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AVA Activity Analytics

Anti-Decubitus Air Alternating Pressure Mattress Replacement System

Instructions for Use

About This Document

Congratulations and thank you for purchasing this high quality anti-decubitus system.
Please read these Instructions for Use carefully before use and observe the safety instructions and the requirements for the operation and maintenance of the device.

Device identification

Identification Details of the Device
These Instructions for Use are intended exclusively for devices with the following specification:
Device name: AVA Activity Analytics System
The serial number is shown on the label on the rear panel of the power unit and on the tag sewn on the mattress.

Validity of the documentation

Details of the Device Documentation
This manual describes the AVA Activity Analytics System. It is part of the device documentation. Do not pass this device to a third party without these Instructions for Use.
For the confirmation of the up-to-date status of the documentation, the end page of the Instructions for Use is marked by edition version.

Subject to change

The contents of the Instructions for use can be changed by the manufacturer at any time without prior notice.

Translations

For translations into languages other than English, the English version of these Instructions for Use is authentic.

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About This Document

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EC REP

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Sales and service

For Support or Complaints
In the event of a complaint, or if you have any questions about the use of the device or a need for spare parts, please contact the supplier, that delivered the device to you or your patients.

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1 Important Notes for Safe Use

Named groups of persons

1.1 Designation of the Groups of Individuals

The named groups of persons in these Instructions for Use are as follows.

Operators

An operator (surgical supplier, health insurance, clinic, etc.) is any legal person, who owns AVA Activity Analytics System and uses it, or on whose behalf the device is in use. The operator is responsible for providing a safe device and to instruct the user properly on the operation and safe use of the device.

Users

Users are people who are entitled, due to their training or a corresponding instruction to:

- Operate the AVA Activity Analytics System
- Supervised patients using the device for therapy or care purposes.

Users are fully responsible for the safe and correct use of the device. A review of the functions has to be carried out and the proper condition of the device has to be checked and confirmed by the user before each use or transfer for use.

Professionals

The authorized persons are skilled personnel, who are as a rule, the employees of the operator and who :

- Have acquired their knowledge through professional training in the medical-technical field,
- Carry out their activity on the basis of professional work experience and instructions according to safety-related regulations and are able to detect possible hazards during work.

In countries in which the pursuit of an activity in the medical-technical area is certified, the classification as qualified personnel is subject to appropriate approvals.

Patients

Patients in the sense of these instructions are persons in need of care, who use the AVA Activity Analytics System for therapy or care purposes.

Lay Operator

A person without the relevant specialized training, the lay operator should contact with manufacturer or manufacturer's representative under following conditions :

- for assistance, if needed, in setting up, using or maintaining the ME Equipment System; or

-to report unexpected operation or events.

1 Important Notes for Safe Use

1.2 Notes for the Users

Note that the AVA Activity Analytics System should only be used by persons who have been trained in the operation and the intended use of the device.

Training on the device

1.2.1 Instruction

The training of users on how to use the device must be carried out by the qualified personnel of the operator using the device. If the device is approved for use, then it is obligatory to comply with the instructions of this guidance.

Device approval

1.2.2 Handing Over the Device

The device may only be used, if the operator has released it for therapeutic or care use and if the hand over was carried out properly and under the supervision of authorized personnel.
After the hand over the users are fully responsible for the safe and dedicated use of the device.

1.2.3 Maintenance and Installation

The maintenance and/or repair of the equipment or parts may only be carried out by an authorized service agent.

Obligation of the user

1.2.4 Information and Test Obligation of the User

Read these Instructions for Use carefully before the first use of the device. This will allow you to experience all the benefits that the device offers and avoid possible personal injury and property damage.
A review of the functions has to be carried out and the proper condition of the device has to be confirmed by the user before each use or transfer for use by patients.
In case of specific issues, which are not covered in enough details in these Instructions for Use please contact the supplier or operator for further guidance.

1.2.5 Rechargeable Coin Cell Replacement Notice

(1) Hazardous situation might develop by the incorrect polarity connection or replacement of a coin cell on the desired Control PCBA.
(2) For Coin cell intended to be changed only by Service personnel with the use of soldering.
(3) The terminals of Coin Cell have clear polarity design and the location for mounting the Coin cell has been designed to prevent accidental short circuiting and/or block ventilation.
(4) Seek medical advice immediately if a coin cell has been swallowed.
(5) Store batteries out of reach of children so that they are not accidentally swallowed.

1.3 Procedures for Accident Prevention

The AVA Activity Analytics System is made according to the current state of the art technology and is reliable. However, hazards may arise during the use of this device if it is operated by untrained personnel or it is not operated as described in these Instructions for Use.

1.3.1 Procedures for Handing Over the Device

In order to comply with the regulations of accident prevention and to prevent accidental damage, the following procedural guidelines are to be followed when handing over the device:

- The initial start-up of the device, as well as the hand over to the user must be carried out by an authorized personnel assigned by the operator.
- After completion of the training, it must be documented that the user has understood the operation and use of the device for therapy or care purposes.

Hygiene measures

1.3.2 Qualification Requirements Hygiene Staff

The nature of hygiene measures is determined by the use environment of the device.

- If the device is used in clinical areas (e.g. in hospitals, clinics, nursing home, elderly homes etc.) the cleaning and disinfection must be carried out on the product or parts only by appropriately qualified personnel, who are familiar with the relevant hygiene regulations.
- When using the device in non-clinical areas the users or trained cleaning personnel can perform cleaning of the device.

Obligation to provide information

1.3.3 Availability of the Instructions for Use

The Instructions for Use are an integral part of the device and must be stored in a place so that the safety instructions and other important information are accessible at any time and can reviewed by the users.
Do not pass the device to a third party without these Instructions for Use. Using the edition version as a guide always ensures that a current and valid Instructions for Use document is supplied with the device.

1.3.4 Home Healthcare Environment

- This is any place a patient lives (either their own home or a nursing home) and other places where patients are present (e.g. being outdoors; in a wheelchair; traveling by any mode and whilst at work)
- Exclusions are: professional healthcare facilities where staff with medicaltraining are continually on hand when patients are present (e.g. hospitals;doctors surgeries; dental surgeries)
- Since the Home Healthcare Environment includes a variety of environments, there is a chance that the medical equipment may be used in locations with unreliable electrical sources and poor electrical grounding.

1 Important Notes for Safe Use

1.4 Purpose of the Device

To ensure the security of patients and users, the device may only be used for its intended use.

1.4.1 Intended Use

Intended use

The therapeutic air alternating mattress / cushion system is designed for patients who endure pressure ulcer and potential patients who wish to reduce the likelihood of pressure ulcer. The device is intended to treat and prevent pressure ulcers by facilitating blood circulation and decreasing pressure of each tissue's contact area.

Contraindications:
Certain patient conditions are not suitable for using this type of device such as fracture of instable vertebrae and illness of instable vertebrae. Always consult a physician or health professional before using this device. The use of this system does not replace the regular repositioning, monitoring, and nursing of the patient.

1.4.2 Attention

Attention

Always consult a physician or health professional before using the AVA Activity Analytics System. Any and all applications outside of the conditions specified above are regarded as unapproved. The user and the operator respectively are exclusively liable for any damage resulting from the unapproved use.

Additional safety points to be aware of:

- Strangulation by extra-long cables and hoses. To avoid entanglement, keep children clear of hoses.
- A Warning indicating that replacement by inadequately trained personnel could result in hazard.
- Do not expose the Home Healthcare System to the sunlight or the dusty environment.
- Keep the Home Healthcare System out of reach of children.
- Choking caused by small parts being inhaled or swallowed Identify any loose or detached small parts that may be an issue.
- Potential allergic reactions to materials used in the equipment Identify any rubber or latex that could be an issue.
- Contact Injuries
  Check for any skin irritation due to prolonged contact with the equipment.
- Expected service life of this medical air pump is 2 years.
- Protection against strangulation or asphyxiation
  Means shall be provided to control the risk of strangulation and asphyxiation of the patient and other to an acceptable level by routing wires or tubings, and using retention devices.
- No modification of this system is allowed.

- For leaning & disinfection Processes of ME equipment being performed by a Lay Operator shall be investigated by the Usability Engineering Process.

EMC and RF notices

1.4.3 EMC and RF Compliance Statement

Use of accessories and/or cables other than those specified or provided by the manufacturer of the SR396 may negatively affect EMC performance.

- Use of the SR396 adjacent to or stacked with other RF communications equipment (including antennas) should be avoided and to be used no closer than 30cm to any part of the SR396, including cables specified by the manufacturer because it could result in improper operation.
- Medical Equipment Immunity Performance Criteria Unacceptable Operating Conditions:
  a. Component failures or error of display numerical value.
  b. Change or failure in programmable parameters if any.
  c. Initiation of any unintended operation or false audible indicator.
  d. Cessation, change or interruption of any intended operating mode.
- All necessary instructions for maintaining Basic Safety and Essential Performance with regard to Electro Magnetic Disturbances for the expected service life.
- This medical device that intentionally receive RF energy shall include:
  a. Radiations Frequency: 2.4GHz
  b. Frequency Band: 2412-2484 MHz
  c. 11Mbps CCK : -91dBm,
  64QAM rate 3/4_54Mbps OFDM: -77dBm,
  HT20_MCS 7_64QAM rate 5/6: -75dBm,
  HT40_MCS 7_64QAM rate 5/6: -72dBm
  d. Frequency characteristic: WLAN (802.11 b/g/n)
  e. EIRP: 20 dBm

IMPORTANT NOTE: To comply with the FCC RF exposure compliance requirements, no change to the antenna or the device is permitted. Any change to the antenna or the device could result in the device exceeding the RF exposure requirements and void user's authority to operate the device.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

1 Important Notes for Safe Use

FEDERAL COMMUNICATIONS COMMISSION INTERFERENCE STATEMENT

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

--Reorient or relocate the receiving antenna.

--Increase the separation between the equipment and receiver.

--Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

--Consult the dealer or an experienced radio/TV technician for help.

RF exposure warning

This equipment must be installed and operated in accordance with provided instructions and the antenna(s) used for this transmitter must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter. End-users and installers must be provide with antenna installation instructions and transmitter operating conditions for satisfying RF exposure compliance

1.5 Warranty

The supplier shall ensure the safety and the correct functioning of the AVA Activity Analytics System only under the following conditions:

Warranty terms and conditions

- The device is used for the intended use and maintained only in accordance with the information provided by these Instructions for Use.
- Only original spare parts or accessories approved by the manufacturer are used.
- No structural changes are made to the device.
- Inspections and maintenance work are carried out by certified personnel according to the specified time intervals.

1 Important Notes for Safe Use

1.6 Safety Information and Symbols of These Instructions for Use

The safety instructions in this Instructions for Use are marked with symbols and key words. Signal words like WARNING, CAUTION or ATTENTION designate the classification of the risk.

1.6.1 Identification of Risks of Injury

WARNING

Means a hazardous situation, which may lead to death or severe injury if it is not avoided.

CAUTION

Means a hazardous situation, which may lead to minor or severe injury if it is not avoided.

1.6.2 Identification of Material Damage

ATTENTION!

Describes a situation that could lead to property damage if it is not avoided.

1.6.3 Identification of Additional Information

NOTE!

Means application tips and useful information.

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1 Important Notes for Safe Use

1.6.4 Additional Symbols to the Safety Information

Additional symbols to the safety information are those listed below

Machine Wash Warm : Max. 60°C

Machine Wash Warm : Max. 71°C


Do Not Bleach


Do Not Iron


Do Not Dry Clean


Tumble Dry Medium - Gentle Cycle


Consult Instructions for Use

Declaration of Conformity to Medical Device Directive


Type BF Applied Part


Double Insulated, Class II Equipment

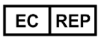

Waste Electrical and Electronic Equipment (WEEE Logo)


Manufacturer


Date of Manufacture


Caution (ISO 7000-0434A)

Catalogue Number



Authorized Representative in the European Community

IP21

Protected against ingress of solid foreign objects ≥12.5mm diameter.
Protected against vertically falling water drops.

NRTL_Safety Certified: SGS_Q Mark logo

2 Security Norms

2.1 Correct Use of the System

(1) In order to guarantee the correct operation, ensure that the system is perfectly assembled and securely fasten the mattress with the specific straps to the bedframe. Make sure that the straps do not interfere with the bed movements.

(2) Hang the power unit to the bed footboard using the specific hanging hooks and do not place any objects onto the power unit. Insert the power cord set into one of the two cable holders placed at each side of mattress base and fix by the press studs on the cable holder. Ensure that power cord set is not kinked or tighten up.

(3) Take care to ensure that the sheets are fitted correctly and not too tight to prevent hammocking. Too many layers of sheets could reduce the effects of the mattress system. Only breathable incontinence sleepers may be used.

(4) Do not use the system in presence of live flame or sources of heat. The power unit extracts the air from the environment and despite its filter system, smoke can damage the internal components.

(5) After each use the system must be disinfected and sanitized to prevent cross-infection.

(6) Ascertain that the patient's weight does not exceed the weight allowed on the bedframe and the maximum therapeutic capacity of the anti-decubitus system.

(7) Information for the Lay Operator:
The equipment and accompanying Operation Manual should be simple to understand and straightforward to use for the Lay Operator, according to IEC60601-1-11 regulation, a lay operator needs to have at least 8 years of education.
The healthcare professional should brief the Lay Operator on the use of the equipment and any precautions to be taken, including:

- Precautions to be taken in the event of changes in the performance of the equipment.
- Precautions to be taken regarding the exposure of the equipment to reasonably foreseeable environmental conditions (e.g. magnetic and electromagnetic fields, external electrical influences, electrostatic discharge, variations in pressure etc.)
- Information about medicinal substances that the equipment is designed for, including any that the equipment is NOT designed for.
- Information about medicinal substances or blood products incorporated into the equipment as an essential part.
- The accuracy of equipment with a measuring function.
- Not using genuine accessories, parts and materials not described in the Operation Manual.
- CAUTION: AVOID ELECTRIC SHOCK, DO NOT OPEN AIR PUMP!
  ATTENTION: ÉVITER LES CHOCS ÉLECTRIQUES,NE PAS OUVRIR LA POMPE À AIR!

2 Security Norms

⚠ **CAUTION:**
Ensure no points, springs protruding from mattress which may pierce the air cells.

2.2 Advice

(1) Use the mattress within the bed side rails and assure that the space between the sides of the bedframe and the mattress is not big enough to insert the patient's head and neck. Neglecting this could cause serious injuries to the patient.
(2) Avoid electric shock, do not open air pump! In case of problems, get in touch with the authorized assistance service.
(3) Safety in the presence of inflammable anesthetic gases: the system is not of category AP or APG protected.
(4) Use of the present system does not exclude repositioning and changes of posture of the patient wherever possible.
(5) Environmental conditions for operating the Medical Electrical system:
Temperature: 5°C to 40°C
Humidity: 15% to 90%
Atmospheric pressure: 700 hPa to 1060 hPa
(6) The plug is used for disconnecting the device. Do not position the power unit in the way which will be difficult to disconnect.
(7) No modification of this system is allowed.

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⚠ **CAUTION**

- Ensure no points, springs protruding from mattress which may pierce the air cells.
- DO NOT expose the AVA Activity Analytics System to the sunlight or the dusty environment.
- May experience potential allergic reactions to accessible material used in the AVA Activity Analytics System.
- Keep the AVA Activity Analytics System out of reach of children.
- Skin irritation due to prolonged exposure to mattress or other accessories.

3 Delivery and Storage

3.1 Packaging

AVA Activity Analytics System is supplied in sturdy cardboard packaging. All packaging materials are recyclable and can be separated.
Following actions could be unsafe as applicable: Use of accessories, detachable parts, and materials not described in the instructions for use.

3.2 Delivery Control

Check immediately after delivery of the device:

- the completeness of the delivery
- the delivery status of the device

AVA Activity Analytics System is delivered with the following components:

- Power unit
  Including: Power unit x 1
  Power cord set x 1
  Instruction for Use x 2
- Mattress replacement
  Including: Mattress x 1
  Coverlet x 1
  Sensors' pad of the Mattress x 1

If the delivery is incomplete or the device and/or the packaging are damaged, in particular in the case of damage caused by moisture or water, you should promptly inform the carrier, as well as the supplier.

3.3 Storage and Transport

Recommended environmental conditions for storage and transport:

- Ambient temperature: -25°C to 70°C
- Relative humidity: 0% to 90%

⚠ **ATTENTION**

Storage of the mattress

- Always roll the mattress, do not fold or bend.
- Do not put or store with any sharp instruments or tool with sharp tips.

For long-term storage the power unit should be covered with a dust protector.

4 Device and Functional Description

4.1 Device Description

Power unit

The power unit is used as the housing for the air source as well as control features:

- A control panel with buttons and lights to adjust the air system.
- Two hooks on the back to hang the power unit to a bedframe.
- A receptacle for an air filter on the rear panel.
- Two air outlets for quick coupling.
- A rapid connector for transfer cable to provide power to sensors' pad and collect sensors' data.
- A power cord set with a plug to connect the device into a wall socket.

Mattress replacement

The mattress replacement consists of multiple set of air cells which work in dynamic or static mode to relief and redistribute pressure.

CPR

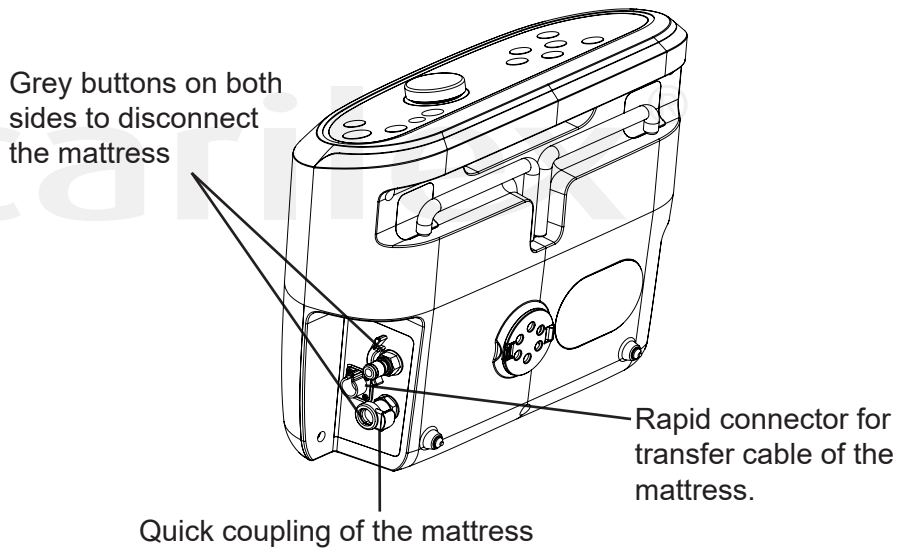
The CPR function is activated by a special valve with circular mechanism located on the right side of the mattress near the torso area. With a rapid maneuver opening the CPR valve, the mattress deflates in the torso area, allowing the Cardiac Pulmonary Resuscitation procedure to be activated within 15 seconds. The CPR valve, well-marked and built-in the side of the mattress prevents accidental opening, and it can be opened with a short clockwise rotation, with a single movement and with the use of one hand only.

4 Device and Functional Description

4.2 Operation and Functional Test

To perform a functional test and at the initial start-up of the power unit take the following actions:

- Fully lay out the replacement mattress. Both air hoses must be able to move easily without any kinks or pressure points.
- Make sure that the CPR valve is closed.
- Push in the quick coupling of the mattress firmly into the air outlet of the power unit.
- Push in the transfer cable of the mattress firmly into the rapid connector of the power unit.
- To disconnect mattress from power unit, simply just press both of the grey button on the quick coupling and pull, then press the black button on the transfer cable and pull.
- For function test details, please refer to Chapter 5 Features, please make sure all functions work normally before use.



Turning on the power unit

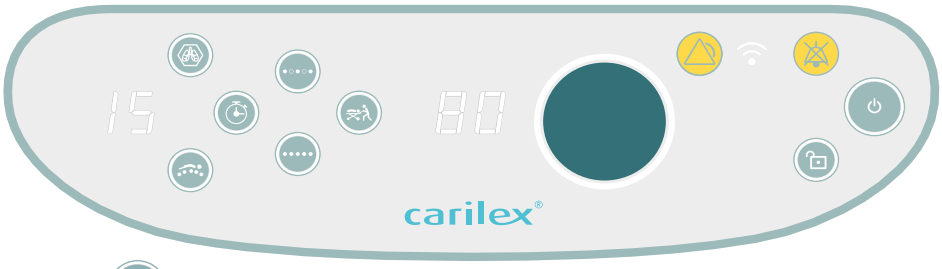
Electric shock!

Touching live parts can result in a death or serious injury by an electric shock. Check for damage of the plug and the main power cable of the power unit before connecting.

- Damaged components may not be used for connection!

5 Features

5.1 Control Panel



Power

Press power button to power on or off the power unit. Please make sure that the power cord is securely inserted into the proper wall socket and the black cable of the mattress is inserted into the power unit. The system will automatically start the initial inflating and calculating the mattress, ring light of knob will be spinning in green. After the calculation is completed, whole ring light of knob will bright in green to indicate that the system is ready for patient placement.

To reset the power unit to default setting (clean the Wi-Fi connection setting and start up in dynamic mode with 10 minutes cycle time), press and hold the Power button for 10 seconds when the power is on.

Ring Light of Knob

AVA Activity Analytics System features with a ring light of knob to indicate three kinds of conditions.

- In initial stage, when compressor is inflating, ring light will spin in green until inflating done.
- When whole ring light of knob bright in green, it means that patient can lay on the system,
- When system detecting patient already lay on the mattress, ring light of knob is spinning again until it shows corresponding envelopment rate, then ring light is shown in static green.
- When patient lay on the mattress, user can change the mattress to the preferred hardness via adjusting the envelopment rate.Turn the knob clockwise to increase the envelopment rate, then the mattress is softer, or turn the knob counter clockwise to decrease the envelopment rate, then the mattress is harder. The range of envelopment rate is from 20% to 80%.

  IMPORTANT :

  Envelopment rate can only be adjustable in Static and Dynamic mode.
- AVA Activity Analytics provide a reposition reminder. When it detects patient keep the same position exceed 120 minutes,the ring light of knob will blink in pink.

Dynamic Mode

Dynamic Mode is a therapy mode in which air cells continuously alternate in an A-B-A-B (odd and even number of air cell sets) pattern to relief pressure and increase blood flow of the patient tissue. The 3 cells at the head are always excluded from the alternate.

5 Features

Multiple Cycle Time

This button is used to select cycle time in dynamic mode. The number indicators correspond to the time for 1 complete cycle.Three cycle times can be selected: 10, 15 and 20 minutes.

Static Mode

Static Mode or Continuous Low Pressure mode is the therapy in which all air cells maintain a constant low pressure support. This therapy mode allows the maximized envelopment of the patient; molding the air around the patient contact surface, therefore creating the optimal pressure redistribution.

Max. Inflation

By pressing the Max. Inflation button, the system will rapidly bring the mattress to maximum steady pressure, which allows caregiver to perform the daily nursing procedures. A white LED with count down of remaining Max. inflation time onleft 7-segement display indicates the activation of this function. In Max. Inflation mode,only Max. Inflation, Power,Transport and Unlock button could be activated. Press this button again to stop this function with one beeping or the system will automatically return to previous setting after 20 minutes with two beeping.

Pulsate Mode

The Pulsate mode, also called DBE (Deep Breathing Exercise) is a function in which the system will cycle between Max. Inflation and proper setting.A white LED indicates the activation of this function. The system will deflate the mattress within 120 seconds to the proper height and maintain the proper height for approximately 60 seconds, then inflate the air to increase the pressure to the proper height in 90 seconds and maintain for approximately 60 seconds. Press to select the pulsate mode cycle time: 20, 40 and 60 minutes. The default cycle time is 60 minutes. After a cycle is complete, the system will switch back to the previous setting automatically.

Please note that there is no DBE function when mattress is upright.

1. When bed is upright, user is not able to active Pulsate function.
2. If user upright the bed In pulsate mode, this function will be deactivate and back to previous mode.

Transport Mode

The transport mode is used to maintain the pressure of mattress for when transporting a patient. Once the Transport button is pressed, the white LED will flash to indicate this mode is activating.When the transport mode is ready, the white LED will stay lit, which signals the user to unplug the power cord. Press this button again to cancel transport mode manually or reconnect the power cord after finish transporting the patient, and the power unit will return to previous mode automatically. If the transport mode is selected, but the power cord is not unplugged, nor the mode is manually canceled, the system will return to the previous setting automatically after 30 minutes.

5 Features

Mute 

User may press this button to turn off the audible indicator. After mute, the audible indicator will not re-start again and only have LED flashing to visually notify the caregivers until the problem is solved.

Panel Unlock 

When there is no operation after 2 minutes, system will automatically lock the control panel. The white LED will light to indicate the panel is locked. All buttons will be locked except the Max. Inflation and Mute button which allow user to mute audible alert. Simply press and hold this button for 3 seconds to release it from locking.

Failure Indicator LED 

This yellow LED is to indicate that the mattress has abnormal pressure including insufficient pressure, excessive pressure and service required including bottoming out,power issue,rator valve issue or sensor communication issue. There will be both audible beeping and visual LED indicators. Audible indicator will turn off after pressing the Mute button and it will not start beeping again to avoid acoustic pollution, but the LED will stay flashing until the problem has been solved.

WiFi Indicator 

There are three kinds of LED colors and four kinds of conditions of Wi-Fi indicator. Please refer another IFU to learn how to set the Wi- Fi Connection.

(1) Amber. There is no Wi-Fi connection setting via mobile APP.
(2) Blinking blue. Power unit is trying to connect to Wi-Fi router
(3) Blinking white. Power unit is trying to connect to server.
(4) Static white. Power unit is connected.
(5) LED is off: Turn off the Wi-Fi function and become standalone version.

- IMPORTANT
  If no action has been done in 30 minutes, the device will turn into standalone version.
- IMPORTANT
  Reset power unit for Wi-Fi settings via press power button for 10 seconds.

Digital Number display - Envelopment rate 

Show Envelopment Rate in the middle digital number display of the panel. The number will be changed via revolving the knob.

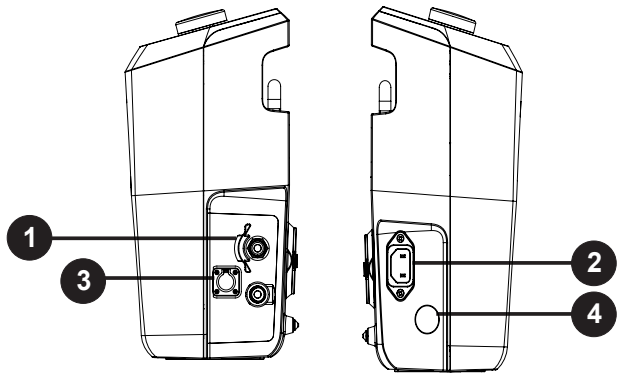
• IMPORTANT :
Strongly suggest that the envelopment rate must higher than 50 to keep the best theraphy and the accurate sensor detection.

Digital Number display - Cycle Time 

Show Cycle time or countdown time in the left side digital number display of the panel.

5 Features

5.2 Side Panel



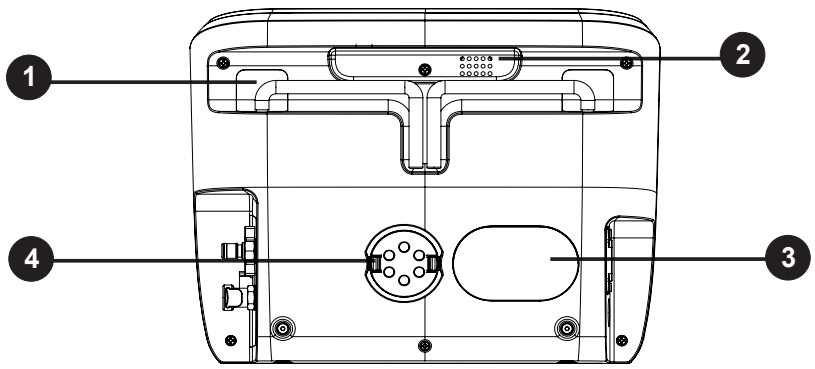
Air Outlet (1)
Quick coupling enables a rapid and firm connection between the mattress and the power unit.

Power Receptacle (2)
Two pin IEC 60320 C18 AC inlet to accept power cord set with 2 Pin_ IEC 60320_Type C17 IEC connector.

Power Unit Outlet (3)
Provide the power to sensors of mattress and collect the sensors' data from the mattress to power unit.

Wi-Fi Mac ID (4)
The QR code of Wi-Fi Mac on the out case is for user setting the Wi-Fi connection easily via "Initial tool"mobile APP.

5.3 Rear Panel



Hanger Hooks (1)
The hooks are designed to fit with multiple footboard widths. They are spring-loaded and fold away on the back panel when not in use.

Convenient Handle (2)
It provides additional gripping surface for user to carry the power unit.

Specification ID Label (3)
This label includes all the information for medical device and safety requirements.

Air Filter (4)
We recommend inspecting and cleaning this filter monthly or more often, depending on the environment the unit is being used. Failure to keep the filter clean will result in shorter life span of the unit and/or unit failure. When replacing, be sure to use Carilex standard filter to optimize the performance of the power unit.

6.1 System Installation

(1) Remove the existing mattress.
(2) Put the mattress on the structure of the bedframe with the logo at the foot of the mattress. Fasten the mattress with the use of the straps ensuring that the functions and movements of the bedframe are not limited before proceeding to the next step.
(3) Hang the power unit at the foot of the bedframe with aid of the hanger hooks.
(4) Push the quick coupling of the mattress firmly into the air outlet of the power unit.
(5) Push in the transfer cable of the mattress firmly into the rapid connector of the power unit.
(6) Insert the power cord set into a wall outlet. Ensure that the cable is not in the way of the operators and the movement of the bedframe.
(7) Check the air cell holder of mattress is flat without any fold before initiating and inflating the mattress.
(8) Check 26pcs rubbers of sensors' pad are protruding.
(9) The power button is bright in static white.
(10) Push the power button to initiate the system.

- **IMPORTANT**
  The initial process will take longer than35 minutes.It takes 35 to 45 minutes depends on mattress size.

6.2 Operation

(1) Initiate the system by pressing the power button and wait for the pump beginning to inflate the mattress air cell. AVA Activity Analytics is equipped with Carilex's IDS technology,and the system will automatically provide the optimal envelopment rate to patient. Once the patient is on the mattress,the system will automatically adjust and customize the pressure setting that is most suitable for the individual patient load and position.
(2) Ensure to select the appropriate therapy mode and cycle time, according to the physician's decision.
(3) IMPORTANT:
Tucking in the coverlet too tensely significantly reduces the mattress' effectiveness.

6 System Installation,Operation,Transfer and Transport of Patient

(4) **WARNING!**
Use the mattress within the boundaries of the bedframe and assure that the space between the sides of the bedframe and the mattress is not big enough to insert the patient's head and neck. Neglecting this could cause serious lesions to the patient.

(5) Always turn off the power unit by using the power button. Failure to do so may cause machine malfunction.

6.3 Transfer and Transport of Patient

Transfer

We recommend carrying out the transfer of the patient by using Max. Inflation to inflate the mattress to maximum pressure and ensure that the bed is well-positioned and steady.

Transport

There are two ways to transport patient with the system. One is using Max. Inflation setting to inflate the entire mattress to maximum pressure. After the mattress inflates to maximum pressure, power off the power unit and detach the quick coupling and transfer cable of the mattress from the air outlets and rapid connectors of the power unit. Then connect the two quick couplings together to retain air in the mattress and the mattress will stay inflated over 15 hours.
Please note that the server will show "Offline" of this bed in transport mode, and the Wi-Fi connection will be resume when the power unit turned on.

Another way is using transport mode to keep the entire mattress pressure and the mattress will stay inflated over 12 hours. For longer transport time, press Max. Inflation before activate transport.

Once the transportation phase is complete, reconnect the mattress to the power unit and switch the power unit back on. If transport mode is in operation, simply reconnect the power cord set and the power unit will back to previous setting automatically. It is not necessary to move the patient during the re-inflating maneuver.

Mandatory bedframe size

It is mandatory to select proper bedframe size for the AVA Activity Analytics System.
Do not operate the AVA Activity Analytics System without safe installing of the mattress onto the bedframe. Make sure that the fixing of the mattress does not impede the adjustment mechanism of the bedframe.

7 Application

Fix the mattress

7.1 Preparing the Application

(1) Place the bedframe in the supine (flat) position.
(2) Fix the mattress with the straps onto the bedframe.
(3) Make sure that the CPR valve is closed.
(4) Hang the power unit with the two hooks on to the footboard of the bedframe and check that the fixing is stable.
(5) Connect the quick coupling of the mattress to the air outlet of the power unit. Make sure that the air hoses are routed without bending, kinks or pressure points.
(6) Set the Wi-Fi connection between power unit and intranet server via mobile APP. Please refer"Server Management System IFU(Distributor usage)" for details.

7.1.1 Inflating the Mattress

In preparation for the patient the air cells may be inflated in advance by the power unit. The head cells should be fully inflated before patient placement to ensure that the head position is stable.

IMPORTANT

- Do not place patient on the mattress before initial calibration ready which knob ring LED show static green. It may cause initial calibration fail and sensor detection abnormal.
- Use the mattress within the appropriate bedframe and assure that the mattress is flat on the bedframe and the air cell is no any extrusion or bending.

7.1.2 Patients Positioning

Carry out the positioning of the patient in accordance with the local patient care guidance.

- The patient should be centered on the mattress, with equal distance from the left and right mattress' sides.
- The head of the patient should rest fully on the head air cells.

CAUTION

Pressure points on protective body areas!

During the application of the AVA Activity Analytics System, the skin of the patient must be regularly checked by medical and nursing staff and caregivers.

CAUTION

- Loose power cord set may cause tripping and serious injury.
- When the patient is on the mattress,do not turn off the power unit manually to avoid the bottoming out and influence the curative effect.

8 Cleaning and Disinfection

In order to prevent cross-contamination, the cleaning and disinfection of the entire the AVA Activity Analytics System must be carried out between uses with different patients.

Check electrical components

WARNING

Electric shock!

Water has a high electrical conductivity. Contact with liquid under voltage can lead to a fatal electric shock. For the cleaning and disinfection operations:

- Turn off the power unit.
- Unplug the power cord set from the power socket.

CAUTION

Health hazard!

The contact with contaminated cleaning fluids can cause infections. Disinfectants can contain harmful substances.

Please follow these Instructions for Use of the manufacturer of the disinfectant and the hygiene of the operator during the cleaning and disinfection. Wear personal protective equipment:

- Safety glasses.
- Protective gloves.
- Mouth and nose protective.

ATTENTION

Incompatible cleaning agents!

The components of the AVA Activity Analytics System are made of thermoplastic polymers. Solvents can spoil synthetic material and coating. Strong acids or alkalis can cause embrittlement.

Cleaning the power unit, the mattress (with air cells) and the coverlet:

- Do not use hydrocarbon solvents, detergents containing alcohol or acids or alkalis.
- Do not use any abrasive cleaning materials.
- Do not splash liquid on sensor's pad of mattress.

Incompatible disinfectants

Cleaning the power unit, the mattress (with air cells) and the coverlet:

- Only use disinfectants without chlorides, halides.
- Do not use disinfectants containing gasoline, paint thinner, alkaline, acid, alcohol, or aldehyde (e.g. ethanol, propanol).

In order to avoid the embrittlement of thermoplastic materials:

- Do not use disinfectants containing alcohol.

8 Cleaning and Disinfection

8.1 Cleaning

When using the AVA Activity Analytics System in non-clinical areas the users or appropriately trained cleaning personnel can carry out the cleaning of the device.

WARNING

Remove the power cord set from the wall socket before cleaning of the power unit. Do not spray any cleaning liquid directly onto the power unit.

Cleaning of the power unit

Cleaning of the Surfaces of the Power Unit

(1) Turn off the power unit and unplug the power cord set from the socket.
(2) Wet a soft cloth with water, mix it with commercially available washing-up liquid.
(3) Wipe off dirt and dust accumulations.
(4) Then dry the surfaces with a clean soft cloth.

Cleaning of the coverlet

Cleaning the Coverlet

The coverlet can be easily removed by derailing the zipper between coverlet and the mattress base. The cleaning of the coverlet can be done by using any of the available disinfectants at their usual concentration. At the end, rinse disinfectant off thoroughly with water and leave to dry. Avoid detergents containing phenols or other corrosive substances. Ensure that the mattress and the coverlet are dry before new use. The hygiene regulations of institution are to be followed in the institutional care environments.

(1) Wet a soft cloth moderately with water, mix it with commercially available washing-up liquid. Wipe off dirt.
(2) Wipe cleaned areas with soft dry cloth.
(3) If heavily soiled the coverlet can be washed in the washing machine using commercially available detergent.
(4) Washing temperature please follow the instruction on the washing care label.
(5) Dry the coverlet thoroughly after washing. Make sure that no moisture remains in folds or creases.
(6) Do not put the coverlet in the dryer or near sources of heat.

8 Cleaning and Disinfection

If the coverlet is soiled or loses its water-resistant properties, it must be replaced.
Any resulting damage of the mattress caused by a spoiled coverlet will be not covered by the warranty.
Please follow the hygiene control regulations of your local authority.

WARNING
If the mattress coverlet is not securely fixed onto the mattress, the air cells and coverlet movement may be unstable and may cause ricks of patient injury.

ATTENTION
Unpermitted after-treatment of the coverlet!
As a follow-up treatment of the coverlet:
- Do not bleach.
- Do not iron.
- Do not dry clean.

8.2 Disinfection

Hygiene requirements of the operator

The operator must be notified about which measures apply to the AVA Activity Analytics System and the actual hygiene directives for disinfection. The disinfection of the AVA Activity Analytics System or parts of it can be performed only by trained personnel, who are familiar with the hygiene requirements of the institution.

Disinfection procedure

Disinfection Procedures
Please follow the procedure required by your local health authority.

CAUTION
For repair, please contact your local distributor.
Please follow the hygiene control regulations of your local authority.

9 Care and Maintenance

9.1 Inspection

The safe operating condition of the AVA Activity Analytics System has to be checked at each use by the operator or during use by the patients and at least once in a year in particular with regards to the following:

- Function of the keys of the power unit.
- Function of the emergency CPR.
- Condition of the air hoses and quick coupling.
- Condition of the air cells.
- Condition of the coverlet.
- Condition of the sensors' pad.

9.2 Maintenance

The air filter should be cleaned regularly. It should be checked often, and depending on the usage environment may require to be changed often.

(1) Power off the power unit and unplug the power cord set from the socket.
(2) Remove air filter from the rear panel and clean or replace with a new filter.
(3) The parts or accessories shipped with the ME equipment is 2 years.
(4) To prevent an unacceptable risk, all information necessary for correct replacement of detachable or interchangeable parts shall be available and replaced by qualified service personnel only.
(5) Following storage and/or transport of the device, please allow the device to sit idle at room temperature for at least 3 hours before powering on.

10 Troubleshooting

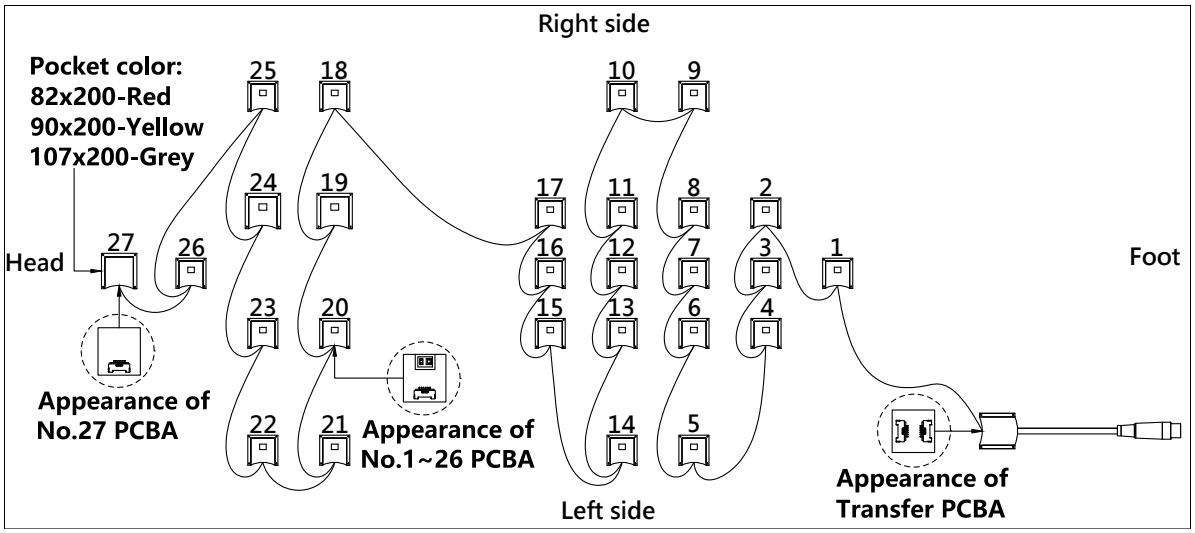
Problem	Control Procedure	Possible Solution
1.) The power unit is working but the mattress is not inflating.	1.1) Verify that air flows liberally across the tubes and the mattress manifold. Check if there are any cuts, blockage or breakages.	1.1) It may be necessary to move the tubes or the manifold if they are kinked or twisted. In case of cuts or rips, replace the air cells or air hoses.
	1.2) Verify that the quick coupling is correctly connected to the air outlets of power unit.	1.2) Firmly connect the quick coupling.
	1.3) Verify that the CPR valve is correctly closed.	1.3) Firmly close the CPR valve.
2.) The patient sinks into the mattress.	2.1) Check the envelopment rate on the power unit.	2.1) Decrease the envelopment rate via knob to make the mattress harder.
	2.2) Check for any abnormal air loss from the mattress.	2.2) Replace the components that are abnormally losing air with an authentic replacement part.
	2.3) Check the air filter.	2.3) Clean or replace the air filter.
	2.4) Verify that the CPR valve is closed correctly.	2.4) Firmly close the CPR valve.
	2.5) Verify the manifold of the static air chamber underneath air cells is connected.	2.5) Reconnect the manifold of the air chamber.
3.) The power unit cannot power on.	3.1) Verify that the power cord set is plug into the proper socket.	3.1) Insert the power cord set of power unit into an appropriate socket and turn the power on.
	3.2) Verify that the power cord set is properly connected to the power unit.	3.2) Insert the power cord set into the power unit and turn the power on.
	3.3) Verify that the power cord set is not damaged.	3.3) Replace with a functioning power cord set.
	3.4) Verify that the fuses are not burned out.	3.4) Contact the authorized distributor for technical service.
	3.5) The power unit is not responding to the control procedures listed above.	3.5) Contact the authorized distributor for technical service.
4.) Failure indicator	4.1) Check if patient is bottoming out.	4.1) Reach out and touch the mattress under the patient's sacrum to make sure it's not bottoming out.

10 Troubleshooting

Problem	Control Procedure	Possible Solution
	4.2) Check if the mattress is insufficient pressure.	4.2) Check if there is any air loss from air cell.
	4.3) Check if the mattress is excessive pressure.	4.3) Check if the mattress is too hard.
	4.4) Check if the power cord is loose.	4.4) Check the power cord is firmly connect with power unit and wall socket.
	4.5) The alternating valve is not working correctly.	4.5) Contact the authorized distributor for technical service.
5) Wi-Fi disconnect fail	5.1) See Wi-Fi indicator LED is amber.	5.1) Check you have set the Wi-Fi connection between power unit, Wi-Fi router and server via mobile APP. (Please refer another IFU)
	5.2) See Wi-Fi indicator LED is blinking in blue.	5.2) Check the Wi-Fi router is on and work well.
	5.3) See Wi-Fi indicator LED is blinking in white.	5.3) Check the server is on and intranet connection work well.
6.) Initial calibration fail	6.1) Check patient is not on the mattress before initial calibration ready.	6.1) Remove patient carefully until initial calibration ready or press “Max inflate” to ignore the fail.
	6.2) Check the mattress is placed flat on the bedframe and all air cells are not extrusion or bending.	6.2) Try to replace the mattress again for a flat condition,
	6.3) Check the air cell holder of mattress is not folded.	6.3) Use hand to check the air cell holder of the mattress.
7.) Sensor pairing fail	7.1) Check the transfer cable is connected before inserting the power cord set into a wall outlet.	7.1) Reconnect the transfer cable with rapid connector of power unit
	7.2) Still see the failure indicator, power LED is blinking in white,and control panel shows the number via digital number display. *Number(N) could be 01~27 *Refer below sensor pad drawing	7.2) Remove power cord
	7.3) Check if the No.N sensor is disconnected form the sensor board cable of mattress sensor’s pad.	7.3) Push the cable into the sensor board connector firmly and you should feel a ”click”.
	7.4) Reconnect the power cord	

10 Troubleshooting

Sensor Pad Assembly Configuration Drawing (Back View):



11 Technical Data

The AVA Activity Analytics System is suitable for continuous operation.

Power unit

System Name.....AVA Activity Analytics
Model SR396
Dimensions(W x H x D).....339 x 266 x 130mm (±5mm)
Weight.....3.4Kg(±0.5kg)
Electrical Rating.....100-240Vac 50/60Hz 0.5-0.3A
Power Consumption.....25W max. (normal operation)
Electrical Class.....Class II
Applied Part.....Type BF mattress
IP Code.....IP21
Rechargeable Coin Cell.....Li-Ion Type LIR2477 rated 3.7Vdc 200mAh

This system is not AP / APG protected.

NRTL_Safety Certified: SGS Q Mark in accordance with ANSI/AAMI ES60601-1:2005+A1+A2 and CAN/CSA C22.2 No.60601-1:14

EMC & Safety & RF Certified Standard
Safety: IEC/EN 60601-1_v3.1 and AS/NZS IEC 60601.1:2005
HomeCare: IEC/EN 60601-1-11_v2.0
EMC: IEC/EN 60601-1-2_v4.0
RF: FCC Part 15C and EN 300328 and AS/NZS 4268:2017

Operating Conditions
Temperature Range: 5°C to 40°C
Relative Humidity Range: 15% to 90%
Atmosphere Range: 700hPa to 1060hPa

Mattress replacement

Min. Patient Weight 30Kg
Max. Patient Weight for Entrix Lux.....180Kg
for FIT.....250Kg
Material of Air Cells.....Nylon with TPU lamination material

The AVA Activity Analytics System must be decontaminated before disposal.
Disposal of old electrical and electronic equipment - valid in the European Union: WEEE Directive 2012/19/EU.

This symbol on the product or on its packaging indicates that this product should not be treated as household waste. Instead, this product should be taken to the appropriate place of disposal for the recycling of electrical waste and electronic equipment.

12 EMC Declaration

Declaration of Conformity

For EN 60601-1-2 (4th Ed.)

Company Name:	**Carilex Medical, Inc.**
Company Address:	**No. 77, Keji 1st Road, Guishan District, Taoyuan City 33383, Taiwan, R.O.C.**
Product Name:	**AVA Activity Analytics System**
Model No.:	**SR396**
Report Number:	**ETC 21-01-RBO-054-01**
Power Supply:	**100-240Vac 50/60Hz 0.5-0.3A**

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

Declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The AVA Activity Analytics System 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 AVA Activity Analytics System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

12 EMC Declaration

Declaration – electromagnetic emissions and immunity – for EQUIPMENT and SYSTEMS that are use in the professional healthcare facility environment or in the home healthcare environment

The AVA Activity Analytics System declaration – electromagnetic immunity

The AVA Activity Analytics System system is intended for use in the electromagnetic environment specified below.
The customer or the user of the AVA Activity Analytics System system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level		Compliance level		Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms ; 6 Vrms 150 kHz to 80 MHz		3 Vrms ; 6 Vrms 150 kHz to 80 MHz		Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF IEC 61000-4-3	3 V/m ; 10V/m 80 MHz – 2.7 GHz 80%		10V/m 80 MHz – 2.7 GHz 80%		
Proximity fields from RF wireless Communications equipment IEC 61000-4-3	27 V/m	385 MHz	27 V/m	385 MHz	
	28 V/m	450 MHz	28 V/m	450 MHz	
	9 V/m	710 MHz	9 V/m	710 MHz	
		745 MHz		745 MHz	
		780 MHz		780 MHz	
	28 V/m	810 MHz	28 V/m	810 MHz	
		870 MHz		870 MHz	
		930 MHz		930 MHz	
	28 V/m	1720 MHz	28 V/m	1720 MHz	
		1845 MHz		1845 MHz	
		1970 MHz		1970 MHz	
	28 V/m	2450 MHz	28 V/m	2450 MHz	
	9 V/m	5240 MHz	9 V/m	5240 MHz	
		5500 MHz		5500 MHz	
		5785 MHz		5785 MHz	

Declaration – electromagnetic immunity

The AVA Activity Analytics System system is intended for use in the electromagnetic environment specified below.
The customer or the user of the AVA Activity Analytics System system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV , ±4 kV , ±8 kV , ±15 kV air	±8 kV contact ±2 kV , ±4 kV , ±8 kV , ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
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	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV ±1 kV differential mode ±2 kV common mode	±0.5 kV ±1 kV differential mode ±2 kV common mode	Mains power quality 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	0 % U_T ; 0 , 5 cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycle Single phase: at 0°	0 % U_T ; 0 , 5 cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycle Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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