Jenny®

Safety and Performance Information

reddot award winner

DESIGN AWARD 2015

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1. Safety Information

This section contains safety information requiring users to exercise appropriate caution while using the Jenny.

Warnings are identified by the WARNING symbol shown above.
Warnings alert you to potential serious outcomes (death, injury, or adverse events) to the patient or user.

Cautions are identified by the CAUTION symbol shown above.
Cautions alert the user to exercise care necessary for the safe and effective use of the Jenny.

NOTE:

Notes are identified by the **NOTE:** symbol shown above. Notes are listed before or after procedural steps or information and provide additional guidelines or information on the subject being described.

Warnings:

Only qualified service personnel should open the Jenny housing, remove and replace components, or make adjustments. If your medical facility does not have a qualified service technician, please contact MSW's Technical Services or your local MSW's representative.

Before attempting to open or disassemble the Jenny, disconnect the power cord to avoid possible injury.

The Jenny data logging extrapolates from the date and time provided by the Jenny time settings at time of installation.

Explosion hazard — Do not use the Jenny in the presence of flammable anesthetics.

Do not spray, pour, or spill any liquid on Jenny, its accessories, connectors, switches, or openings in the chassis, since this may cause damage to the Jenny.

The LCD panel contains toxic chemicals. Do not touch broken LCD panels. Physical contact with a broken LCD panel can result in transmission or ingestion of toxic substances.

The use of accessories, sensors, and cables other than those specified may result in inaccurate readings of the Jenny and increased emission and/ or decreased electromagnetic immunity of the system.

When installing the Jenny's AC-DC power, ensure the cord is carefully positioned to prevent tripping and entanglement.

Jenny, in all product configurations, is restricted to be used with one patient at a time.

Cautions

Observe standard ESD (electrostatic discharge) precautions when disassembling, reassembling, and when handling any of the components of the Jenny.

When installing the Jenny or its module PCB, tighten the screws with suggested torque. Over tightening could strip out the screw holes in the case, rendering it unusable.

During the assembly and disassembly of Jenny-Docking station and Jenny-modules, keep attention over all cables and antenna cable, over pulling of cables may damage the whole module

When connecting the Jenny to any instrument, verify proper operation before clinical use. Both the Jenny and the instrument connected to it must utilize same grounded outlet. Accessory equipment connected to the Jenny's data interface must be certified according to IEC Standard 60950 -1: 2005 for data-processing equipment or IEC Standard IEC 60601-1:2005 + A1:2012 for electro medical equipment. All combinations of equipment must be in compliance with IEC Standard 60601-1- :2014 Requirements for Medical Electrical Systems. Anyone connecting additional equipment to the signal input port or signal output port (data port connector) is configuring a medical system and, therefore, is responsible for ensuring that the system complies with the Requirements for Medical Electrical Systems the electromagnetic compatibility IEC Standard 60601-1-2:2014 Jenny may degrade if it is connected to secondary I/O devices when the equipment is not connected to earth reference.

Dispose of battery in accordance with local requirements and regulations.

2. General Introduction

This references guides provides a concise description of the Jenny Critical Care System. This guide is for informational purposes only.

2.1. Manufacturer’s liability

MS Westfalia GmbH (Here after MSW) is a manufacturer of electro medical equipment. MSW will only accept to be held responsible for the safety, reliability and performance of units and systems if:

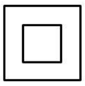
- Installation, upgrading, additions, changes or repairs are conducted by people who have been authorized by MSW to perform such services.
- The electrical system of the room in which the respective unit(s) is (are) operated corresponds to the requirements of the IEC standards.
- The unit(s) is (are) operated in accordance with the respective user manual.
- The unit(s) or system(s) have been operated with the respective official accessory and components.

MSW will reject to be held responsible for any damage of devices caused by improper usage or by using other accessories or components as the ones mentioned in the respective user manual.

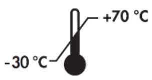
2.2. Equipment symbols

The following symbols printed on labels and packaging. For additional symbols printed on the Docking Station, batteries or modules...etc. described at following sections

Symbol	Description
Symbols on labels	
MD	Medical Device
	Manufacturer
	Date of manufacture
	CAUTION! Consult accompanying documents for safety-relevant information

Symbol	Description
	Consult Instructions for Use for complete information
	The device meets the requirements for electrical protection Class II
	Defibrillation-proof type BF applied part
	Disposal per European Directive 2002/96/EC or WEEE (Waste Electrical and Electronic Equipment)
IP54	Protected against dust and splashing water. Protected against solid objects over 1mm, e.g. wires & nails and protected against water splashed from all directions, limited ingress permitted.
SN	Serial number
REF	Catalogue or model number
UDI	Unique Device Identifier (UDI) with Product Identifiers (PI)
CE 2797	CE Marking of Conformity, Notified Body 2797, BSI

Symbols on packaging

Symbol	Description
	Single use only. DO NOT REUSE
	Storage Temperature range: - 10 … to …+ 50 °C

2.3. Service information

The system is subject to annual inspections and maintenances that can only be performed by trained and educated authorized personnel. Furthermore, only authorized persons are allowed to conduct repairs on the system. The mandatory service and maintenance intervals must be followed.

Only original spare-parts of the manufacturer as well as exchange-parts recommended by the manufacturer may be used. Furthermore, service-contracts are recommended by the manufacturer or authorized distributor.

2.4. Equipment and Accessories identification

The following section gives the details of label on Jenny and modules and information identification from label.

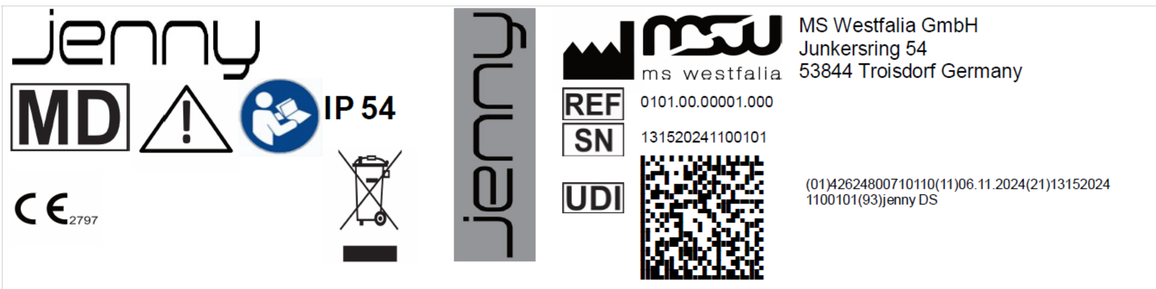


Figure 2-1: Docking Station Label

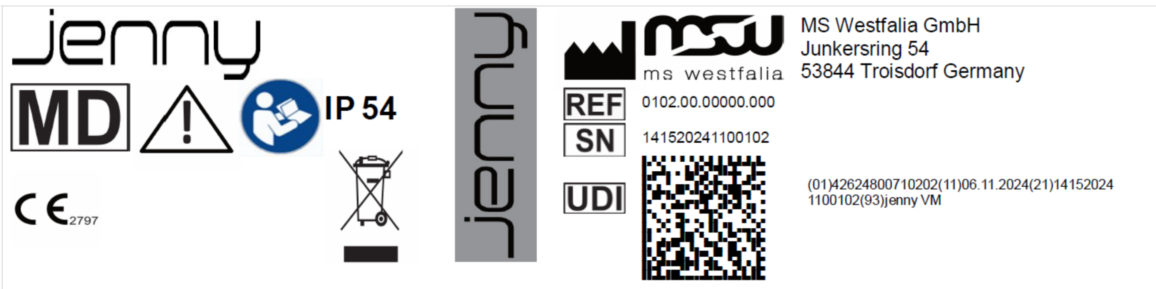


Figure 2-2: Ventilator Module Label

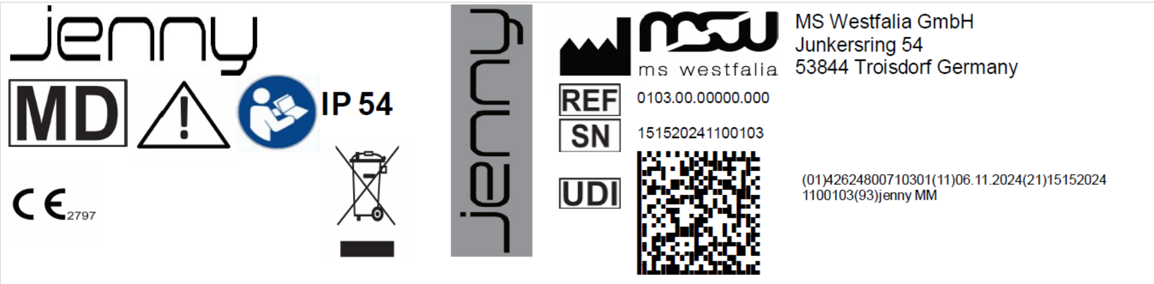


Figure 2-3: Monitoring Module Label

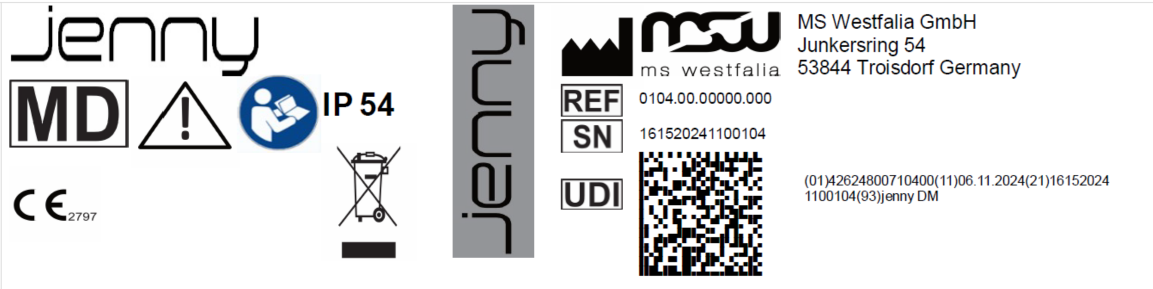


Figure 2-4: Defibrillation Module Label

3. Jenny functional overview

3.1. Overview Jenny

Jenny is a mobile, modular intensive care station. Its function includes ventilation, monitoring and defibrillation.

Jenny consists of:

- Docking Station (DS)
- 3 Modules
  - -Ventilation Module (VM),
  - -Monitoring Module (MM)
  - -Defibrillation Module (DM)
- Additional mounting features
  - -Transport Frame (TF)
  - - Wall Mount Hospital (WMH)
  - - Transport Wall Mount for ambulance car (TWM),
  - -Trolley (TR) Docking arm for Hospital (DAH).

The areas of application are:

- Pre-clinical - outside hospitals or clinics, or any other medical service facility.
- Inter-clinical - during transport to and from a medical service facility (ambulance car, helicopter).
- Intra-clinical - during transport inside a medical service facility.
- Intensive care unit
- Emergency care - in emergency service facilities dedicated other to out-of-hospital acute medical care, transport to definitive care, and other medical transport.
- Routine medical care - in routine medical care facilities including but not limited to primary health care centres, secondary health care centres, tertiary health care, clinics, and clinical facilities.
- Jenny is intended for use under the direct supervision of licensed health care practitioner only.

NOTE:

The most recommended configurations to carry and mounting Jenny at different environments are listed below

Use case	Environment	Required components
1	Pre-clinical	Transport Frame
2	Inter-clinical	Transport Frame Transport Wall mount
3	Intra-clinical	Transport Frame
4	Intensive Care Unit	Wall mount hospital Docking arm hospital Trolley
5	Emergency care	Wall mount hospital Docking arm hospital Trolley
6	Routine medical care	Wall mount hospital Docking arm hospital Trolley

3.2. Intended use of Jenny

Jenny system is a mobile, modular, medical device. Its functionality includes vital parameter monitoring, ventilation and defibrillation in stationary and transport use (only with TF and TWM). The intended use of each module is described in the corresponding chapter.

Patient population:

- Adults
- Children
- Neonates

Operator information:

- The operator is responsible for selecting the appropriate:
  - Accessories
  - Single use parts
  - Module settings

Alarm settings for each patient

⚠ Jenny is not intended for use in a home use environment.

3.3. Docking station

3.3.1. Intended use of DS

The Docking Station is intended for the operation and control of the connected modules.

The Docking Station functions as:

- Graphical user interface
- Alarm system
- Power supply
- Telemetry
- Data storage

Patient population: **N/A.**

3.3.2. Physical Views

Docking station

	
Rear view	**Front view**

Symbols and abbreviations

Symbol	Description
⏏	Module locking and ejection knob
⏻	Power ON/OFF* button

SD	External memory card slot
	GPRS SIM card Slot
	WLAN
	Extended display with DVI out
USB	USB 2.0

**OFF function is in combination with touch control.*
**Continuous hold of power button for 10Sec, will lead to force shutdown of Jenny.*

3.4. Ventilation Module

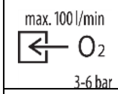
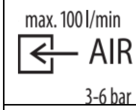
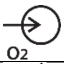
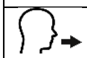
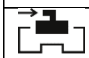
3.4.1. Intended use of VM

The Ventilation module is intended for adults, children, infants, term and preterm neonates (minimum body weight 300 g) who require respiratory support or mechanical ventilation. The Ventilation module is intended to provide long-term invasive and non-invasive continuous positive pressure ventilation, high-flow and low-flow oxygen therapy, inspiratory nebulization of pharmaceuticals under ventilation and monitoring capnography (EtCO_2) under direct supervision of a trained physician.

3.4.2. Physical Views

Ventilation Module

Symbols and abbreviations

Symbol	Description
	Consult Instructions for Use for complete information
	Defibrillation-proof type BF applied part
	Oxygen inlet
	Air inlet
	External oxygen sensor connection
	Nebulizer connection
	Endotracheal cuff
	Exhalation port
	Inspiration port
	IRMA™ and ISA™ sensor
	Auxiliary pressure
	Patient flow sensor
	Exhalation valve control line

3.5. Patient Monitoring Module

3.5.1. Intended use of MM

The Monitoring Module is intended for monitoring the following physiological parameters and direct supervision of a trained physician:

- Diagnostic support (HES®) and non-diagnostic ECG and related printouts
- Arrhythmia detection
- Automatic ST segment analysis
- Respiratory Rate

- Masimo Rainbow SET® Pulse Oximetry Parameters: SpO2, PR, PI and Pulse CO-Oximetry Parameters: SpHb, SpCO, SpMet, SpOC, PVI, ORI Capnography (EtCO2)

- Four-channel Invasive Blood Pressure (IBP): Invasive Blood Pressure (IBP), Central Venous Pressure (CVP), Intracranial Pressure (ICP)

- Non-Invasive Blood Pressure (NIBP)

- Two-channel Temperature

The diagnostic ECG (HES®) printout is supporting but not replacing the diagnosis by a physician.

Arrhythmia detection and ST Segment Analysis are intended for adults and pediatric patients only.

The arrhythmia detection is not intended for atrial fibrillation and/or flutter.

The pulse CO-oximeter parameters (Masimo Rainbow ® parameter set) should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.

The pulse CO-oximeter is not an apnea monitor.

The pulse CO-oximeter should not be used for arrhythmia analysis.

3.5.2. Physical Views

Monitor Module

Symbols and abbreviations

Symbol	Description
	Consult Instructions for Use for complete information
	Defibrillation-proof type BF applied part
	IRMA™ and ISA™ sensor connection
	ECG connection
	Pulse Oximetry (SpO_2) connection

	IBP connection
	NIBP connection
	Temperature 1 connection
	Temperature 2 connection

3.6. Defibrillation Module

3.6.1. Intended use of DM

The defibrillation module is intended for the termination of ventricular fibrillation (VF) and pulse absent ventricular tachycardia (VT).
The defibrillation module provides the following modes of operation:

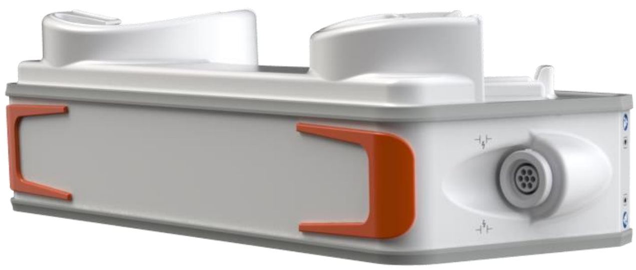
1. Manual defibrillation
2. Cardioversion
3. Non-invasive pacing

The manual defibrillation is intended for patients who are pulseless and unresponsive.
The cardioversion mode is intended to revert unstable supraventricular tachyarrhythmia, unstable atrial fibrillation, unstable atrial flutter, and unstable monomorphic (regular) VT.
The non-invasive pacing mode is intended to revert bradycardia, bradyarrhytmia, and symptomatic heart blocks (clearly dependent on physician's decision).
Operator information:

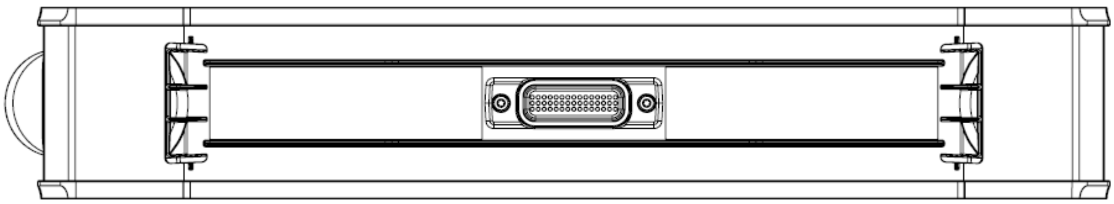
- The Defibrillation, Cardioversion and Non-Invasive Pacing modes are intended for use by responders with ACLS training and qualification, or other physician authorized by emergency medical response program

3.6.2. Physical Views

Paddle Version

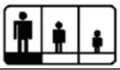
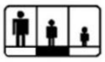
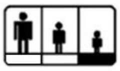


Slim Version



Symbols and abbreviations

Symbol	Description
Symbols on the module	
	Defibrillation
Symbols on accessories packaging	
	Single use only. DO NOT REUSE
	Expiry date. USE BY
LOT	Lot number. BATCH CODE
SN	Serial number
REF	Item reference number. CATALOGUE NUMBER
STERILE	STERILE
	Manufacturing date

	Adult use only. From 8 years and/or 25 kg
	Pediatric use only.
	Neonatal use only.

3.7. Product configurations

The following product configurations are possible:

Configuration	Description	Additional instructions
1. Docking station only	No modules attached. No therapeutic, monitoring or diagnostics functions are possible.	In this combination, only system settings and patient data management functions are available
2. Docking station + Ventilator	Therapeutic functions: Ventilation	For a proper device operation, you have insert the ventilator module into the two lower bays (slots 1&2)
3. Docking station + Monitor	Patient monitoring functions only	The monitoring module must be inserted into the bottom bay (slot 1)
4. Docking station + Defibrillator	AED defibrillation only	The defibrillator module must be inserted into the bottom bay (slot 1)
5. DS + Ventilator + Monitor	Ventilation and patient monitoring	The ventilator module must be inserted into the two lower bays (slots 1&2). The monitor must be inserted into bay 3.
6. DS + Ventilator + Defibrillator	Ventilation and AED defibrillation	The ventilator module must be inserted into the two lower bays (slots 1&2). The defibrillator module must be inserted into bay 3
7. DS + Monitor + Defibrillator	Patient monitoring and therapeutic function: AED and Manual defibrillation, external Pacemaker.	The monitoring module must be inserted into the bottom bay (slot 1). The Defibrillator must be inserted on top of the monitoring module (slot 2).
8. DS + Ventilator + Monitor + Defibrillator	Complete configuration	The ventilator module must be inserted into the two lower bays (1&2) On top of it the monitor (slot 3) and at the top the defibrillator module (slot 4)

4. Product specifications and compliance

This section contains Jenny physical and operational specifications. Ensure all product requirements are met prior to installation.

4.1. *Electromagnetic compatibility (EMC)*

Guidance and manufacturer's declaration – electromagnetic emissions		
The Jenny® critical care hybrid is intended for use in the electromagnetic environment specified below. The customer or the user of the Jenny® critical care hybrid should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment- Guidance**
RF emissions CISPR 11:2016	Group 1	The Jenny® Critical Care Hybrid uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11:2016	Class B	The Jenny® Critical Care Hybrid 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 61000-3-2:2018	Class A	
Voltage fluctuations/ flicker emission IEC 61000-3-3:2017	Complies	
RTCA DO 160G:2010 RTCA DO 160G Section 21.4 RTCA DO 160G Section 21.5	Cat. M	The Jenny is powered using internal battery .Jenny is not connected to Aircraft power

Electromagnetic Immunity:

Guidance and manufacturer's declaration – electromagnetic immunity			
The Jenny® Critical Care Hybrid is intended for use in the electromagnetic environment specified below. The customer or the user of the Jenny® Critical Care Hybrid should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2:2008	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electric fast transient/burst IEC 61000-4- 4:2012	± 1 kV for input/output lines ± 2 kV for power supply lines	± 1 kV for input/output lines ± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5:2014	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11:2017	< 5 % UT (> 95 % dip in UT) for 1/2 cycle 40 % UT (60 % dip in UT) for 5 cycles 70% UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	< 5 % UT (> 95 % dip in UT) for 1/2 cycle 40 % UT (60 % dip in UT) for 5 cycles 70% UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Jenny® Critical Care Hybrid requires continued operation during power mains interruptions, it is recommended that the Jenny® Critical Care Hybrid be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8:2009	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6:2013	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Jenny® Critical Care Hybrid including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $D = 1,2 \sqrt{P}$ $D = 1,2 \sqrt{P}$
Radiated RF IEC 61000-4-3:2010	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	

			80 MHz to 800 MHz $D = 1{,}2\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) per 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 near equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Jenny® Critical Care Hybrid is used exceeds the applicable RF compliance level above, the Jenny® Critical Care Hybrid should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Jenny® Critical Care Hybrid [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between **portable and mobile RF communications equipment and the Jenny® Critical Care Hybrid**
The Jenny® Critical Care Hybrid is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Jenny® Critical Care Hybrid can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Jenny® Critical Care Hybrid as recommended below, per the maximum output power of the communications equipment.

Rated maximum output power of transmitter, W	Separation distance per frequency of transmitter, m		
	150 kHz to 80 MHz d = 1,2 $\sqrt{P}$	80 MHz to 800 MHz d = 1,2 $\sqrt{P}$	800 MHz to 2,5 GHz d = 2,3 $\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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

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

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

4.2. Compliant cables and accessories:

> ⚠ The use of accessories, sensors, and cables other than those specified may result in inaccurate readings of the Jenny and increased emission from system.

Name	Identification Code/Issue/Serial Number	Description
Medical grade power Supply	ATM250T-1P190-2270	Input: AC 100-240V, 50-60Hz, 3.3-1.3A, output: DC 19V,13.2A, 250W Max

Name	Identification Code/Issue/Serial Number	Description
ECG	Nicolay 10-Lead Cable	3m
	Smith Medical Adaptor cable, single	0,5m
	Smith Medical Adaptor cable, double	0,5m
	Smith Medical Adaptor cable, single	1m

IBP	Smith Medical Adaptor cable, double	1 m
	Smith Medical Adaptor cable, single	1.6m
	Smith Medical Adaptor cable, double	1,6m
Temp	Sensotronic temperature sensor for skin for all patient types, reusable	3m
	Sensotronic temperature sensor rectal for all patient types, reusable	3m
Masimo Pulse Oximetry	RD Rainbow SET 25, RA-05 Patient Cable, reusable	NA
	RD SET Patient cable RA25-08, reusable	NA
	RD SET Adt, adult adhesive sensors, > 30 kg, disposable	NA
	RD SET Pdt, pediatric adhesive sensor, 10-50 kg , disposable	NA
	RD SET Inf, infant adhesive sensor, 3-20 kg, disposable	NA
	RD SET Neo, neonatal/adult adhesive sensor, < 3 kg, disposable	NA
	RD SETNeiPt, Neonatal adhesive Spo2 sensor, disposable	NA
	RD rainbow SET-2 Adt, > 30 kg, disposable	NA
	RD rainbow SET-2 Pdt, 10-50 kg , disposable	NA
	RD rainbow SET-2 Inf, 3-20 kg, disposable	NA
	RD rainbow SET-2 Neo, < 3 kg, disposable	NA
	RD rainbow Lite SET-1 Adt, Adult Adhesive SpO2, SpMet, SpHb Sensor	NA
	RD rainbow Lite SET-1 Pdt, Pediatric Adhesive SpO2, SpMet, SpHb Sensor	NA
	RD rainbow Lite SET-1 Inf, Infant Adhesive SpO2, SpMet, SpHb Sensor	NA
	RD rainbow Lite SET-1 Neo, Neonatal Adhesive SpO2, SpMet, SpHb Sensor	NA
	RD SET DCI, adult reusable sensor, > 30 kg,	NA
	RD SET DCIP, pediatric reusable sensor, 10-50 kg	NA
	RD SET YI, multisite reusable sensor	NA

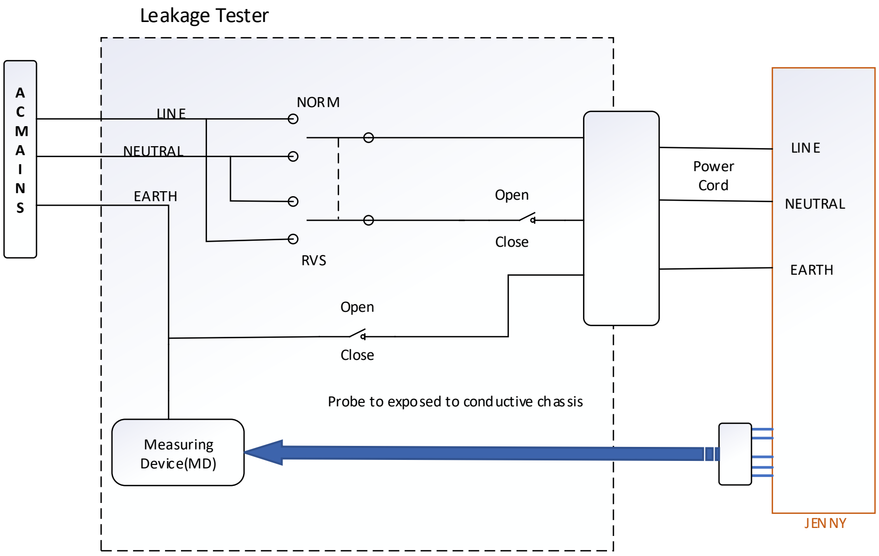
Accessories	Battery Lithium-Ion	NA
	Power Cord	1.8m
	RJ45 Series category 5 cable	NA
	CO2 - Capnography (Main Stream, Side Stream)	NA
	Battery charger Adaptor	NA

4.3. Electrical Safety Tests

- Electrical safety tests are a proven means of verifying the electrical safety of the Jenny. They are intended for determining potential electrical hazards. Failure to find out these hazards timely may cause personnel injury.
- Commercially available test equipment such as safety analyzer, etc. can be used for electrical safety tests. Be sure that the test equipment can be safely and reliably used with the Jenny before use. The service personnel should acquaint themselves with the use of the test equipment.
- Electrical safety tests should meet the requirements of the new edition of standards EN 60601-1 and IEC 62353.
- These electrical safety tests do not supersede local requirements.
- All devices using the AC mains and connected to medical equipment within patient environments must meet the requirements of the IEC 60601-1 medical electrical systems standard and should be put under electrical safety tests at the frequency recommended for the patient monitor.
- The safety tests should perform after training completion from MSW

Electrical safety tests are intended to check if potential electrical hazards to the patient, operator or service personnel of the equipment. Electrical safety test should be performed under normal ambient conditions of temperature, humidity and pressure.
The electrical safety test plan described here as per procedure with any standard safety analyser. Different safety analysers may be used in different areas. Be sure to choose applicable test plan.

Patient Leakage Current Test



Enclosure Leakage Current				
Condition	**AC Line Polarity**	**Neutral Line Cord**	**Power Line Ground**	**IEC 60601-1**
Normal	Normal	Closed	Closed	100uA
Single fault		Open	Closed	500uA
		Closed	Open	
Normal	Reversed	Closed	Closed	100uA
Single fault		Open	Closed	500uA
		Closed	Open	

5. Preventive maintenance

- *Failure on the part of all responsible individuals, hospitals or institutions, employing the use of Jenny, to implement the recommended maintenance schedule may cause equipment failure and possible health hazards. The manufacturer doesn't, in any manner, assume the responsibility of for performing the recommended maintenance schedule, unless an Equipment Maintenance Agreement exists. The sole responsibility rests with the individuals ,hospitals or institutions utilizing Jenny*
- *Jenny should have their maintenance performed only by a qualified technician, trained and authorized by MSW*
- *The Jenny and its modules should be carefully inspected once every 12 months*

Daily checks and prior to use

- Cleaning and disinfecting the Jenny (Clean the printer head as usage demands)
- Integrity of the power cord to Jenny;
- Correct operation of the visual and audible alarm system;
- Installation and cleaning of filters;
- Correct display of the screen;
- Correct use of touch screen;
- Full battery;
- Correct operation of the equipment home screen GUI ;
- Correct installation of the breathing circuit

⚠	Daily check should be performed with the patient disconnected

Battery maintenance:

How to charge the battery:

The battery can be charged by one the two methods

- Outside of the Jenny by using MSW recommended external charger
- Inside a Jenny that is connected to an AC power source

Charging the battery with MSW external charger:

1. Insert the battery into the battery charger. The LED should lights
2. To know the charging status PUSH the button, It appears by lighting the number of LEDs

NOTE:
If the FAIL LED lights, Remove the battery from the battery charger and reinsert it.Wait for around 5 min to light of the first LED, In case of battery was completely discharged. If fail to light up after sometime, Then the battery is defective and should be replaced.

Charging the battery inside Jenny:

NOTE:

Non-recommended (In compatible) batteries will not charge in the Jenny

The battery is charged whenever the Jenny is connected to AC power. Jenny only charge battery, if the charge percentage is at least 10%.

If the battery was fully discharged or less than 10%, it's mandatory that remove the battery from Jenny and charge with external charger for at least 10%.

How to store the battery:

- Store the battery outside of the Jenny at temperature between 20ºC to 25ºC
- When the battery is stored inside a Jenny that is powered by an AC power source, the battery cell temperature is increased by 10ºc to 15ºc. Jenny warns with ALARM.

- It is recommended remove the batteries from Jenny if not using for long time.
- With recommended operating guideline battery can provide its best performance for 12 months only.

This Jenny recommended always connected to the mains power, so that there is sufficient charge during a power outage.

How to replace the batteries:

⚠	The battery must be replaced as indicated in the technical specifications so that capacity in normal operation is as specified. Replacement of internal battery should be performed only by a qualified technician, trained and authorized by MSW EXPLOSION OR FIRE --- Using non recommended batteries could result in injury/burns to the patient or users

- Open the battery doors on the bottom left and right of the Jenny
- Remove the faulty batteries
- Replace with a new battery. Install the battery as flat surface the battery is facing upwards
- Close the battery doors
- Verify the jenny operated correctly
- Confirm that the battery icons displays in the lower left corner of the Jenny
- Verify the Cap touch screen are illuminating after connected to AC power along with batteries

Recycling the batteries:

When the battery no longer holds a charge. It should be replaced .The battery is recyclable. Remove the old batteries from the Jenny and follow your local recycling guidelines.

⚠	EXPLOSION HAZARD- Do not destroy the battery or store at high temperatures. Serious injury or death could result

Maintenance procedures:

Visual inspection:

- Carefully inspect the equipment for physical damage to the case, the display screen .Don't use the jenny if damage is determined .Refer the damaged part replacement procedure with qualified personnel.
- Inspect all external connections for loose connectors and all cables. Have any damaged connectors or cables replaced by qualified personnel.
- Inspect the display face for marks, scratched, or other damage. Physical damage to a flat panel display glass may lose an implosion hazard. Have the flat panel display replaced by qualified service personnel if necessary
- Safety labels and inscriptions on the device are clearly legible.

Cleaning and disinfecting the Jenny:

⚠	Disconnect the external AC DC adaptor from Jenny before cleaning or disinfecting its surface. Turnoff the power from battery power before cleaning or disinfecting its surface.

Note:
Cleaning the exterior surface on regular basis in compliance with your institution's infection control and bio medical engineering department.

Complete the following procedure to clean the exterior surfaces if this equipment.

1. For cleaning all displays, including touchscreen with standard display, do the following:
    a) Turn off the power to the Jenny, before start cleaning display.
    b) Wipe the exterior with a soft lint-free cloth, lightly moistened with household glass cleaner.
2. For cleaning and disinfecting the equipment, wipe the exterior with a soft lint-free cloth, using the following solution as recommended in the APIC guidelines for selection and use of Disinfectants(1996) .
3. When disinfecting the equipment, allow disinfectant solution to remain on device for a minimum of one minute per hospital guidelines.
4. Wipe off cleaning solutions with a clean, lightly moistened cloth.
5. Dry thoroughly with a dry lint-free cloth and let air dry for at least 30 minutes

Note:
Drying times may vary based on the environmental conditions.

6. Take care not let fluid pool 2 around connection pins and pads. If this should happen, blot dry with a soft lint-free cloth.

⚠	Use the following precautions to prevent damaging the equipment: ▪ Never immerse the device in any liquid ▪ Do not pour or spray any liquid directly on the device or permit fluid to seep into connections or openings ▪ Never use conductive solutions, Solutions that contains chlorides, wax, or wax compounds to clean the device. ▪ Never autoclave or steam clean the device. ▪ Always use household glass cleaner to clean the touchscreen.

For detailed cleaning agent refer to user manual

Functional Check out Procedures:

Docking station Power-On tests:

Note:

Procedure noted down is to verify the power switching and to verify the safety concepts feature.

With all the power sources, Jenny should be ERROR/WARNING free to do therapies.

1. Unplug the external DC input and remove the batteries from the Jenny.
2. Plug the DC power and start the Jenny with external power (Error: Batteries missing)
3. Shut down the Jenny and Unplug the DC power jack
4. Safety buzzer start beeping continuously.
5. Plug the DC jack again and start the system. Insert the batteries one after another

6. Display screen should show battery status (If the battery charging is less than 80%, Observe charging symbol)
7. Switch between different power sources between DC Jack, L_Battery and R_Battery. Observe the Jenny should not disturb with this, also observe power source change at bottom of the screen with ICONs change.
8. During the power-ON, Alarm LED will change with different colors and Touch buttons too.

⚠	If the batteries were discharged less than 10%, Jenny cannot recognize them at startup. Those batteries should charge by using external battery charger up to 10% min.

MM Module:

The following tests can be performed once successful detection of monitor module by docking station successfully.

ECG tests:

<u>Test equipment:</u>

- Multi parameter patient simulator
- ECG patient cables

<u>12-Lead ECG test:</u>

Perform this test if the jenny acquires 12 lead wires ECG data:

<u>Connections:</u>

1. Attach the ECG patient cable to MM port **"3"** and ECG leads set to the patient simulator in order.
2. Select 12-Lead configuration in Jenny ECG settings

<u>Patient simulator Configurations:</u>

3. Set up the patient simulator as follows:

- Heart rate -80bpm
- Heart rate amplitude - 1.0mV
- 12-Lead ECG cable properly attached.

4. Observe the following
   Verify the 12 leads ECG waveforms are noise free leads
   After acquiring data select to print the wave from using printer ICON.

Leads OFF detection:

5. Select ECG lead II to view in the top trace position on the jenny display
6. Disconnect the RA lead wire from patient simulator
   Observe the following
7. An RA FAIL message appears on the display, and Lead III automatically displays in place of lead II in the top trace position.
8. Reconnect the RA lead wire to the patient simulator and discharge the Jenny

Temperature tests:

Test equipment:

- A multi parameter patient simulator
- Temp adaptor cable

Temperature test procedure:

1. Port 2&6 in monitor module are for temperature measurement.
2. Connect the Jenny TEMP1 to patient simulator to adaptor cable.
3. Set the patient simulator temperature settings as 37°C
4. Verify the temperature parameter window (TEMP1) in Jenny monitor screen should display as 37°± 0.1°C
5. Move the temperature adaptor cable to TEMP2 port in jenny.
6. Verify the temperature parameter window (TEMP2) in Jenny monitor screen should display as 37°± 0.1°C
7. Remove the temperature adaptor and patient simulator from the Jenny.

Invasive blood pressure tests:

Test equipment:

- A multi parameter patient simulator
- IBP adaptor cables

The IBP tests provide a method of verification for all IBP connectors (IBP1&IBP2, IBP3&IBP4) of monitor module equipped with this optional function.

Patient simulator configurations:

- Set up the patient simulator as follows:
- Blood Pressure (BP) polarity - positive
- BP output -- 0mmHg

- BP transducer output: 5uVolts

IBP connector test procedure:

1. Connect the BP simulator with adaptor cable to enabled BP connector you are testing.
2. Verify the BP parameter window, waveform label, corresponding graticules, and waveforms appearing on the jenny display
3. Press the “ZERO ALL” key on the front panel of the patient monitor to zero-reference the BP waveform
4. Change the patient simulator output to 240mmHg
5. Observe a reading of 240/240(±4mmHg) in the BP parameter window on the jenny display.
6. Change the patient simulator BP output to wave 120/80 wave from
7. Observe a distortion-free BP waveform and a reading of Approx. 120/80 in the BP parameter window on the Jenny display.
8. Disconnect the BP simulator cable from the BP connector of the Jenny.
9. Repeat steps for each enabled BP connector.

Pulse oximetry tests for Masimo SpO2 Oximeter:

Test equipment:

- Masimo SpO2 test kit. Includes Masimo tester and SPO2 sensor adapter cable

NOTE:

The Masimo Tester is intended for use only with Masimo instruments or Instruments containing Masimo SET oximetry with standard Masimo PC series patient cable connectors. See the Masimo “Directions for use” that came with the Tester for more information.

The PPR and SPO2 values for the Masimo Tester must be within these limits: PPR: 61bpm ± 1bpm and SPO2 value 81%± 3%.

Procedures:

1. Connect the Masimo-style SPO2 simulator cable between the SPO2 connector of the Jenny and the SPO2 Simulator
2. Turn on the Jenny
3. Verify the following are displayed at the Jenny
    - A waveform with SPO2 label
    - A SPO2 % reading between 78-84%
    - A PPR reading between 60 and 62 bpm
4. Disconnect the simulator cable from the module.

Noninvasive blood pressure (NIBP) tests:

Test equipment:

- NIBP cuff coupling
- NIBP hose coupling
- NIBP tee
- NIBP tubing 2 feet
- NIBP simulator: Digital (Fluke ProSim 8)
- NIBP tube

- NIBP cuff
- PVC pipe

NIBP Testing:

- Insert the NIBP cuff with T extension to Jenny.
- Connect the Simulator in the T Junction of TUBE between jenny and CUFF
- Make sure cuff is tied to Volume cone to get inflated properly
- Start NIBP function in Jenny
- Measured BP value in simulator should same with allowed deviation (with in 3mmHg)

The faulty modules sent back to MSW factory as communication details given in the contact sheet.

Detailed functional procedures after repair are available in IFU.

VM Module:

The Jenny Ventilation Module is designed to provide the maximum amount of utilization with a minimum amount of maintenance. When determining the frequency of required preventive maintenance, many factors must be considered, including:

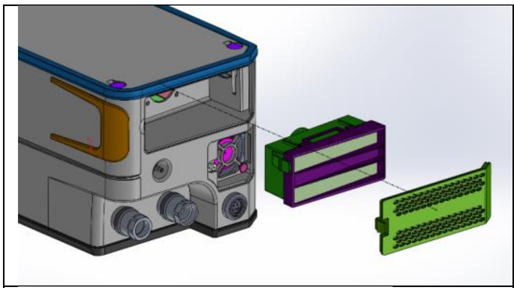
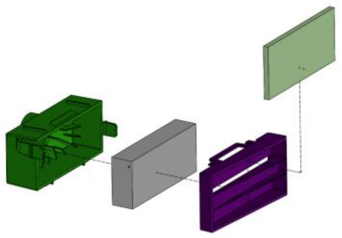
- Frequency and length of use
- Quality of the compressed air source(s)
- Environmental conditions

The Jenny Ventilation Module, like other pieces of healthcare equipment, will require routine maintenance over time

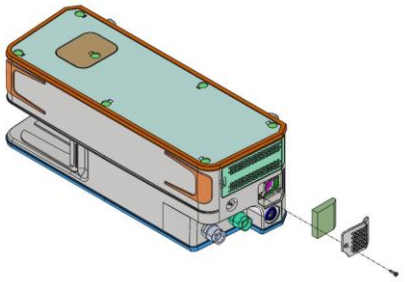
Refer to the following for recommended maintenance procedures and intervals.

Replacing the Air intake filter:

The following explains the procedure to change the air intake filter.

	1.Remove the filter cover on the left side of the ventilation module 2.Remove the filter assembly from module
	3. Follow the filter separation as shown in image. 4. Clean the seating area of the filter with a cotton ball soaked in water and mild soap solution. 5.After drying, introduce a new filter 6. Install the filter cover and check if the set is firmly close

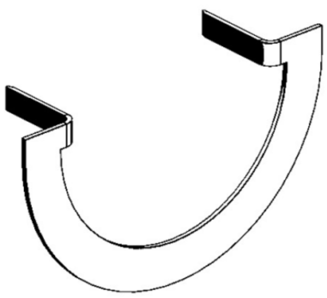
Replacing the FAN out filter:

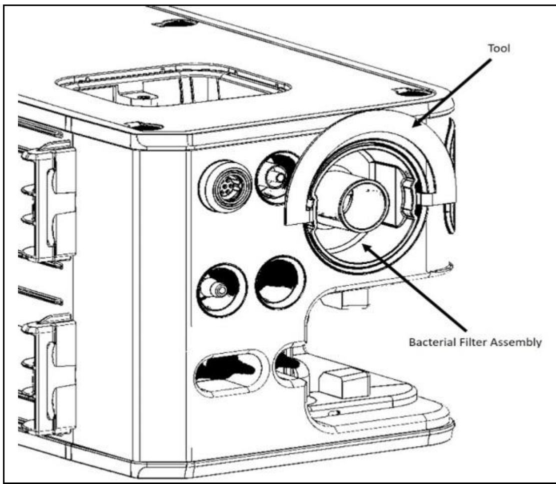
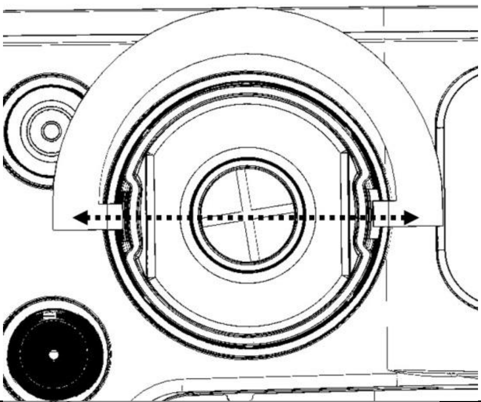
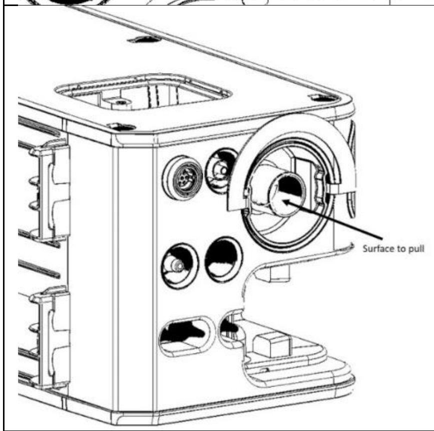
	Replace the Fan filter with using the tool Allen key 2.0mm Replace intervals of the filter as recommended

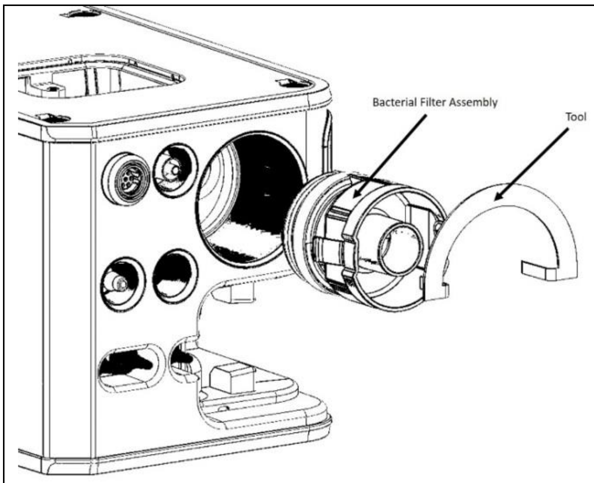
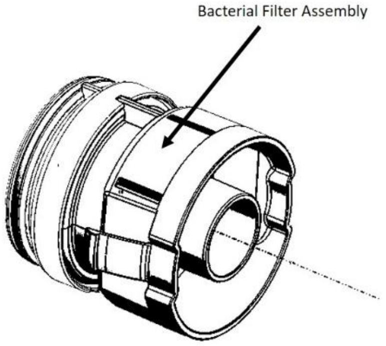
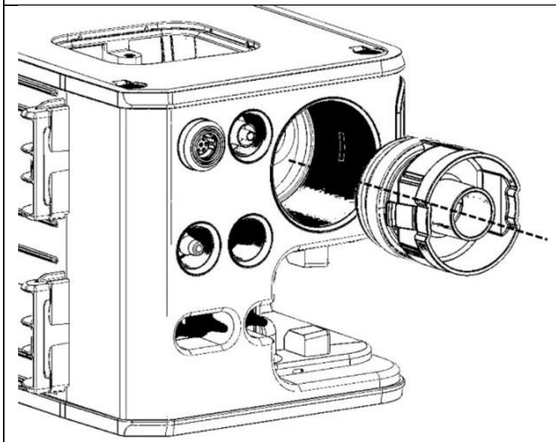
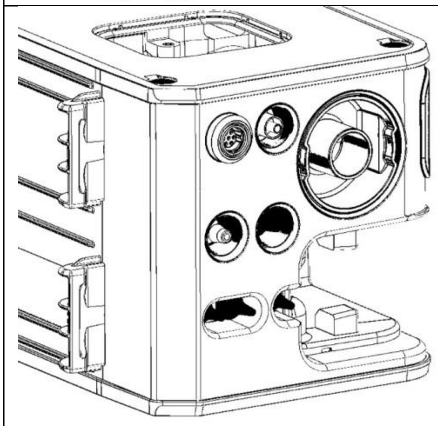
⚠	Do not use compressed air for cleaning, as this may introduce dust and dirt in the gas mixing system. Do not operate the equipment without this filter, because it may damage the system controlling the air/oxygen mixture.

⚠	▪ Use only filters, parts, pieces and accessories specified by MSW listed in this manual, which have been tested and approved for use in conjunction with this equipment; otherwise, this can jeopardize the operation endangering the patient or user; ▪ Replace the ambient air intake filter every 500 hours of use, or at shorter intervals, if there is much ▪ particulate matter suspended in the environment in which the ventilator is used; ▪ This filter when saturated generates an increase in the resistance of the ambient air inflow and can make the minimum concentrations (35% O2) to not be met. In this case, replace the filter.

Replacing the Bacterial Filter:

	In order to replace the bacterial filter, the VM Tool is required.

	Set the VM Tool as shown in the picture at the Ventilator Module Filter Male Housing.
	Ensure that the VM Tool touches the arms of the housing.
	Grab with the thumb in the middle of the VM Filter Male Housing. The surface to pull is indicated with a black arrow

	Pull out the VM Bacterial Filter Assembly. Light rotational movements can be helpful for the removal of the assembly.
	Separate the VM bacterial filter assembly by pulling the VM filter male housing and the VM filter female housing
	Replace with new bacterial filter assembly
	Press the Bacterial Filter Assembly in the main Housing of the Ventilator Module.

Assembly of expiration filter

	Expiration filter will be assembled in place of green cut-out shown side image
	Preassembled expiration valve can be assembled as show

⚠	Other than above listed procedures, it's not permitted to do any repair on VM module. If found operation fault with VM module replace with new module.

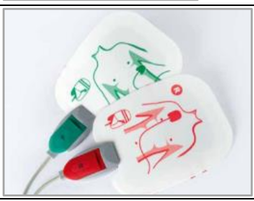
The faulty modules sent back to MSW factory as communication details given in the contact sheet.

Detailed functional procedures after repair are available in IFU.

DM Module

- All AEDs perform self-maintenance checks on a daily, weekly and monthly basis to ensure that they are ready for use. In the event that the machine fails part of the test, it will 'beep' to alert you that there is a fault
- In standby mode, maintenance is simply a visual inspection.
- Replacement of consumables:
- Pads – every 2 years

List of accessories will be used with Jenny recommended as below.

	▪ Adult ▪ Pediatric
	▪ Adult

	▪ Children from 1 to 8 years. ▪ Max. 25 kg
	▪

Paddle change procedure:

⚠	Other than above maintenance procedure, it’s not permitted to any repair on DM module. If found operation fault with DM module replace with new module. Shocking capacitor is limited, please contact MSW communication channel for further steps to replacement procedures.

The faulty DM modules sent back to MSW factory as communication details given in the contact sheet.

5.1. Service mode for customer maintenance:

In mode, customer can find the hardware and software versions of Jenny functions and also export of the log file can be done with external USB memory extension.

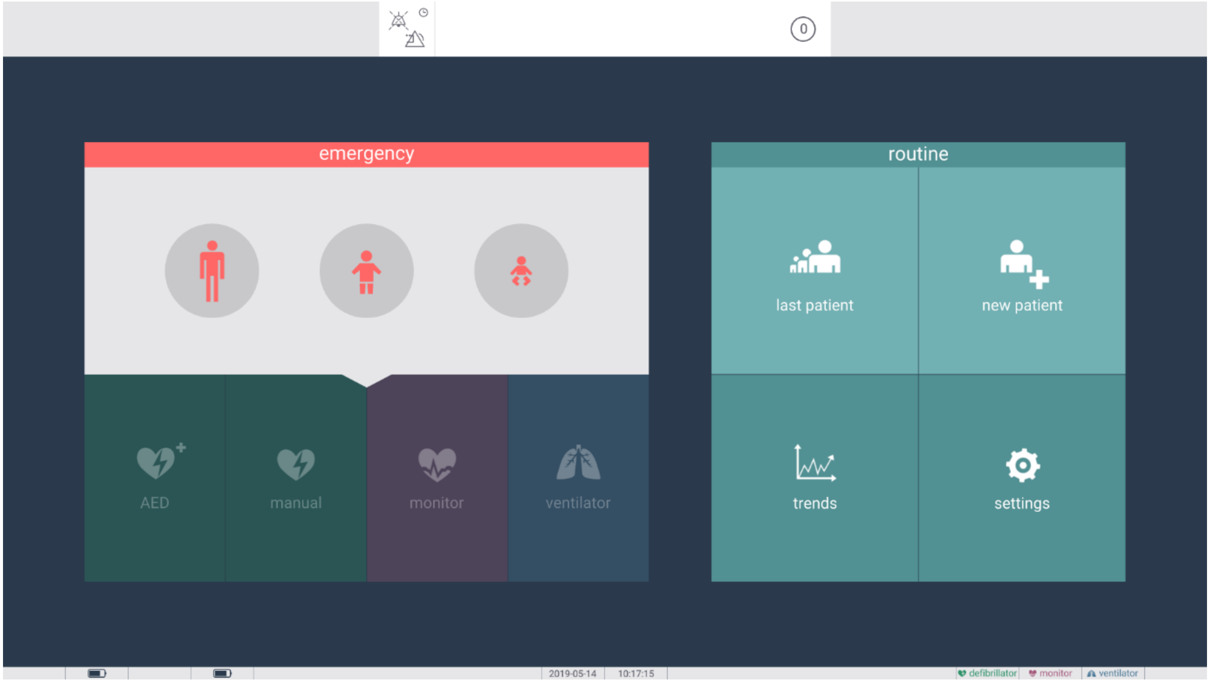
Steps to enter into service mode:

On the HOME screen select the settings ( )

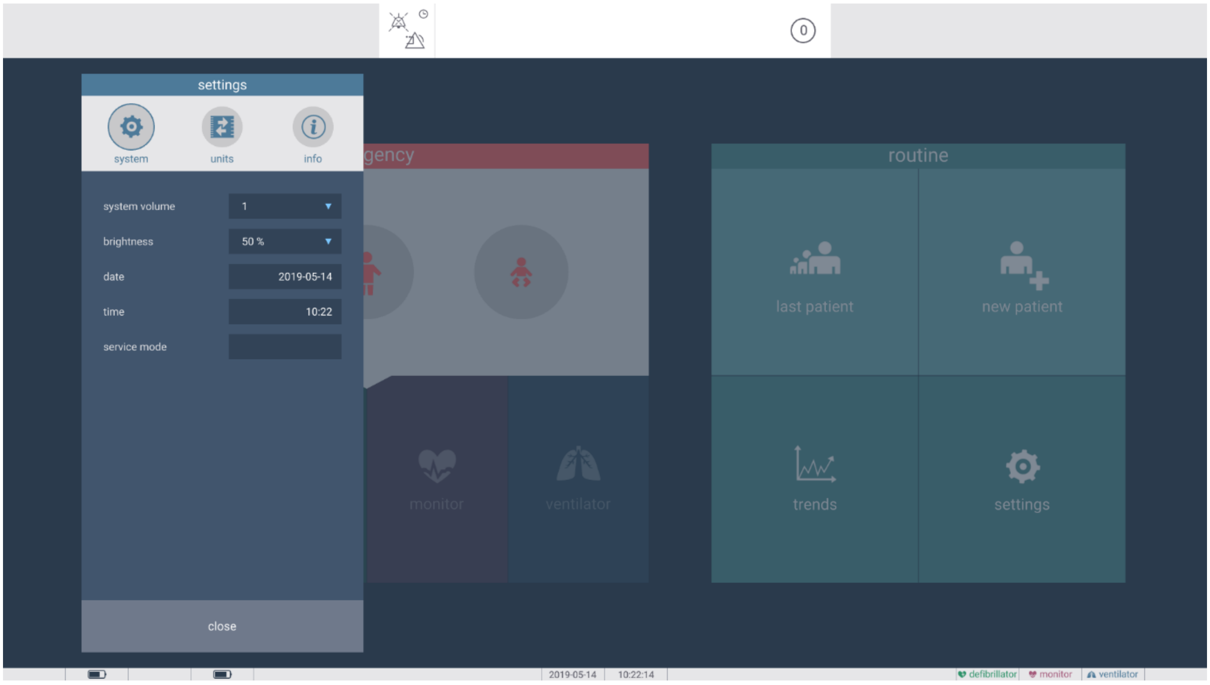
Jenny has 2 kind of service modes. Every mode has its own features and area of usage defined as below.

Procedure to enter into any type of service mode:

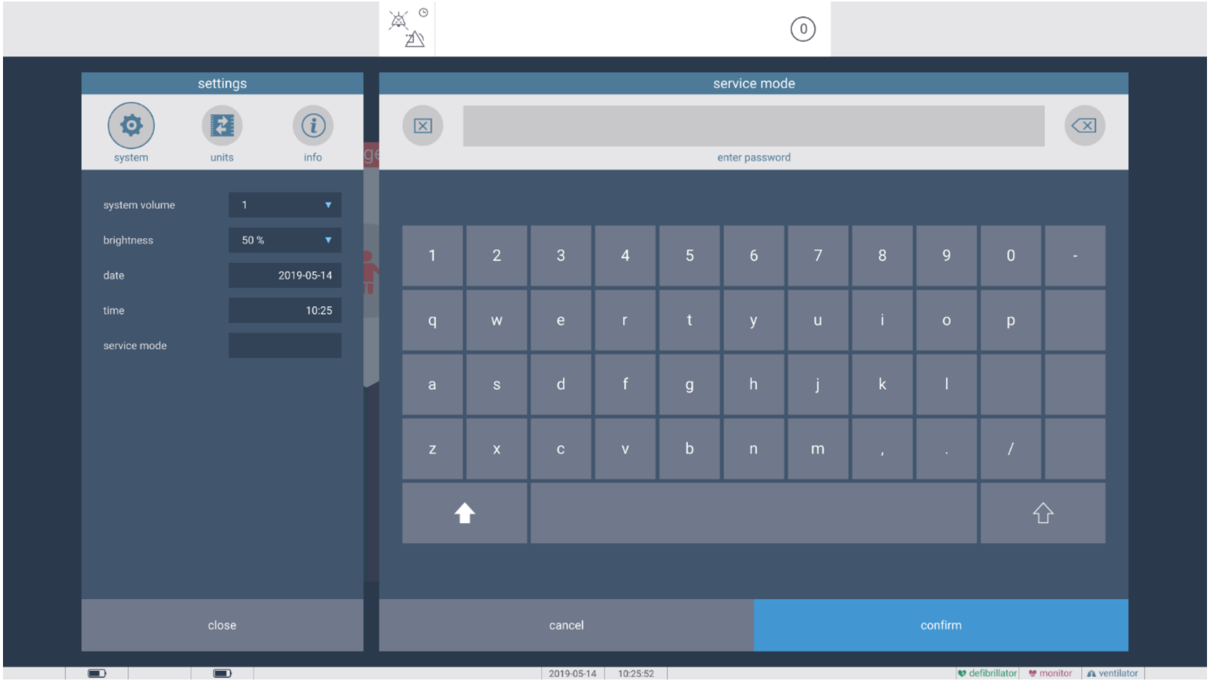
Step1: After power on Jenny, Tap on “Settings” icon on home screen.



Step2: Tap on the “service mode” tab to enter password



Step3: Password Screen


settings
system
units
info
system volume
1
brightness
50 %
date
2019-05-14
time
10:25
service mode
close
service mode
enter password
1 2 3 4 5 6 7 8 9 0 -
q w e r t y u i o p
a s d f g h j k l
z x c v b n m , . /
cancel
confirm
2019-05-14
10:25:52
defibrillator
monitor
ventilator