version shown. For non-printer versions, the print key will need to be trimmed before installation. See FRU installation instructions and parts drawing for further details

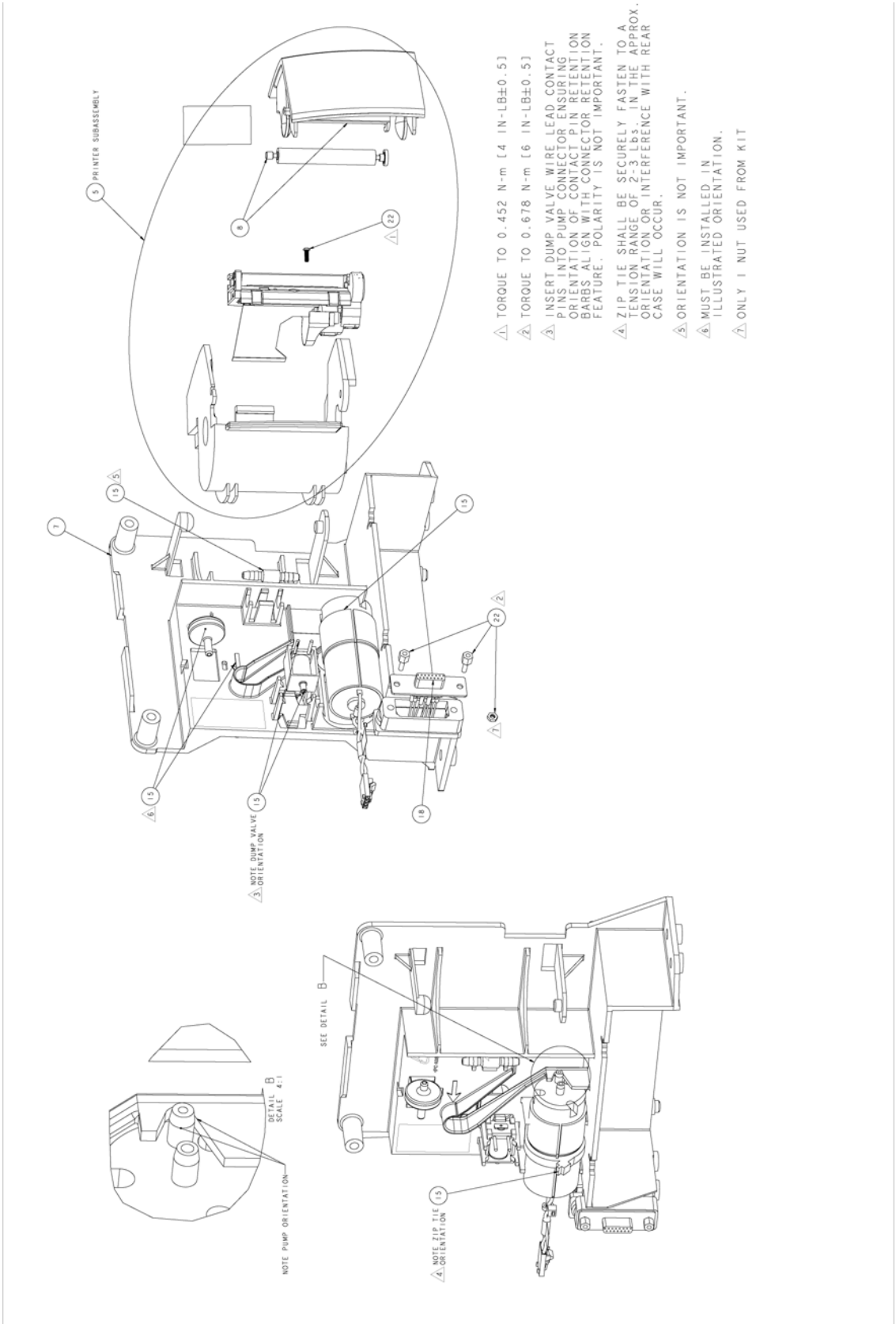
FRU Main Reference Guide Drawing

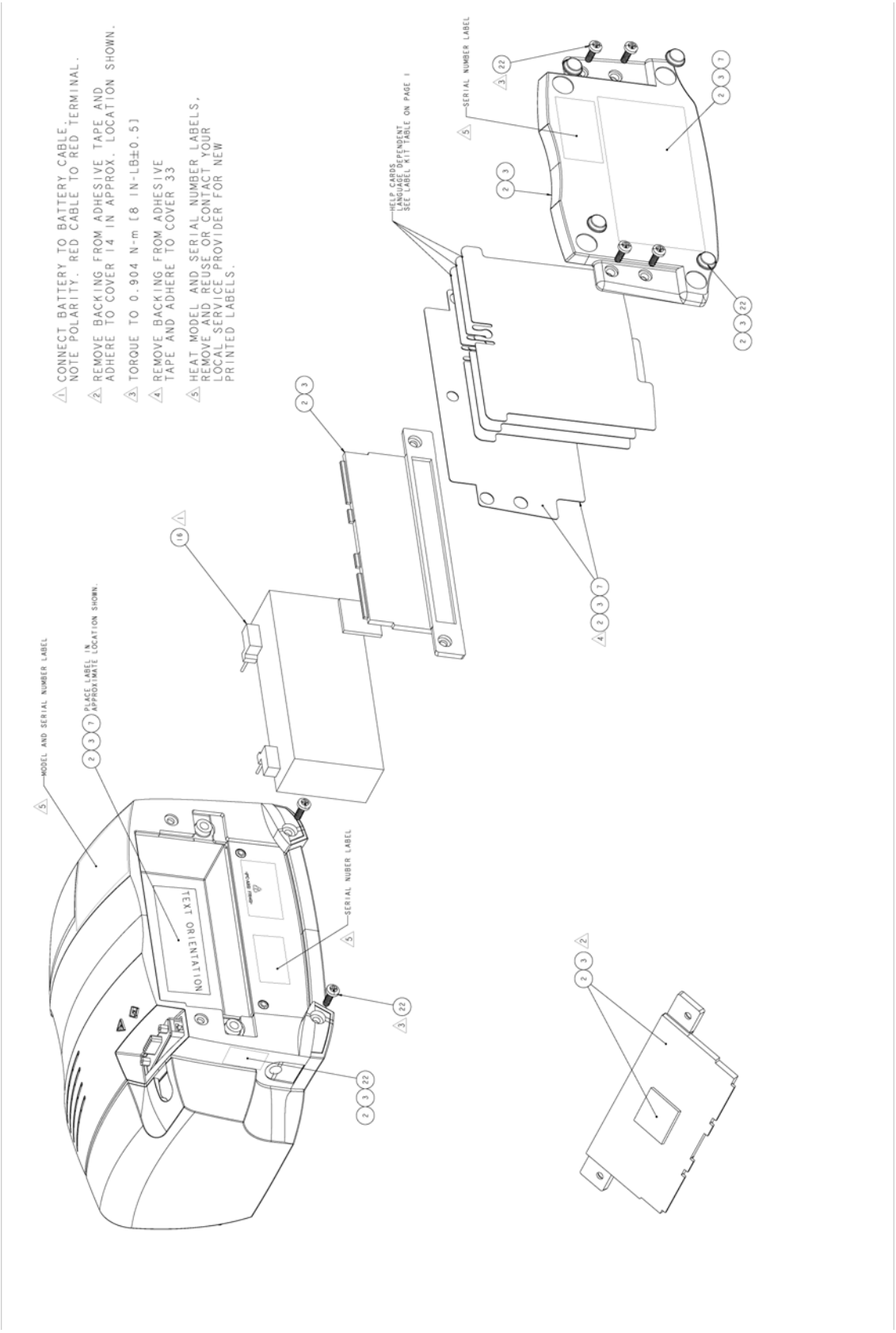
For quick reference use the following FRU Main Reference Guide drawing.

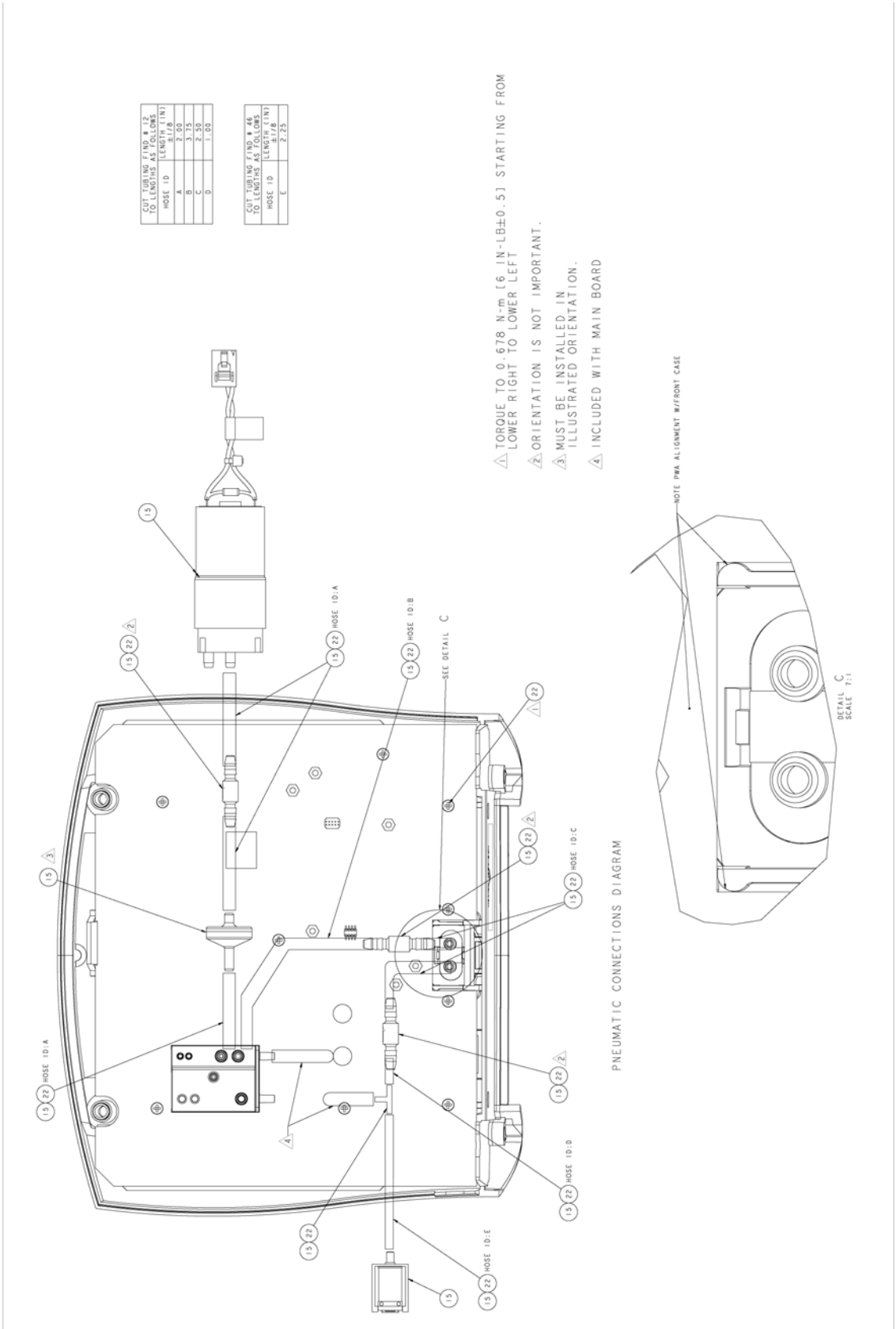


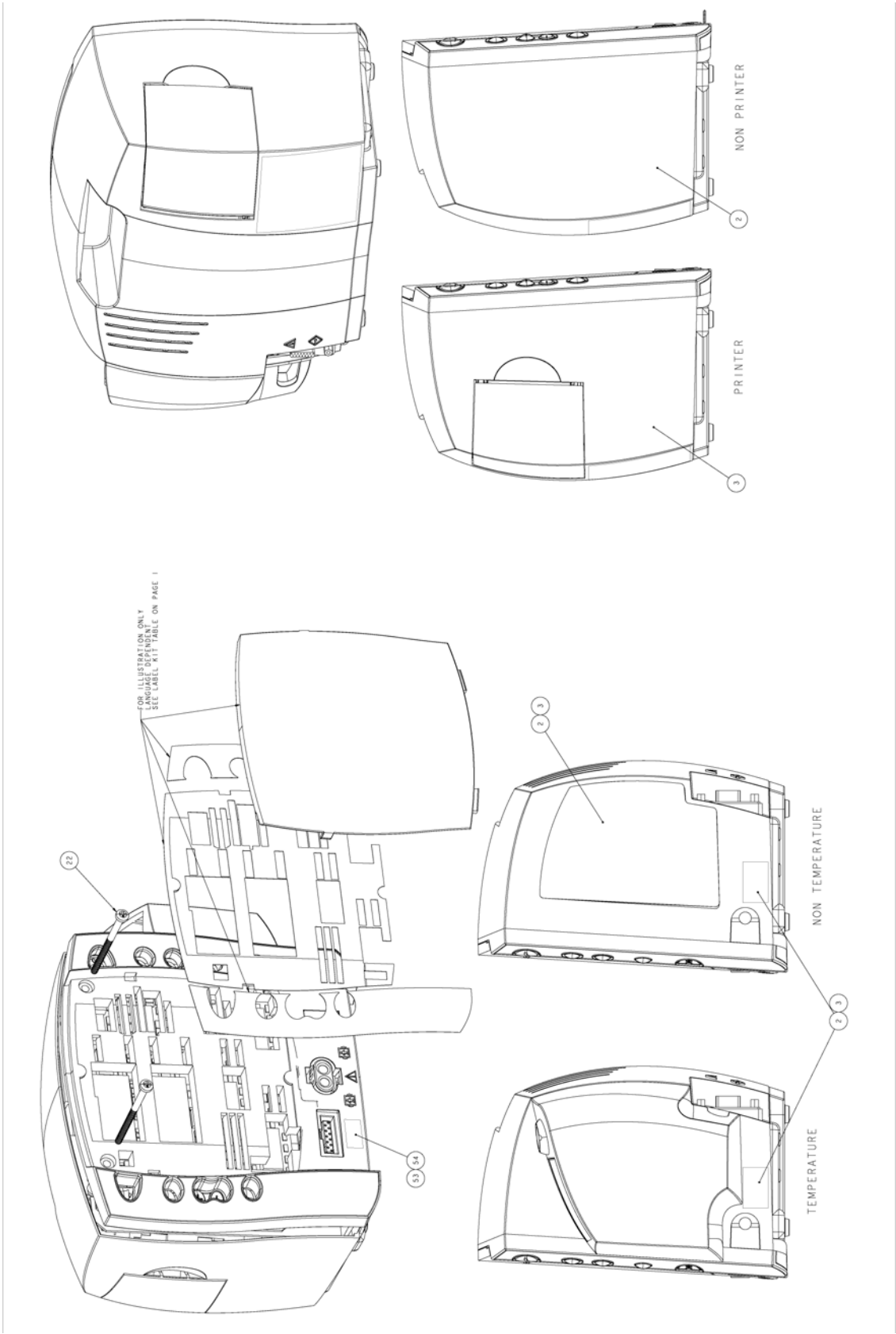

NON-PRINTER VERSION ONLY
0.3 SHOULD BE LEFT ON KEYPAD
CUT THIS BUTTON TO THE APPROXIMATE AMOUNT SHOWN ON THE PROJECTED VIEW.
1 TORQUE TO 0.678 N-m [6 IN-LB±0.5]
2 TORQUE TO 0.904 N-m [8 IN-LB±0.5]

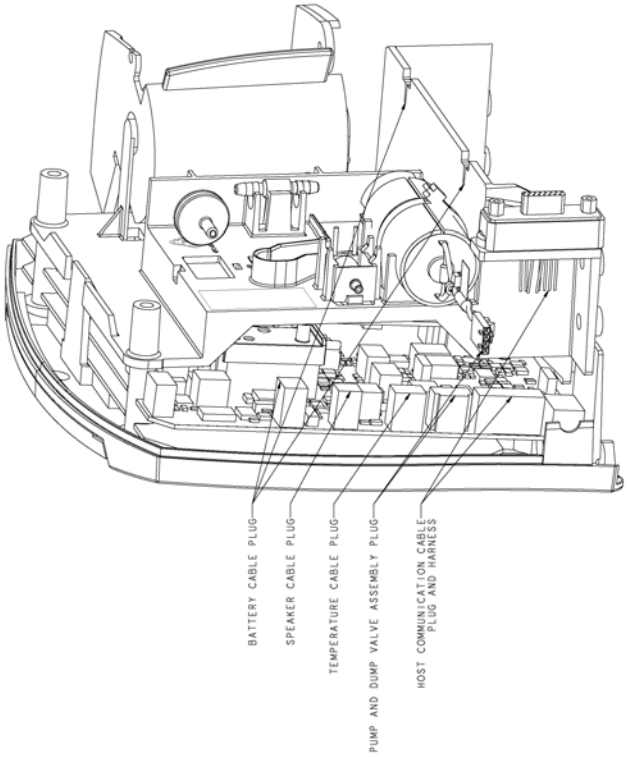

4 TEMP. SUBASSEMBLY
SECTION DETAIL A-A
SCALE 5:2
1 TORQUE TO 0.678 N-m [6 IN-LB±0.5]
2 TORQUE TO 0.904 N-m [8 IN-LB±0.5]
3 FEED SPEAKER CONDUCTORS THROUGH BRACKET AND ALIGN WITH NOTCH.
4 ENSURE HANDLE GROVE OVERLAPS PLASTIC TONG AS ILLUSTRATED.
SCALE 1:2
SEE DETAIL A
SEE SECTION DETAIL A-A
DETAIL
SCALE 3:1
0.75


5 PRINTER SUBASSEMBLY
8
22
7
15
18
2
NOTE DUMP VALVE ORIENTATION
NOTE PUMP ORIENTATION
DETAIL B
SCALE 4:1
SEE DETAIL B
NOTE ZIP TIE ORIENTATION
1 TORQUE TO 0.452 N-m [4 IN-LB±0.5]
2 TORQUE TO 0.678 N-m [6 IN-LB±0.5]
3 INSERT DUMP VALVE WIRE LEAD CONTACT PINS INTO PUMP CONNECTOR ENSURING ORIENTATION OF CONTACT PIN RETENTION BARBS ALIGN WITH CONNECTOR RETENTION FEATURE. POLARITY IS NOT IMPORTANT.
4 ZIP TIE SHALL BE SECURELY FASTEN TO A TENSION RANGE OF 2-3 Lbs. IN THE APPROX. ORIENTATION OR INTERFERENCE WITH REAR CASE WILL OCCUR.
5 ORIENTATION IS NOT IMPORTANT.
6 MUST BE INSTALLED IN ILLUSTRATED ORIENTATION.
7 ONLY 1 NUT USED FROM KIT


1. CONNECT BATTERY TO BATTERY CABLE. NOTE POLARITY. RED CABLE TO RED TERMINAL.
2. REMOVE BACKING FROM ADHESIVE TAPE AND ADHERE TO COVER 14 IN APPROX. LOCATION SHOWN.
3. TORQUE TO 0.904 N-m [8 IN-LB±0.5]
4. REMOVE BACKING FROM ADHESIVE TAPE AND ADHERE TO COVER 33
5. HEAT MODEL AND SERIAL NUMBER LABELS, REMOVE AND REUSE OR CONTACT YOUR LOCAL SERVICE PROVIDER FOR NEW PRINTED LABELS.
HELP CARDS LANGUAGE DEPENDENT SEE LABEL KIT TABLE ON PAGE 1
SERIAL NUMBER LABEL
MODEL AND SERIAL NUMBER LABEL
PLACE LABEL IN APPROXIMATE LOCATION SHOWN.
TEXT ORIENTATION
SERIAL NUBER LABEL


CUT TUBING FIND # 12 TO LENGTHS AS FOLLOWS
HOSE ID | LENGTH (IN) ±1/8
A | 2.00
B | 3.75
C | 2.50
D | 1.00
CUT TUBING FIND # 46 TO LENGTHS AS FOLLOWS
HOSE ID | LENGTH (IN) ±1/8
E | 2.25
1 TORQUE TO 0.678 N-m [6 IN-LB±0.5] STARTING FROM LOWER RIGHT TO LOWER LEFT
2 ORIENTATION IS NOT IMPORTANT.
3 MUST BE INSTALLED IN ILLUSTRATED ORIENTATION.
4 INCLUDED WITH MAIN BOARD
NOTE PWA ALIGNMENT W/FRONT CASE
DETAIL C SCALE 1:1
SEE DETAIL C
HOSE ID:A
HOSE ID:B
HOSE ID:C
HOSE ID:D
HOSE ID:E
PNEUMATIC CONNECTIONS DIAGRAM


NON PRINTER
2
PRINTER
3
FOR ILLUSTRATION ONLY
LANGUAGE DEPENDENT
SEE LABEL KIT TABLE ON PAGE 1
22
53
54
2 3
NON TEMPERATURE
2 3
TEMPERATURE


BATTERY CABLE PLUG
SPEAKER CABLE PLUG
TEMPERATURE CABLE PLUG
PUMP AND DUMP VALVE ASSEMBLY PLUG
HOST COMMUNICATION CABLE PLUG AND HARNESS

Assembly/Disassembly of FRUs

Monitor Disassembly Procedure

The following procedure is sequential (i.e., you must remove the battery and rear case to remove the printer, etc.

CAUTION
Internal electronic components are susceptible to damage by electrostatic discharge. To avoid damage when disassembling the monitor, observe the standard precautions and procedures for handling static-sensitive components.

Battery

1. Remove 4 screws securing the instruction cards.

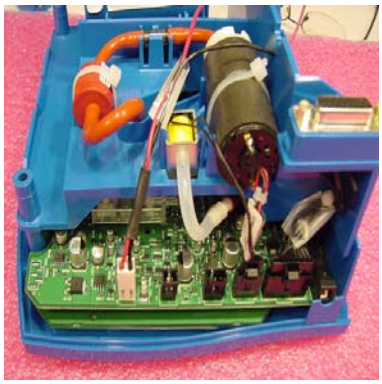
2. Remove the battery compartment door and adhesive pad.
3. The battery can now be removed.

Rear Case

1. Remove remaining two screws from the bottom of the monitor.
2. Set monitor upright.
3. Carefully remove the front faceplate.

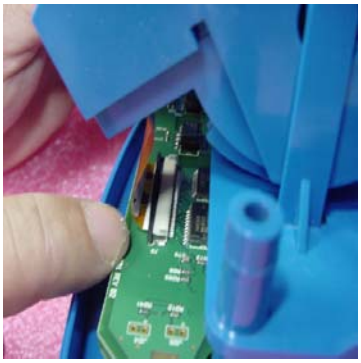
4. Remove 2 screws behind black overlay.

5. Set monitor on its face and open the printer door.
6. Carefully remove the rear case.
7. Unplug speaker cable and temperature module cable (if installed) from circuit board.

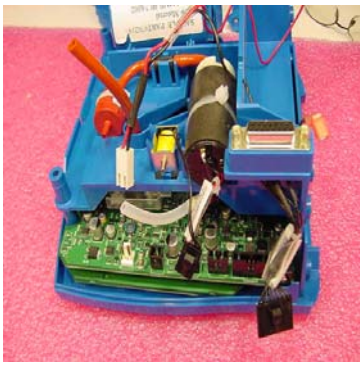


Printer

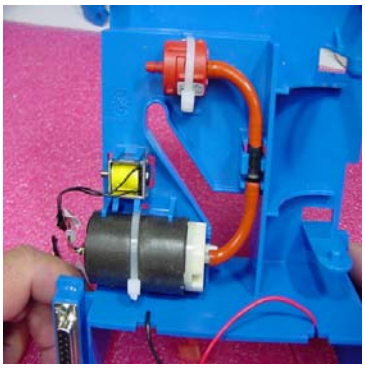
1. Lift the 2 black tabs and remove printer cable.



2. Remove printer assembly.
3. Unplug air hose from valve and filter.
4. Remove remaining 3 cable assemblies.



5. Locate and release retention tab and slide back sub chassis.
6. Remove sub-chassis and set aside.

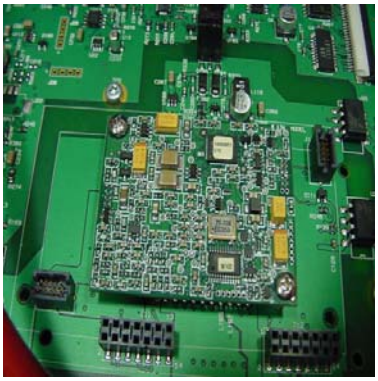


7. Remove pneumatic assembly from sub-chassis.

SpO_2 Board

1. Remove 2 screws securing SpO_2 board.

   NOTE: Threaded standoffs have screws on both ends.



2. Remove SpO_2 board.

Front Bezel

1. Remove 2 SpO_2 connector screws.
2. Unplug 2 pneumatic hoses from bezel.
3. Remove 4 torx-head screws along the bottom of main board.
4. Lift unit and remove bezel.

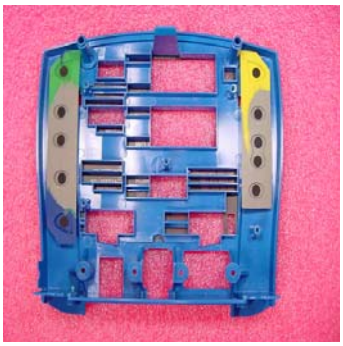
Main Board

1. Remove 5 torx-head screws.

Display Board

1. Carefully lift the Main board away from the UI board.

2. Collect the 5 spacers used to align the Main and UI board.
3. Lift the UI board away from the front panel.



4. The monitor is now completely disassembled.
5. Reverse the above sequence to reassemble the monitor.
6. Be careful not to pinch any cables or tubing during reassembly.

NOTE: Updated Instructions may be included in your replacement parts kit, always review all material included in your kit.

A Technical Specifications and Default Settings

For your notes

Specifications

General

General Specifications	
Mechanical	
Dimensions	
Height	7.7 in (19.5 cm)
Width	8.6 in (21.9 cm) without temperature 10.0 in (25.4 cm) with temperature
Depth	5.3 in (13.5 cm)
Weight (Including battery)	5.4 lb (2.4 kg)
Mountings	Self-supporting on rubber feet or pole mounted
Portability	Carried by recessed handle
Power requirements	
Power converter universal	P/N: 2018859-001
Protection against electrical shock	Class II
AC input	100 to 250VAC, 12VA
DC output voltage	12VDC at 1A The AC mains power adapter contains a nonresettable and nonreplaceable fuse.
Monitor	
Protection against electrical shock	Internally powered or Class II when powered from specified external power supply.
DC input voltage	12 VDC, supplied from a source conforming to IEC 60601-1.
Fuses	The monitor contains three fuses. The fuses are mounted within the monitor. The fuses protect the low voltage DC input, the battery, and the remote alarm output. The +5 V output on the host port connector is regulated by internal supply.
Battery	Refer to *"Battery"* Section
Environmental	
Operating temperature	+ 5°C to + 40°C (+ 41°F to + 104°F)
Operating atmospheric pressure	700 hPa to 1060 hPa

General Specifications	
Storage/transportation	
Storage temperature	– 20°C to + 50°C (– 4°F to + 122°F)
Atmospheric pressure	500 hPa to 1060 hPa
Humidity range	5% to 95% noncondensing
Radio frequency	Complies with IEC Publication 60601-1-2 (2004) Medical Electrical Equipment, Electromagnetic Compatibility Requirements and Tests and CISPR 11 (Group 1, Class B) for radiated and conducted emissions

Printer

Printer Specifications	
Printer type	Thermal dot array
Resolution	384 dots/inch horizontal
Paper type	The paper roll used by the printer must be compatible with GE PN 770137.
Languages printed	English, German, French, Italian, Spanish, Portuguese (Brazil and Portugal), Hungarian, Polish, Czech, Finnish, Swedish, Danish, Dutch, Norwegian, and Slovak
Languages not printed (text printed in English only)	Russian, Greek, Korean, and Japanese

NIBP

NIBP Specifications	
Cuff pressure range (Normal operating range)	0 to 290 mmHg (adult/ped 0 to 145 mmHg (neonate)
Blood pressure accuracy (Classic and Auscultatory)	Meets ANSI/AAMI standard SP-10:1992 (mean error ≤ 5 mmHg, standard deviation ≤ 8 mmHg)
Blood pressure accuracy (SuperSTAT)	Meets ANSI/AAMI standard SP-10:2002 (mean error ≤ 5 mmHg, standard deviation ≤ 8 mmHg)
Maximum determination	120 s (adult/ped) 85 s (neonate)
Overpressure cutoff	300 to 330 mmHg (adult/ped) 150 to 165 mmHg (neonate)

NIBP Specifications	
BP range (Classic and Auscultatory)	
Systolic	30 to 245 mmHg (adult/ped) 40 to 140 mmHg (neonate)
MAP	15 to 215 mmHg (adult/ped) 30 to 115 mmHg (neonate)
Diastolic	10 to 195 mmHg (adult/ped) 20 to 100 mmHg (neonate)
BP range (SuperSTAT)	
Systolic	30 to 290 mmHg (adult/ped) 30 to 140 mmHg (neonate)
MAP	20 to 260 mmHg (adult/ped) 20 to 125 mmHg (neonate)
Diastolic	10 to 220 mmHg (adult/ped) 10 to 110 mmHg (neonate)
Pulse rate range (Classic and Auscultatory)	30 to 200 beats/min (adult/ped) 30 to 220 beats/min (neonate)
Pulse rate range (SuperSTAT)	30 to 240 beats/min (adult/ped) 30 to 240 beats/min (neonate)
Pulse rate accuracy	± 3.5% or 3 bpm
NOTE: All CARESCAPE V100 Monitor regulatory and accuracy studies have been performed using GE CRITIKON BP cuffs Use only GE CRITIKON BP cuffs. The size, shape, and bladder characteristics can affect the performance of the instrument. Inaccurate readings may occur unless GE CRITIKON BP cuffs are used.	

Ohmeda SpO_2

Ohmeda SpO_2Specifications	
Measurement range	
SpO_2	1 to 100%
Pulse rate	30 to 250 bpm
Perfusion range	0.03 to 20%
Accuracy*	
Saturation	
Adult*	70 to 100% ±2 digits whichever is greater, (without motion)
Neonate*	70 to 100% ±3 digits (without motion)
Adult/Neonate**	70 to 100% ±3 digits (during clinical motion)

Ohmeda SpO_2Specifications	
Measurement range	
Low perfusion	70 to 100% ±2 digits (during clinical low perfusion)
Pulse rate	
Adult /Neonate	30 to 250 bpm: ± 2 digits or ± 2%, whichever is greater, (without motion) 30 to 250 bpm: ± 5 digits (during motion)
Low perfusion	30 to 250 bpm: ± 3 digits

*SpO_2 measurement accuracy is based on deep hypoxia studies using OxyTip+ sensors on healthy adult volunteer subjects. Arterial blood samples were analyzed simultaneously on multiple CO-oximeters. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

**Applicability: OXY-AF and OXY-AP sensors.

NOTE: Accuracy may vary for some sensors; always check the instructions for the sensor.

Specifications: Ohmeda sensor accuracy	
Sensor model	**SpO_2 range 70% to 100%**
OxyTip+	
OXY-F-UN	±2 digits without motion
OXY-W-UN	±2 digits without motion
OXY-E-UN	±2 digits without motion
OXY-SE	±2 digits without motion
OXY-AP	±2 digits without motion
OXY-AF	±2 digits without motion
OXY-F2-GE	±2 digits without motion
OXY-F4-GE	±2 digits without motion
OXY-E2-GE	±2 digits without motion
OXY-E4-GE	±2 digits without motion
Sensor light source	
Wavelength*	Infrared: 930 to 950 nm (nominal) Red 650 to 670 nm (nominal)
Average power	< 1 mW

* Information about wavelength range can be especially useful to clinicians.

Nellcor SpO_2

Nellcor SpO_2 Specifications	
Measurement range	
SpO_2	1 to 100%
Pulse rate	20 to 250 bpm
Perfusion range	0.03 to 20%
Accuracy	
Saturation	
Adult*	70 to 100% ±2 digits
Neonate*	70 to 100% ±3 digits
Low perfusion**	70 to 100% ±2 digits
Pulse Rate	
Adult and neonate	40 to 250 bpm ±3 digits
Low perfusion**	40 to 250 bpm ±3 digits
*Adult specifications are shown for OxiMax MAX-A and MAX-N sensors with the N-600. Saturation accuracy will vary by sensor type. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population. Accuracy is based on deep hypoxia studies on healthy adult volunteer subjects. Arterial blood samples were analyzed simultaneously on multiple CO-oximeters. **Applicability: OxiMax MAX-A, MAX-AL, MAX-P, MAX-I, and MAX-N sensors.	

Specifications: Nellcor sensor accuracy	
NOTE: All Nellcor OxiMax sensors must be used with the NELL cable; the SCP-10 cable. RS-10 and Oxisensor II sensors are not compatible with the V100 Vital Signs Monitor.	
Sensor Model	**SpO_2 Range 70% to 100%**
OxiMax	
MAX-A, MAX-AL	± 2 digits
MAX-N (adult)	± 2 digits
MAX-N* (neonate)	± 3 digits
MAX-P	± 2 digits
MAX-I	± 2 digits
MAX-FAST	± 2 digits
SC-A (adult)	± 2 digits

Specifications: Nellcor sensor accuracy	
SC-PR (neonate)	± 3 digits
SC-NEO	± 3 digits
MAX-R**	± 3.5 digits
OxiCliq	
OxiCliq A	± 2.5 digits
OxiCliq P	± 2.5 digits
OxiCliq N (adult)	± 2.5 digits
OxiCliq N* (neonate)	± 3.5 digits
OxiCliq I	± 2.5 digits
Reusable sensor models	
D-YS (infant to adult)	± 3 digits
D-YS (neonate)	± 4 digits
D-YS & D-YSE	± 3.5 digits
D-YS & D-YSPD	± 3.5 digits
DS-100A	± 3 digits
OXI-A/N (adult)	± 3 digits
OXI-A/N (neonate)	± 4 digits
OXI-P/I	± 3 digits
Neonatal sensor accuracy	When sensors are used on neonatal subjects as recommended, the specified accuracy range is increased by ±1 digit, as compared to adult usage, to account for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood. For example, MAX-N accuracy on neonates is ±3 digits, rather than ±2 digits.
Sensor light source	
Wavelength***	Infrared: 890 nm (nominal) Red: 660 nm (nominal)
Power dissipation	Infrared: 22.5 mW (max) Red: 30 mW (max)

* The MAX-N, D-YS, OXI-A/N, and OxiCliq N were tested on patients >40 kg.

** The accuracy specification has been determined between saturations of 80%-100%.

*** Information about wavelength range can be especially useful to clinicians.

Masimo SpO_2

Masimo SpO_2Specifications	
Measurement range	
SpO_2	1 to 100%
Pulse rate	25 to 240 bpm
Perfusion range	0.02 to 20%
Accuracy and motion tolerance	
Saturation	
Without motion - adult/pediatric*	70 to 100% ± 2 digits
Without motion - neonate*	70 to 100% ± 3 digits
With motion - adult/pediatric/neo**†	70 to 100% ± 3 digits
Low perfusion‡	70 to 100% ± 2 digits 0 to 69% unspecified
Pulse rate	
Without motion	25 to 240 bpm ±3 digits
With motion	normal physiologic range 25 to 240 bpm ±5 digits

* The Masimo SET SpO_2 parameter with LNOP-Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

**The Masimo SET SpO_2 parameter with LNOP-Adt sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and a nonrepetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

†The Masimo SET SpO_2 parameter with LNOP-Neo Pt sensors has been validated for neonatal motion accuracy in human blood studies on neonates while moving the neonate's foot at 2 to 4 cm against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus, one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

‡The Masimo SET SpO_2 parameter has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 stimulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus, one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Specifications: Masimo sensor accuracy	
Sensor model	**SpO_2 range 70% to 100%**
LNOP	
LNOP ADT	± 2 digits without motion
LNOP NEO	± 3 digits without motion

Specifications: Masimo sensor accuracy	
LNOP NEO-L Foot Finger	 ± 3 digits without motion ± 2 digits without motion
LNOP NEO PT-L	± 3 digits without motion
LNOP Adtx	± 2 digits without motion
LNOP Pdtx	± 2 digits without motion
LNOP DCI	± 2 digits without motion
LNOP DCIP	± 2 digits without motion
LNOP Hi Fi-Neo/adult Foot Finger	 ± 3 digits without motion ± 2 digits without motion
LNOP Hi Fi-Infant/Ped	± 2 digits
LNOP Blue Infant Thumb/Toe*	± 3 digits (for 80-100) without motion ± 4 digits (for 60-80) without motion ± 3.3 digits (for 70-100) without motion
LNOP YI Multi-Site Foot/hand Finger/toe	 ± 3 digits without motion ± 2 digits without motion
LNOP DC-195	± 2 digits without motion
LNOP TC-I	± 3.5 digits without motion
LNCS TCI	± 3.5 digits without motion
LNCS DC-I	± 2 digits without motion
LNCS DC-IP	± 2 digits without motion
LNCS Adult Adtx	± 2 digits without motion
LNCS Ped Pdtx	± 2 digits without motion
LNCS Infant-L	± 2 digits without motion
LNCS Neo PT-L	± 3 digits without motion
Resolution	
Saturation (% SpO_2)	1%
Pulse rate (bpm)	1
Low perfusion performance	
0.02% Pulse amplitude and % transmission >5%	Saturation (% SpO_2) ±2 digits Pulse rate ±3 digits

Specifications: Masimo sensor accuracy	
Interfering substances	Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.
Sensor light source	
Wavelength**	Infrared: 905 nm (nominal) Red: 660 nm (nominal)
Power dissipation	Infrared: 22.5 mW (max) Red: 27.5 mW (max)
*Masimo SET Technology with LNOP Blue sensors have been validated for no motion accuracy in human blood studies on neonatal, infant, and pediatric patients with congenital, cyanotic cardiac lesions in the range of 60% to 100% SpO_2 against a laboratory co-oximeter. This variation equals plus or minus one standard deviation, which encompasses 68% of the population. ** Information about wavelength range can be especially useful to clinicians.	

Temperature

Temperature Specifications	
Scale	°Fahrenheit (F)° °Celsius (C)
Range	
Predictive mode	Max: 41.1°C; 106.0°F Min: 35.6°C; 96.0°F
Monitor mode	Max: 41.1°C; 106.0°F Min: 26.7°C; 80.0°F
Monitor mode accuracy	±0.1°C ±0.2°F (when tested in a calibrated liquid bath; meets ASTM E1112, Table 1, in range specified)

Temperature Specifications	
Scale	°Fahrenheit (F)° °Celsius (C)
Determination time	approx. 10 seconds, typical
NOTE: Use only IVAC probes and P850A probe covers. The size, shape, and thermal characteristics of the probe covers can affect the performance of the instrument. Inaccurate readings or retention problems may occur unless IVAC probes and probe covers are used. Refer to Appendix D for reorder codes.	

Battery

Battery Specifications	
Capacity	6V; 3.3 Ahr sealed lead acid battery
Battery life	8.1 hours (standard deviation of 0.46) with a usage scenario of: NIBP determinations every 15 minutes with SpO_2 and temperature active. 11.5 hours (standard deviation of 0.53) non-SpO_2 versions with a usage scenario of: NIBP determinations every 15 minutes with temperature active
Charge time	Approx. 5 hours from full discharge when the monitor is off Approx. 8 hours when the monitor on

Default Settings

Alarms

Alarm volume	5

NIBP

	Adult/ped	Neonate	Non-patient specific
Systolic (mmHg)			
HIGH	200	100	
LOW	80	40	
Diastolic (mmHg)			
HIGH	120	60	
LOW	30	20	

Inflation pressure (for Auscultatory)	160	100	
Inflation pressure (for SuperSTAT)	135	100	
Inflation pressure (for Classic)	160	110	
Cycle button default			15 min

Ohmeda SpO_2

SpO_2 (%) HIGH alarm limit	100
SpO_2 (%) LOW alarm limit	90
Line frequency mode	60 (for 60 Hz)

Nellcor SpO_2

SpO_2 (%) HIGH alarm limit	100
SpO_2 (%) LOW alarm limit	90
Response mode	1 (for Mode 1: Normal response)
SatSeconds™	0

Masimo SpO_2

SpO_2 (%) HIGH alarm limit	100
SpO_2 (%) LOW alarm limit	90
Averaging time	12 seconds
FastSAT mode	0 (for Off)
Sensitivity mode	2 (for Low Perfusion)

Temperature

Unit of measure	°F

B Appropriate Use of NIBP Simulators

For your notes

Appropriate Use of NIBP Simulators

NIBP Accuracy

Noninvasive Blood Pressure (NIBP) monitors are approved for sale in the U.S. by the FDA (1) and in Europe through the CE Mark. Both of these processes require that the accuracy of NIBP monitors be established through clinical testing - the use of NIBP simulators is not acceptable.

GE Healthcare has established accuracy using the AAMI SP-10 standard (2) and a similar standard exists in Europe (3). The AAMI standard specifies that the accuracy of NIBP monitors can be determined using either an invasive (intra-arterial) or noninvasive (auscultatory) blood pressure reference. Over the last 30 years, DINAMAP® accuracy has been established using an invasive central aortic blood pressure reference. More recently, the CARESCAPE V100 Monitor has also been validated against a manual auscultatory reference.

Clinical vs. Simulator Readings

There are a number of reasons why the clinical studies are required for the measurement of NIBP accuracy. Many physiologic measurements (e.g. ECG, HR, eTCO2) can be taken with little interaction between the monitor and the patient. These devices can typically be validated using previously recorded patient data.

Unlike the transducers/electrodes used in these devices, the NIBP cuff has two functions. In addition to sensing the pressure pulses in the cuff, the cuff occludes and then releases the patient's artery to create the conditions that allow blood pressure to be measured.

An "artificial arm" would need to test both the sensing and occluding functions of the cuff, and mimic the nonlinear dynamics of the artery to provide an effective clinical simulation. While this has been attempted (4), there are no effective "arms" available.

Commercial NIBP simulators do attempt to test both functions of the NIBP cuff. Pressure signals are generated by the simulator in response to the inflation and deflation cycles of the monitor. While the cuff may be in the system, it is wrapped on a mandrel. The ability of the cuff to transducer pressure signals or to occlude the artery is not tested.

There are further limitations to the pressure pulses used by simulators. During the deflation of the cuff, the shape of the generated pressure oscillations changes as the cuff goes from systolic to diastolic pressures. This is due to the fact that the artery is only open when the arterial pressure is above cuff pressure. As can be seen in Figures 1A-1C, the shape of the oscillation changes as the cuff pressure changes, and the artery opens. Commercial NIBP simulators use one waveform shape at all pressure levels, which is simply scaled to reflect the oscillometric envelope.

In addition, the shape of the oscillation generated by commercial simulators does not match the shape of a typical oscillation measured during clinical

testing (Figures 2A-2B). These differences in the shape of the pulses can effect how an NIBP monitor analyzes the oscillometric envelope. While it is possible to develop an algorithm, which produces readings that correspond to the simulator settings, it is preferable to use the clinical data for algorithm development.

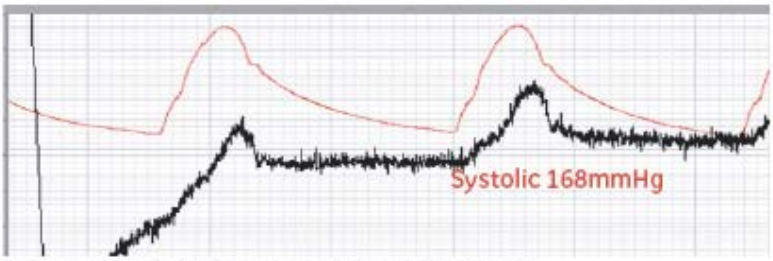


Figure 1A: Cuff Oscillation At Systolic Pressure
(— Invasive Pressure; — Cuff Pressure)

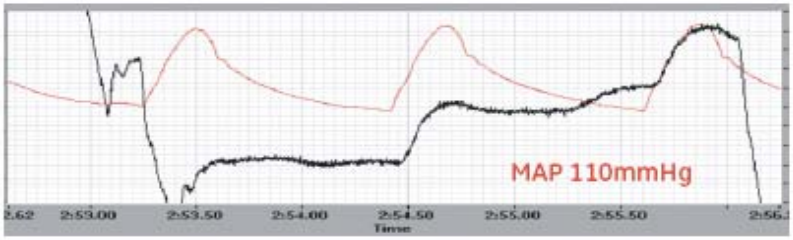


Figure 1B: Cuff Oscillation From A Clinical Measurement
(— Invasive Pressure; — Cuff Pressure)

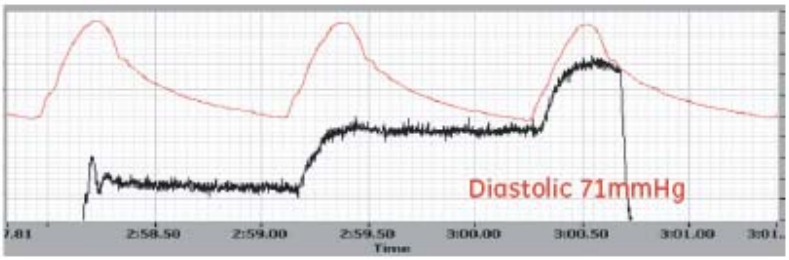


Figure 1C: Cuff Oscillation From A Clinical Measurement
(— Invasive Pressure; — Cuff Pressure)

What Do Simulator Manufacturers Say?

The DNI Nevada (Fluke Biomedical) CuffLink manual states:

"Since the CuffLink produces the same response independent of the inflate/deflate cycle or the algorithm used by the monitor, we offer the term "Target Value" as an approximation of the patient's actual blood pressure" (5)

BioTek® NIBP Pump 2™ (Fluke Biomedical) manual, in response to the question of why monitor readings differ from the target values on the simulator, states:

"Neither the monitor or the NIBP Pump 2 is broken. Some monitors were designed to give readings close to those obtained by the Auscultatory method of blood pressure determinations. Other monitors have been designed to agree with Invasive blood pressure readings. It is well known that Invasive and Auscultatory NIBP readings on the same subject can be quite different" (6)

Both of these statements indicate that these simulators cannot be used to demonstrate the accuracy of an NIBP monitor.

Why Use Simulators?

Simulators provide a method for producing repeatable signals that can be used to check that the monitor is responding to noninvasive blood pressure signals. Reference values obtained from a particular make and model of an NIBP monitor can be used to confirm that no changes have occurred after service to that same type of monitor.

Simulators can also be used to test for leaks and conduct static pressure calibration of NIBP monitors and as part of preventive maintenance programs.

Summary

The accuracy of an NIBP monitor can only be determined by comparison to a clinical blood pressure reference. NIBP simulators are useful for certain types of testing, but should not be used for accuracy testing.

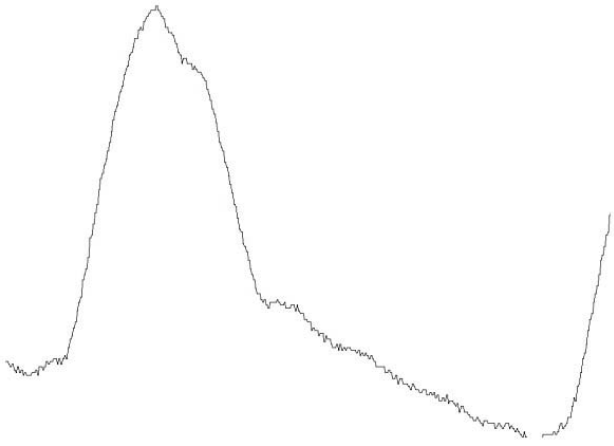


Figure 2A: Cuff Oscillation From A Clinical Measurement

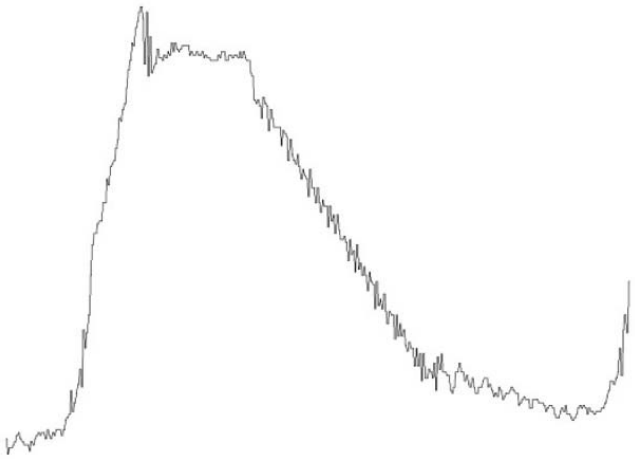


Figure 2B: Cuff Oscillation From A Simulator Measurement

References

1. FDA, CDRH, Non-Invasive Blood Pressure (NIBP) Monitor Guidance, March 10, 1997
2. ANSI/AAMI SP10:2002, Manual, Electronic or Automated Sphygmomanometers
3. EN 1060-4 2004 Specification for non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
4. Mieke, S, Substitute of simulators for human subjects; Blood Press Monit, October 1, 1997; 2(5): 251-256
5. DNI Nevada CuffLink Non-Invasive Blood Pressure Analyzer, Operating and Service Manual; Revision E, 11/97
6. NIBP Pump 2 Noninvasive Blood Pressure Simulator and Tester, Operations Manual; Revision C, January 2003

C Electromagnetic Compatibility (EMC)

For your notes

Electromagnetic Compatibility (EMC): CARESCAPE V100 Monitor

Changes or modifications to this system not expressly approved by GE Medical Systems can cause EMC issues with this or other equipment. This system is designed and tested to comply with applicable regulation regarding EMC and must be installed and put into service according to the EMC information stated in this appendix.

CAUTION
Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The V100 Monitor is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to assure that the V100 Monitor is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions EN 55011	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions EN 55011	Class B	The equipment 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 CARESCAPE V100 Monitor is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to assure that the V100 Monitor is used in such an environment.

Immunity Test	EN 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 ±1 kV for input/ output lines	Mains power should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_t (>95% dip in U_t) for 0.5 cycles <40% U_t (>60% dip in U_t) for 5 cycles <70% U_t (>30% dip in U_t) for 25 cycles <5% U_t (>95% dip in U_t) for 5 s	<5% U_t (>95% dip in U_t) for 0.5 cycles <40% U_t (>60% dip in U_t) for 5 cycles <70% U_t (>30% dip in U_t) for 25 cycles <5% U_t (>95% dip in U_t) for 5 s	Mains power should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power Frequency (50/ 60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

NOTE:

U_t is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The V100 Monitor is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to assure that the V100 Monitor is used in such an environment.

Immunity Test	EN 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 V rms	Portable and mobile RF communications equipment should not be used closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by reflection from structures, objects, and people.

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

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

Recommended Separation Distances

The table below provides the recommended separation distances (in meters) between portable and mobile RF communications equipment and the V100 Monitor.

The V100 Monitor is intended for use in the electromagnetic environment on which radiated RF disturbances are controlled. The customer or the user of the V100 Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the V100 Monitor as recommended below, according to the maximum output power of the communications equipment.

	Separation Distance in Meters (m) According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter in Watts	**150 kHz to 80 MHz** [a] $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** [a] $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** [a] $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
[a]At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			

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

NOTE:

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

Compliant Cables and Accessories

CAUTION
The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

The table below lists cables, transducers, and other applicable accessories with which GE Medical Systems claims EMC compliance.

NOTE: Any supplied accessories that do not affect EMC compliance are not included.

Part No	Description	Maximum Lengths
Temperature Cables and Probes		
2008774-001	Turbo Temp Oral Probe, White cord, Blue	3.0m / 10 ft
2008775-001	Turbojets Rectal Probe, White cord, Red	3.6 m / 12 ft
Oximetry Cables and Sensors		
70124033	Nellcor Multisite Sensor, D-YS, Reusable	Not Specified
70124021	Nellcor DuraSensor Reusable Finger Probe (DS100A)	1.0 m / 3.3 ft
2021406-001	Cable Assy SpO_2 Nellcor OxiMax - Smart	3.0 m / 10 ft
2025350-001	Cable Assy SpO_2 Nellcor OxiMax - Coro Version - EF keying	3.0 m / 10 ft
2021406-002	Cable Assy SpO_2 Nellcor OxiMax - Smart	1.2M / 4 ft
407705-005	SpO_2 Sensor, Max-R, Adhesive, Nasal, 24/box	Not Specified
70124026	SpO_2 Sensor, Max-I Infant, Adhesive, Sensor, 24/box	Not Specified
70124032	SpO_2 Sensor, Max-N Neonate Foot Adhesive Sensor, 24/box	Not Specified
70124022	SpO_2 Sensor, Max-P Pediatric Finger Adhesive Sensor, 24/box	Not Specified
70124027	SpO_2 Sensor, Max -A Adult Finger Adhesive Sensor, 24/box	Not Specified
2028117-001	SpO_2 Sensor, Max -AL Adult Long Finger Adhesive Sensor, 24/box	Not Specified
414248-001	OXIBAND (OXI-P/I) Pediatric/Infant Sensor	Not Specified
41428-002	OXIBAND (OXI-A/N) Adult/Pediatric Sensor	Not Specified
2017002-001	Masimo LNOP, SpO_2 cable assembly	3.6 m / 12 ft
2017002-003	Masimo LNOP, SpO_2 cable assembly	2.4 m / 7.9 ft

Part No	Description	Maximum Lengths
2002800-001	Masimo LNOP Reusable Finger Sensor LNOP/DCI Adult	1.0 m / 3.3 ft
2027263-002	Masimo LNC-10 cable assembly	3.0 m / 10 ft
2002799-001	Masimo LNOP Reusable Finger Sensor LNOP/DCI Pediatric	1.0 m / 3.3 ft
2027258-001	Masimo LNCS Reusable Adult Sensor	Not Specified
2010458-001	Masimo Disp Adhesive Sensor, LNOP-ADT. Adult (20/box)	Not Specified
2010459-001	Masimo Disp Adhesive Sensor, LNOP-PDT. Pediatric (20/box)	Not Specified
2010461-001	Masimo Disp Adhesive Sensor, LNOP-NeoPT. Neonatal (20/box)	Not Specified
2010460-001	Masimo Disp Adhesive Sensor Bridge, LNOP-NEO. Neonatal (20/box)	Not Specified
2017089-001	Masimo Disp Adhesive Sensor, LNOP-Neo-L. Neonatal (20/box)	Not Specified
2017090-001	Masimo Disp Adhesive Sensor, LNOP-NeoPT-L. Neonatal (20/box)	Not Specified
2027269-001	Masimo Disp Adhesive Sensor Transparent Tape LNOP, Adult (20/box)	Not Specified
2027270-001	Masimo Disp Adhesive Sensor Transparent Tape LNOP, Pediatric (20/box)	Not Specified
2027271-001	Masimo LNOP Disposable LNOP Hi Fi Sensor Neonatal/Adult (20/box)	Not Specified
2027272-001	Masimo LNOP Disposable LNOP Hi Fi Sensor Neonatal/Adult (20/box)	Not Specified
2027273-001	Masimo LNOP Disposable LNOP Blue Infant Thumb/Toe Sensor (20/box)	Not Specified
2010463-001	Masimo LNOP Reusable Multisite Sensor LNOP-YI	Not Specified
2027274-001	Masimo LNOP Reusable Tip-Clip Ear Sensor LKNOP TC-I	Not Specified
2009745-001	Masimo LNOP Reusable Finger Sensor Adult DC-195	Not Specified
2027259-001	Masimo LNCS DC-IP Reusable Pediatric Sensor	Not Specified
2027261-001	Masimo LNCS TC-I TipClip Reusable Ear Sensor	Not Specified
2027253-001	Masimo LNCS Adult Adhesive Sensor, 20/box	Not Specified
2027254-001	Masimo LNCS Pediatric Adhesive Sensor, 20/box	Not Specified
2027255-001	Masimo LNCS Infant Adhesive Sensor, 20/box	Not Specified
2027256-001	Masimo LNCS Neonatal Adhesive Sensor, 20/box	Not Specified
2027257-001	Masimo LNCS Neonatal PT Adhesive Sensor, 20/box	Not Specified
OXY-ES3	Ohmeda interconnect cable, reusable	3.0 m / 10 ft
OXY-F-UN	Ohmeda Finger sensor with UN connector	1.0 m / 3.3 ft

Part No	Description	Maximum Lengths
OXY-W-UN	Wrap Sensor with UN connector	1.0 m / 3.3 ft
OXY-E-UN	Ear Sensor with UN connector	1.0 m / 3.3 ft
OXY-E4-GE	Integrated Ear Sensor	4.0 m / 13.1 ft
OXY-F4-GE	Integrated Finger Sensor	4.0 m / 13.1 ft
OXY-SE-3	Sensitive Skin Sensor with UN connector	4.0 m / 13.1 ft
OXI-AF-10	ALLfit Adhesive Sensor, 10/box	0.9M / 3 ft
OXY-AP-25	Adult/Pediatric Adhesive Sensor - 25/box	Not Specified
OXY-AP-10	Adult/Pediatric Adhesive Sensor - 10/box	Not Specified
Accessories		
600028	AC cable, Hospital Grade, AHA,	2.4 m / 8 ft
2018859-001	Universal AC/DC adapter	Not Specified
320760	Isolated Level Converter, ILC 1926	Not Specified
354550CR	Isolated Level Converter, ILC 1931	Not Specified
2024500-001	Patient ID IR Cable	Not Specified
487208CR	DINAMAP Compact Remote Alarm Cable	Not Specified
418497-002	Cable Assy, Telemetry Interface, Dinalink	1.8m / 6 ft
683235	Cable Assy, Dinamap PLUS / Compact to V-link transmitter, EX	165cm

For your notes

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