Operator's Manual

SALI™ Model D

EMPOWERING EMERGENCY CARE

INOVYTEC
THE POWER TO SAVE LIVES

INV-IFU-2001, Rev. 09, Last update September 2021

Important

This User Manual is subject to periodic review, update and revision.

Do not use a defective product. Do not repair this product or any of its parts. If this device does not perform properly, contact an Inovytec representative.

The user of this product has sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, unauthorized service, damage, or alteration by anyone other than Inovytec Medical Solutions Ltd.

The safety, reliability, and performance of this device can be assured only under the following conditions:

- The device has been used according to the accompanying operating instructions.
- All fittings, extensions, readjustments, changes, or repairs have been carried out by Inovytec Medical Solutions Ltd.'s authorized representatives.

Inovytec Medical Solutions Ltd. reserves the right to change or improve its products and accompanying technical literature without specific notice of changes or improvements.

This product is protected by patents listed on the Inovytec website.

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Disclaimer

Information provided by Inovytec Medical Solutions Ltd. is believed to be accurate and reliable. However, Inovytec assumes no responsibility for the use of such information, nor for any infringements of patents or other rights of third parties, that may result from its use.

FDA Tracking Requirements

U.S. Federal Law (21 CFR 821) requires the tracking of AEDs. Under this law, owners of this AED must notify Inovytec Medical Solutions Ltd. if this product is received; lost, stolen, or destroyed; donated or resold; or otherwise distributed to a different organization. If any such event occurs, contact Inovytec in writing with the following information:

- Originator's organization – Company name, address, contact name, and contact phone number.
- Model number, and serial number of the ventilator
- Disposition of the ventilator (for example, received, lost, stolen, destroyed, distributed to another organization), new location and/or organization (if known and different from originator's organization) – company name, address, contact name, and contact phone number.
- Date when the change took effect.

Please address this information to Inovytec Medical Solutions Ltd. at the address given above.

PLEASE READ THIS USER MANUAL BEFORE OPERATING THE SYSTEM.

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Obtaining Help

If you have a problem that you cannot solve, and the product was purchased **directly from Inovytec,** you may contact Inovytec at info@Inovytec.com.

If you have a problem that you cannot solve, and the product was purchased **from an authorized Inovytec distributor,** please contact your distributor directly to report the problem.

Note: If this product has not been purchased directly from Inovytec, please ensure that it has been purchased from an authorized distributor of Inovytec. To obtain a list of authorized distributors, contact Inovytec at info@Inovytec.com.

1. ABOUT THIS USER MANUAL

This User Manual provides the information necessary to operate and maintain the SALI-D system.

PLEASE READ THIS USER MANUAL BEFORE OPERATING THE SYSTEM. If any part of this User Manual is not clear, contact Customer Support for assistance.

PLEASE RETAIN THIS USER MANUAL FOR FUTURE REFERENCE.

1.1 TYPES OF WARNINGS, CAUTIONS AND NOTES

Three types of special message appear in this User Manual:

Warning: A warning indicates precautions to avoid the possibility of personal injury or death.

Caution: A caution indicates a condition that may lead to damage to equipment, or a lower quality of treatment.

Note: A note provides other important information.

1.2 GLOSSARY AND ABBREVIATIONS

Term	Description
AED	Automated External Defibrillator
BPM	Breaths Per Minute
LPM	Liter Per Minute
SPO2	Blood Saturation Levels (Percentage)
ECG	Electrocardiogram
HR	Heart Rate Per Minute

2. OVERVIEW OF SYSTEM

2.1 DESCRIPTION OF DEVICE

SALI-D is a new-breed solution for medical emergencies. It is a full critical aid system that creates a virtual hospital environment at the scene to significantly increases the effectiveness of the medical first aid treatment. The SALI-D offers the following features:

- Automated Oxygen Therapy
- Defibrillation
- Airway Management - SpO2 (oxygen saturation) measurement
- Lead ECG / Heart Rate measurement
- Breath Rate measurement

The device is fully self-contained for administering critical first aid in the field. The User is instructed through easy to follow, visual and audible walk-through instructions on how to use the device.

Each parameter measured is displayed and the data is transmitted to a web-based server, allowing a remote healthcare provider to interact with the user. The SALI-D is equipped with GPRS communication for off-site communication with an Emergency Care Center.

The SALI-D also provides offsite communication to a Service Center when it is stowed in its sleep mode to ensure it is continuously maintained in a state of readiness.

Do not use the SALI-D in MR environment, as safety in MR environment has not been tested.

3. CONDITIONS FOR USE

3.1 INDICATIONS FOR USE

The SALI-D is intended for use in medical emergencies on patients weighing at least 25 kg showing signs of physical distress. This may include:

- Respiratory distress (such as shortness of breath)
  Note: in cases of upper airway foreign body obstruction, the obstruction must be addressed first before the SALI-D is used.
- Sudden Cardiac Arrest (SCA) - the patient will be unconscious, not breathing without a pulse
- Suspected Coronary Artery Disease (CAD) - the patient will be conscious, showing signs of chest pain and respiratory distress as well as an elevated or irregular heart rate.

The SALI-D is intended for use by persons who are trained to use the system.

Note: The laws and regulations for the use of AEDs differ from country to country. Some countries allow laypersons to use AEDs without any special training. In those countries, the SALI can be used by any layperson. Please check your national regulations regarding any restrictions on the use of AEDs.

3.2 CONTRAINDICATIONS

- Treatment or alleviation of disease.
- Suspected spinal injury where the patient should remain immobile.

3.3 LIMITATIONS OF USE

Clinical situations potentially affecting accuracy or performance:

- Controlling the flow in the presence of difficult airways, such as severe lung blockage and asymmetric air entrance to the lung.
- Low compliance of the airways.
- Laryngospasm and or water in the upper and lower air way as well as edema may interfere with the device ability to monitor the patient breath rate.
- Hypothermia can cause vasoconstriction which will interfere with the SPO2 measurements.
- Drug abuse may cause vasoconstriction which will interfere with the SPO2 measurements.
- When treating COPD patients, the targeted SpO_2 measurement is 88-92% this may affect the oxygen administration as the SALI-D algorithm stipulate an increase of O_2 flow to 10 LPM as such, in cases where the saturation levels are below 90, the increase in O_2 flow may potentially decrease respiration rate.

4. SAFETY

4.1 ELECTRICAL SAFETY

The device complies with requirements of IEC/EN 60601-1 for general requirements for safety of medical electrical equipment:

- Class I Equipment BF type applied part
- Mode of operation: Continuous measurement
- Degree of mobility: Portable

4.2 EMC COMPLIANCE

The SALI-D is suitable for the electromagnetic environment of typical commercial or hospital settings.

During the immunity testing described below, the SALI-D continued to provide uninterrupted delivery of data within the device specifications.

4.2.1 EMISSIONS

Electromagnetic Emissions		
The SALI-D is intended for use in the electromagnetic environment of commercial and hospitals. The user should assure that it is used in such an environment.		
Emission Tests	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The SALI-D uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The SALI-D is suitable for use in hospitals, pre-hospital (transport) and field environments.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Class D	

4.2.2 IMMUNITY

Electromagnetic Immunity		
Immunity Test	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ±6 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	± 1 kV for signal ports ± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environments.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environments.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Reduction of >95%/ dip 0.5 cycle 60%/dip 5 cycles. 30%/dip 25 cycles. >95%/ dip 5sec.	Mains power quality should be that of a typical commercial or hospital environments.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	10 A/m	Main power quality should be that of a typical commercial or hospital environment. If a dip or an interruption of mains power occurs, the current of the display series may be dropped off from normal level, and it may be necessary to use uninterruptible power supply or a battery

Conducted RF IEC 61000-4-3 Radiated RF IEC 61000-4-6	10 V/m 10 Vrms	The SALI-D is suitable for use in typical commercial or hospital environments. Portable and mobile RF communications equipment should be used no closer to any part of the SALI, including cables, then the recommended separation distance of 800 MHz to 2.5 GHz.

4.3 SAFETY INSTRUCTIONS

Warnings

DO NOT USE BEFORE READING THIS USER MANUAL.

Product must be used by personnel trained in the use of the device.

DO NOT use the device on pediatric patients less than 25 Kg.

DO NOT use this device for any purpose other than specified in this manual without written consent and approval from Inovytec Medical Solutions Ltd.

DO NOT use the device or any device part should it show any signs of damage. The device should always be maintained in a ready to use state.

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

In case of failure or incorrect operation of the device is detected, the device should not be used. The User should disconnect the patient and apply additional treatment such as CPR until professional help arrives.

DO NOT touch the patient during the defibrillator charging and discharging period.

DO NOT use the defibrillation pads on a wet patient or if the pads are wet.

Defibrillation current can cause injury. DO NOT touch the patient during defibrillation.

DO NOT touch equipment connected to or metal objects in contact with the patient during defibrillation. Conductive parts should not contact other conductive parts including the earth grounding.

Remove excessive body hair, which may cause skin burns or ineffective energy transfer.

Warnings

Do not use alcohol, iodine or other skin preparations.

Before defibrillating, disconnect other electrical equipment which has no DEFIBRILLATION-PROOF applied parts from the patient.

DO NOT allow defibrillation pads to touch each other, or to touch other electrodes, lead wires, dressings, transdermal patches, etc.

During defibrillation, the operator and all other people must stand clear of the patient, bed, and all conductive surfaces in contact with the patient.

The Defibrillator contains an automatic disarm of the stored energy. If the operator has not delivered the energy to a patient or a test load, an internal timer will disarm the stored energy. This stored electrical energy can potentially cause death or injury if discharged improperly. Follow all instructions in this User's Manual.

DO NOT move patient. Handling or transporting the patient during ECG analysis can cause incorrect or delayed diagnosis

Cardiac pacemakers may affect rhythm analysis. Patient pacemakers may reduce the sensitivity of device analysis and errors in detecting shockable rhythms.

Radio frequency (RF) interference. Do not operate the defibrillator in conjunction with electrocautery or diathermy equipment. Any equipment that emits strong radio frequency signals can cause electrical interference and distort the analysis signal to cause inaccurate interpretation of rhythm.

Possible explosion and fire hazard if used in areas where flammable agents are used.

DO NOT immerse or clean pads with alcohol or solvents

DO NOT perform chest compressions (CPR) through pads. These actions may damage the electrode pads and cause the Jump Start to function improperly.

Warnings

Improperly placed pads may produce incorrect analysis and an inappropriate "shock" or "no shock" decision by the AED.

Cautions

- If the device packaging is not intact, do not use the device.
- If the device does not turn on, or is not working correctly, discontinue use. Refer servicing or replacement to qualified service personnel.
- Do not disassemble any part of the system components. This system is not user-serviceable.
- Do not use the equipment if it is not working properly or if it has suffered any damage, for example, by dropping the equipment or splashing water on it.
- Use only Medical Grade Oxygen when refilling the Oxygen Cylinder. The Oxygen cylinder, if not used, should be replaced once a year
- Handle the device with care. Hold the device by its handle when carrying the system.
- Properly store the device in its assigned control station when not in use.
- The ECG Electrodes, AED Pads and Face Mask are single use only. If it is not removed from a new container, it may have already been used and should not be used.
- Confirm that the expiration date, found on the ECG Electrodes and the AED Pads packaging, has not been reached.
- Repairs should be undertaken only by personnel trained or authorized by Inovytec Medical Solutions Ltd. Do not modify this equipment without authorization from Inovytec Medical Solutions Ltd.
- The device may not operate correctly if used or stored outside the relevant temperature or humidity ranges, as described in the performance specifications.
- Strictly follow the warning instructions in this manual.
- This instrument is fragile. To prevent damage, please handle with care, including while packing and unpacking.

Cautions

- User is prohibited from changing, adding, removing or disassembling any system parts. Warranty shall not apply to any defects, failure or damage caused by improper use and/or improper or inadequate maintenance and care.
- The device is not intended for use in the presence of flammable substances.
- The device is not intended for use in the rain and when exposed to water or other liquids.
- To prevent damage, avoid liquid spillage while cleaning.
- It is strongly recommended that all SALI-D parts be replaced with parts purchased from Inovytec Medical Solutions Ltd. or an authorized distributor. Use of other parts may damage the unit and void the warranty.
- Discarded used or unused ECG Electrodes, AED Pads and Face Mask are classified as clinical waste. As such, the user is responsible for complying with all local and national regulations regarding discarding of clinical waste.

Notes

- Dispose of this device and its accessories in accordance with local regulations.
- Use the equipment only for the purpose described in these instructions for use.
- The contents of this manual are subject to change without prior notice.

Notes

The user or any technical personnel who are not formally authorized by Inovytec Medical Solutions Ltd. should not open the device under any circumstances. Opening the device could damage the unit and will void the warranty provided by Inovytec Medical Solutions Ltd.

5. SYMBOLS

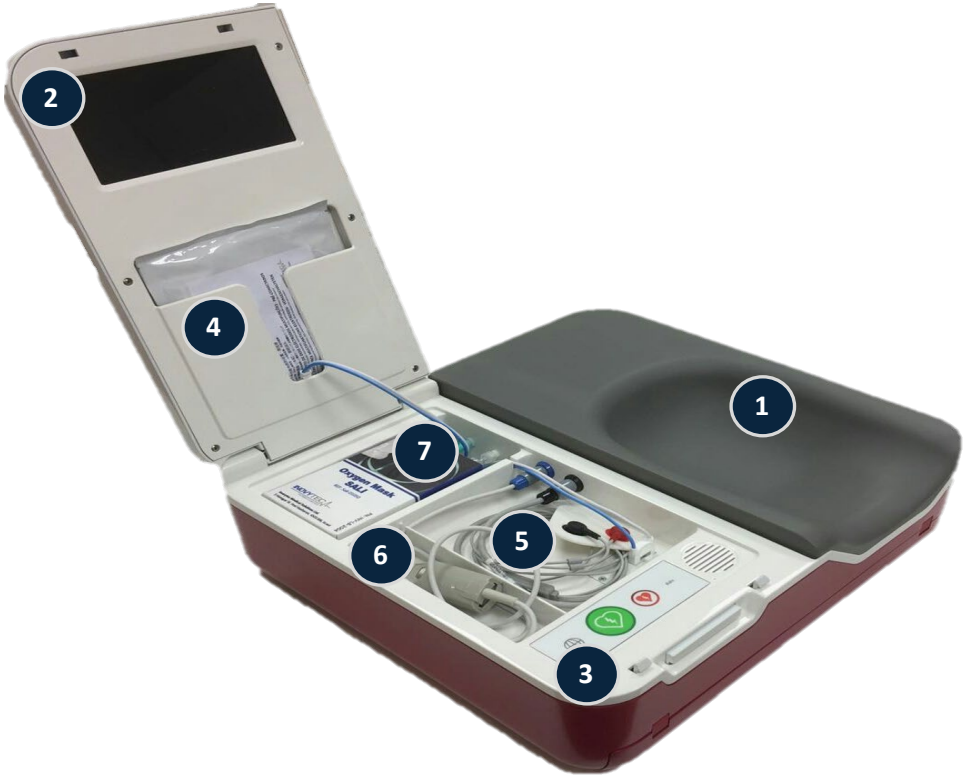
The following table explains the meaning of each symbol on the label.

Symbol	Meaning
	Consult instructions for use
	Manufacturer
	European approval mark
	Authorized representative in the European Community
	Serial Number
	Catalogue Number
	Batch code
	Date of Manufacturing
	Direct current
	Alternating current
	Do not dispose of, contact for recycling
	Caution: Law prohibits dispensing without prescription
	Caution: Consult accompanying documents
	Defibrillation proof type BF applied part protection
	MRI Symbol
	Defibrillator

	Meaning
	AED
	Oxygen Cylinder
	Use by date
	Do not expose to rain
	Do not expose to the sun
	Product is non- sterile
	Product contains Phthalate's type DEHP
	Product is Latex Free

6. SYSTEM COMPONENTS

6.1 SALI-D – MAIN COMPONENTS



(1) *Patient Head Rest,* ***(2)*** *display,* ***(3)*** *Keyboard,* ***(4)*** *Defibrillator Pads,* ***(5)*** *ECG Wrist Electrode stickers,* ***(6)*** *SpO_2 Sensor,* ***(7)*** *Face Mask*

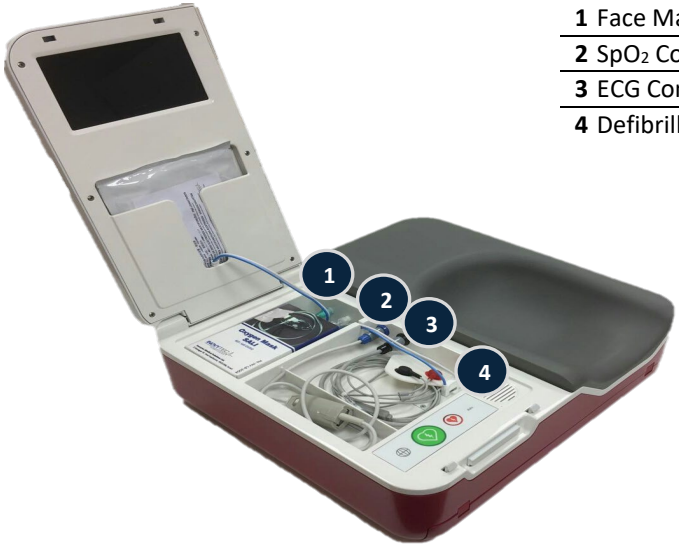
(8) *Battery and SIM compartment,* ***(9)*** *O_2 Cylinder compartment,* ***(10)*** *Docking Station charging points*

7. CONNECTING THE SALI-D

7.1 EXTERNAL CONNECTIONS

1 ON/OFF Switch
2 Auxiliary 9 -36 VDC Connector
3 Auxiliary O2 Connector

7.2 INTERNAL CONNECTIONS



1 Face Mask Connectors
2 SpO_2 Connector (Blue)
3 ECG Connector (Black)
4 Defibrillator Connectors

8. SALI-D INSTALLATION

The device requires a Wall Mount Cabinet for its storage and for the charging of its batteries when the system is not in use.

In the storage "Sleep Mode" the device performs periodic self-testing for reporting to a Service Center that the system is fully functional (See section ***Service and Maintenance***).

The Wall Mount Cabinet requires connection to a 100-240 AC power source. Charging of the batteries is performed by RF (radio frequency) and is isolated from the system.

The installation of the device Wall Mount shall be performed only by an approved Inovytec Representative and according to Wall Mount Installation Instructions .

8.1 TURNING THE SYSTEM ON

To turn on the system, switch the **Power On/Off** button on the back panel

Power On/Off button

Note: System is turned on during installation and should not be turned off.

9. SALI-D OPERATION

9.1 GENERAL SYSTEM OPERATION

The SALI-D is a safe and easy to use device. Once the SALI-D is removed from its control station it immediately informs the Medical Emergency Center that it is now in operation.

When the Operator arrives to the patient, he opens the SALI-D door. With the door open, the SALI-D immediately becomes fully operational, instructing the operator as to how to respond to a conscious or unconscious patient and to place the patient's head on the head rest. The SALI-D then begins to instruct the operator to connect each of the accessories to the patient (Face Mask, ECG electrode stickers, SpO_2 sensor and defibrillator pads, as needed).

SALI-D recognizes patient heart rate, oxygen saturation level and ECG. When properly connected to a patient the system analyzes the patient's condition and provides visual prompts and audio instruction to guide the operator through the process of administering treatment to the patient. The SALI-D will determine if defibrillation is needed (shockable rhythm) and, if appropriate, will guide the operator through the process of administering a shock to the patient. At the same time, it will record the vital signs data obtained and will transmit this data to a remote medical center.

If the patient losses consciousness (the patient has no pulse, or and, is in ventricular fibrillation/ventricular tachycardia), the SALI-D will instruct the operator to press the green heart button. This will turn on the defibrillator which will begin to analyze the patient's condition. If the defibrillator determines that a shock is necessary, it will automatically charge the defibrillator. Once the defibrillator is charged the SALI will instruct the Operator to press the red heart button to deliver the shock.

Warning: Don't touch the patient during the charging period.

The SALI--D will instruct the operator to perform CPR (Cardiopulmonary Resuscitation) in two scenarios:

a) If there is no heart no heart rate is detected.
b) If ventricular fibrillation (VF) or ventricular tachycardia (VT) is detected.

9.2 DEFIBRILLATOR OPERATION

The defibrillator recognizes ventricular fibrillation and ventricular tachycardia. When properly connected to a patient who is unconscious, the defibrillator analyzes the patient's heart rhythm to determine if a shockable rhythm exists and if defibrillation is necessary.

The defibrillator requires between 8-10 seconds to complete the analyzing process. Since the analyzing result depends on the heart rhythm of the patient, the patient should not be touched or moved during this process as it may lead to an incorrect analyzing result.

The defibrillator delivers the defibrillation shock through two self-adhesive, pre-gelled, low-impedance electrode defibrillator pads. The pads, cable, and connector are sold as disposable kits.

The defibrillator is designed for INFREQUENT USE, the term is used to describe a defibrillator designed to endure less than 2500 discharges. The device features biphasic energy output and lock-out protection to prevent inadvertent defibrillation.

The three energy levels used by the defibrillator*:*

- First energy level 150 J
- Second energy level 150 J
- Third energy level 200 J

Defibrillator Pad Connection:
If the defibrillator pads are improperly connected, the system will start an internal discharging and give a voice prompt to the operator.

Normal heart rhythm is detected:
If a normal heart rhythm is detected, the defibrillator will start an internal discharging.

Discharging Procedure
When the charging procedure of the defibrillator is finished, the defibrillator will enter the discharging procedure and give voice prompts to the operator.

> **Warning:** During the discharging procedure the following instruction will appear "Don't touch patient, rhythm analysis" during that time the patient should not be touched, the operator should clear any bystanders near the patient before pressing the red shock button.

After delivering a shock, the defibrillator will initiate the CPR procedure and will provide CPR guidance to the user.

Cardiopulmonary Resuscitation (CPR) Procedure
SALI-D will enter cardiopulmonary resuscitation procedure when the condition "No shockable heart rhythm" is detected.

During the heart rhythm analyzing period, if the heart rhythm is not considered to be a shockable rhythm by the defibrillator, a cardiopulmonary resuscitation procedure (CPR) will start.

During the period of charging, if the defibrillators detects that the shockable rhythm has changed to a normal one, the defibrillator will stop the current procedure and switch to CPR procedure.

> **Note:** During the cardiopulmonary resuscitation period, the AED will ignore the heart rhythm analyzed result and the improper placement of the AED pad connection.
> If the patient is not breathing and has no pulse, a cardiopulmonary resuscitation should be performed on the patient immediately.
>
> **Note:** The CPR time is fixed at 120 seconds.
> At the end of a CPR cycle, the AED will give a prompt to indicate that the operator must stop CPR and not touch the patient so that the AED can re-analyze the heart rhythm and determine if a shockable rhythm exists.

An emergency cancellation

If any unpredictable situation occurs, the operator can use ON/OFF button at the rear of the device to make an emergency cancellation.

Waveform details

The table below provides details of the biphasic truncated exponential waveform delivered by the AED (set to 200J) when connected to resistive loads of 25 through 175 Ohms. The waveforms are characterized by typical values for peak current (Ip), duration of the first output phase, and duration of the second output phase. Values are within 10%.

Output Energy (J)	Patient Impedance (Ω)	I_{p1} (Amps)	I_{p2} (Amps)	Phase1 (MS)	Phase2 (MS)	Interval (MS)
200	25	46	34.0	5.5	3.3	0.7
	50	23	17.0	10.9	6.6	0.7
	75	15.3	11.3	16.3	8.9	0.7
	100	11.5	8.5	19.7	9.6	0.7
	125	9.2	6.8	20.5	11.2	0.7
	150	46	34.0	5.5	3.3	0.7
	175	23	17.0	10.9	6.6	0.7

Rhythm Recognition Performance

The AED algorithm exceeds the requirements of ANSI/AAMI DF39-1993, section 3.3.18 and the sensitivity and specificity levels recommended by the AHA - Automatic External Defibrillators for Public Access Use: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance.

The test database includes shockable rhythms consisting of ventricular fibrillation rhythms (>150uV) and wide-complex ventricular tachycardia at a rate greater than 160 BPM. Non-shockable rhythms include various sinus rhythms including supraventricular tachycardia, atrial fibrillation, atrial flutter, sinus rhythm with PVC's, asystole, pacemaker rhythms, and ventricular tachycardia with a rate less than 160 BPM and/or narrow complexes.

Rhythms	Test Sample Size	Performance Goal	Conclusion
Shockable rhythm: VF	1067	＞ 90% sensitivity	Meets the AAMI DF39 requirement and AHA recommendation
Shockable rhythm: VT	22	＞ 75% sensitivity	
Non-Shockable rhythm: NSR	4000	＞ 99% sensitivity (AHA)	
Non-Shockable rhythm: Asystole	179	＞ 95% sensitivity	
Non-Shockable rhythm: All other rhythms	25732	＞ 95% sensitivity	

9.3 GETTING STARTED

1. Lay the SALI-D down flat beside the patient so that it is resting on its bottom legs
2. Open the SALI-D Door. This will provide access to the required accessories.
3. Place the patient's head on the head rest.
4. Observe if the patient is conscious or unconscious.

5. Unconscious Patients:
   5.1. Press the **green** button to start defibrillator protocol and follow the instructions given by SALI-D.
   5.2. Place the AED pads as described in section ***AED Pads***.

6. Conscious Patients:
   6.1. Place Face Mask as described in section ***Face mask***.
   6.2. Place ECG electrodes as described in section ***ECG electrodes***.
   6.3. Place SpO2 Sensor as described in section ***SpO_2 sensor***.

The device will automatically begin to monitor the patient, continue to follow the instructions, and **wait for the professional paramedic to arrive.**

Note: During monitoring, the device will also send the patient data to a remote Emergency Center, should the system be connected to one

Note: The SALI-D has a built in Microphone, should the Emergency Center paramedic wish to correspond with the care provider. This function is not operable and is blocked during the defibrillation procedure.

For Professional Medical staff Only:

1. If required, switch to Advance Mode by pressing the ADV button. This will allow you to see on the display all the vital signs and historical major events that have taken place.
2. SALI-D can be connected to external auxiliary devices through the auxiliary panel on the device.
   System can be connected to an auxiliary O_2 supply and/or to an auxiliary external 9-36 VDC power source.

9.4 ACCESSORIES PLACEMENT

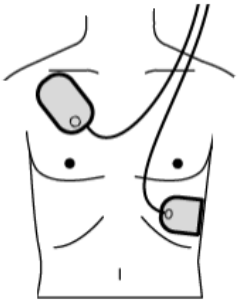
Note: In case the accessories are not properly placed, the SALI-D will instruct the operator to check placement.

Note: All accessories should already be connected to the device.

9.4.1 AED PADS

The AED pads must be correctly placed on the patient. Before placing the pads, the following procedures must be done:

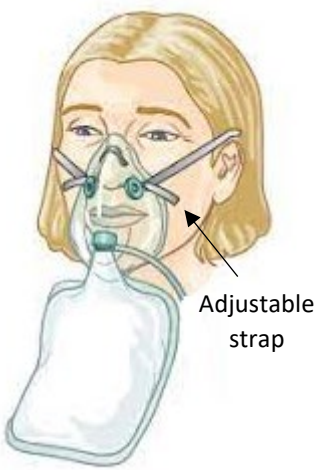
1. Remove the AED pads from the compartment located below the screen.
2. Open the AED package and remove the two AED pads.
3. Remove all the clothing covering the chest of the patient
4. Wipe off any water or perspiration on the patient's chest.
5. Place the pads on the patient, as shown.



9.4.2 FACE MASK

The Face Mask should be correctly placed over the patient's face. Before placing the Face Mask, the following procedures must be done:

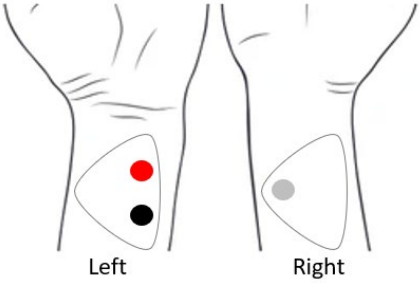
1. Remove the Face Mask from its storage compartment.
2. Before placing the Mask on the patient, check that there are no secretions or vomiting present around the mouth. If so, wipe the area clean.
3. Place the Face Mask over the face with the breathing bag towards the chest and slip the head strap around the back of the head.
4. Secure the Face Mask by pulling the two straps.
5. Observe that the patient is breathing properly.



9.4.3 ECG ELECTRODES

The ECG electrode stickers should be correctly placed on the patient's wrists. Before placing the stickers, the following procedures must be performed:

1. Remove the ECG stickers envelope from its storage compartment.
2. Open the ECG envelope and remove two protective stickers.
3. Wipe off any water, perspiration or grime on the patient's wrists.
4. Place a single sticker on each wrist.

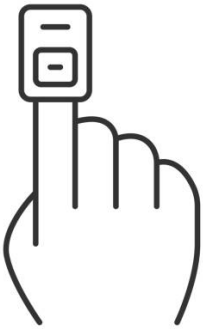


Warning: Do not use expired or dry electrodes .

9.4.4 SpO_2 SENSOR

The SpO_2 Finger Probe should be correctly placed on the patient's index finger. Before placing the probe, the following procedures must be done:

1. Remove the Finger Probe from its storage compartment.
2. Wipe off any water, grease or any grime that may be present on the finger.
3. Place the Finger Probe on the patient's index finger.



9.5 STEP-BY-STEP SYSTEM GUIDANCE

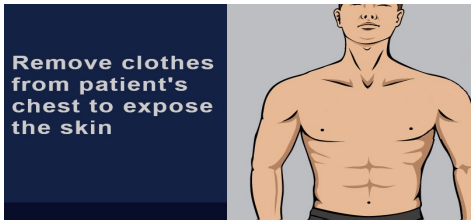
When the SALI-D is in operation, the operator is guided through the following visual and audible prompts:

Place head on headrest

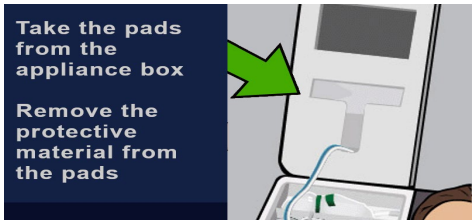
Non-Responsive Patient:

Press green button

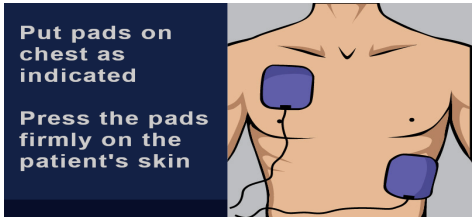
Remove clothes from patient's chest to expose the skin



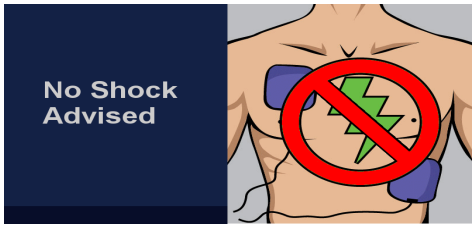
Take the pads and remove protective material



Place the pads



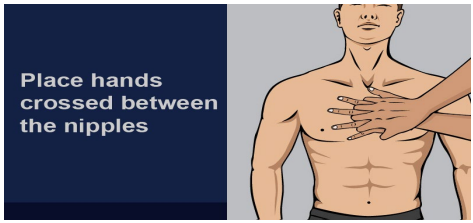
Advise whether a shock is required



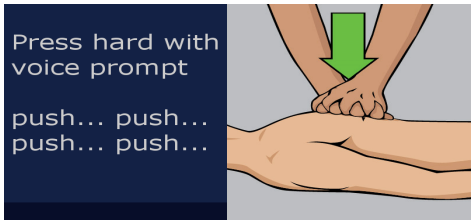
Or

Perform CPR:

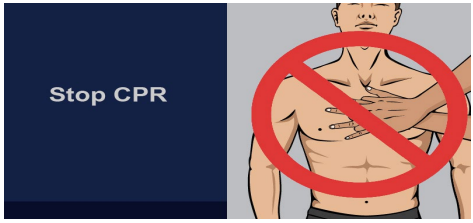
Hand placement



Compression rhythm



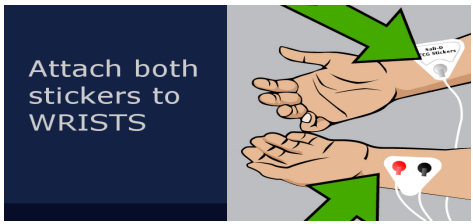
Stop



Responsive Patient:

Place Mask on face

Place ECG electrodes



Place SpO_2 sensor

10. SPECIFICATIONS

10.1 DIMENSIONS AND WEIGHT

Dimension	Measurement
Width	420 mm
Length	390 mm
Height	120 mm
Weight	10 kg with oxygen

10.2 ENVIRONMENTAL SPECIFICATIONS

Operating Temperature	-18 °C to 40 °C (0°F to 122 °F)
Storage Temperature	-40 °C to 70 °C (-40 °F to 158 °F)
Relative Humidity	10% to 90%
Water and Dust Resistance	IP55 **Note:** First digit relates to object size protection (<1 mm). Second digit indicates protection from water jets from any direction.
Atmospheric Pressure	101 hPa to 619 hPa
Altitude	0 to 3,962 m (0 to 13,000 feet)

10.3 POWER SUPPLY

Wall Mount (External AC-DC Adapter)	Input 100 to 264 VAC, 50-60 Hz, max 0.4 A Output 24 VDC, 30 W
Internal Battery	12 x 18650 Li-FePO4 for 12.8 VDC rechargeable configuration (4S3P)
Recharge Time	4 hours
Operating Time	5 hours of continuous use

10.4 OPERATIONAL SPECIFICATIONS

Oxygen Supply Cylinder	
Flow	5 or 10 lpm
Duration	20 min. at 10 lpm
ECG 3-Lead	
Measure range	-2.0mV – 2.0mV ± 0.02mV or 10% whichever is greater
Indication	Suspected VF/VT
SPO2 saturation	
Measuring Range	0 – 100 % ± 1%
Accuracy	70 % – 100 % ± 2%, < 69 % not specified
Indication	Below 94 %
Respiration	
Range	6 – 40 BPM ± 1 BPM
Resolution	1 BPM
Indications	Above 35 BPM, below 6 BPM
AED	
Energy Sequence	Adult – 150 J, 200 J
Charge Time	8 – 10 sec. to 200 J
Analysis Time	~ 9 sec
Maximum time from initiation of rhythm analysis to readiness for discharge	New battery: less than 30 sec After 6 shocks: less than 35 sec
Disable Control	20 to 200 ohms

10.5 STANDARDS AND SAFETY REQUIREMENTS

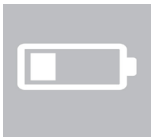
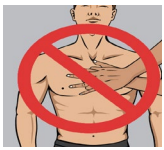
The SALI-D meets the requirements of the following international standards:

IEC 60601-1	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
EN 60601-1-8	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-1-11	Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment
IEC 60601-1-12	Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
EN 60601-2-4	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
IEC 60601-2-27	Medical electrical equipment - Part 1-2: particular requirements for the safety of electrocardiographic monitoring equipment
IEC 60601-2-49	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
ISO 80601-2-61	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

EN ISO 10524-1	Pressure regulators for use with medical gases -- Part 1: Pressure regulators and pressure regulators with flow-metering devices
EN ISO 10524-3	Pressure regulators for use with medical gases -- Part 3: Pressure regulators integrated with cylinder valves
AAMI/ANSI EC53	ECG Trunk Cables and Patient Lead wires

11. ALARMS AND INDICATIONS

This section provides information about alarms and system indicators.

Low Battery	
Low Oxygen	
System not operational	Indication LED will light red: 
Stop CPR	
Do Not Touch Patient	

12. SERVICE AND MAINTENANCE

The system requires maintenance on a routine basis in accordance with SALI-D Service Manual. The device performs periodic self-testing according to the requirements of the Service Center. If the Service Center obtains a malfunction indication, the Service Center will automatically alert the Client that Service is required.

Service should only be provided by an authorized Inovytec Medical Solutions Ltd. representative.

12.1 CLEANING AND ROUTINE MAINTENANCE

The following maintenance activities are required to be performed after each use of the SALI-D:

Part	Procedure	Comments
SALI-D	• Spray entire surface with 70% Alcohol • Wait for 1 min. • Wipe device with pharma wipes 70% alcohol	Including – head rest, SALI-D door, and SpO_2 Sensor.
Part Replacement	Single-use items must be replaced: • Face Mask • ECG Electrodes • AED Pads • Oxygen Cylinder	Oxygen Cylinder needs to be replaced after every use or according to local regulation.

Warning: Do not use defibrillation pads, ECG electrodes, SpO2 Finger Probe, Face Mask, O2 Cylinder, batteries, and any other accessory not approved by Inovytec. Use of unauthorized accessories may cause the device to operate improperly and provide false measurements.

13. PARTS AND ACCESSORIES

This section outlines information for ordering and shipment of replacement parts for the SALI-D.

Main Accessories:

Part Number	Description
ECG-1001	ECG Electrodes
Sali-00211	AED pads
MSK-1001	Face Mask
CYC-1001	Oxygen Cylinder
Sali-01080	SpO_2 Sensor
Sali-01040	Battery Pack

All equipment and accessories are available directly from Inovytec Medical Solutions Ltd. or from an authorized local distributor. For a Inovytec Medical Solutions Ltd. local distributor please contact Inovytec email as specified below.

Note: Consumables may be available in pre-prepared kits, please contact Inovytec Medical Solutions Ltd. or an authorized local distributor.

When ordering parts, specify the part number of the item(s) ordered. For the Equipment and Accessory list, see our website as specified below.

Forward orders to:

Inovytec Medical Solutions Ltd.
5 HaTidhar St.,
Raanana 4366507, Israel
Tel: +972 9 965 64 70

Fax: +972 9 965 64 79
E-mail: Info@Inovytec.com;
Web Site: http://www.Inovytec.com

14. REGULATORY

Manufacturer:

Inovytec Medical Solutions Ltd.
5 HaTidhar St.,
Raanana 4366507, Israel
Tel: +972 9 965 64 70
Fax: +972 9 965 64 79

E-mail: Info@Inovytec.com
Web Site: http://www.Inovytec.com

EC REP Européen Agent Information:

OBELIS S.A.
Bd Général Wahis, 53

B-1030 Brussels
Belgium
Telephone +3227325954
Fax: +3227326003
E-mail: mail@obelis.net
Website www.obelis.net

CE 2797

15. WARRANTY

Service Support

Repairs of the System under warranty must be made by authorized repair centers. If the device needs repair, contact Inovytec Medical Solutions Ltd. service department or your local distributor.

If shipping the device is required, pack the device and its accessories carefully to prevent shipping damage.

Duration

Inovytec Medical Solutions Ltd. will repair or replace, at its sole discretion, the product or any defective part, provided it is returned to Inovytec Medical Solutions Ltd. service within 30 days.