

AVACEN CSS™

Cardiovascular

&

Stress

Screening

User Manual

AVACEN medical®

Contents

GENERAL	4
Requesting Service.....	4
How to Contact	4
1.0 About User Manual.....	5
2.0 Notices and Precautions	5
2.1 Notice and Precautions for Use.....	5
2.2 Electrical Safety and Precautions.....	6
2.3 Cleaning and Maintenance.....	6
2.4 Precautions.....	7
2.4.1 Prior to Measurement	7
2.4.2 Preparation before Measurement.....	7
2.4.3 Preparation on Measurement Day.....	7
2.4.4 During the Measurement	7
2.4.5 Why you may get a different result when testing multiple times.....	7
3.0 Overview	9
3.1 Purpose of Using the AVACEN CSS CPU	9
3.2 Product Contents	9
3.3 CSS Descriptions.....	9
4.0 Cable Connections	10
4.1 AVACEN CSS Connections	10
4.2 Printer Connections	10
4.3 Laptop Connections.....	10
5.0 Method of Measurement	11
5.1 Advice for Users Using AVACEN CSS	11
5.2 Direction for Use	11
5.2.1 Main screen.....	11
5.2.2 SETUP Screen.....	12
5.2.3 User Registration / Edit	13
5.2.4 Measurement	14
5.2.5 Report Screen	15
5.2.5.1 Measurement Time and Report.....	15
6.0 AVACEN CSS Troubleshooting	18
PRODUCT WARRANTY	19

GENERAL

Thank you for using the AVACEN CSS. Please read this User's Manual carefully before operating this equipment for proper handling, maintenance, and becoming familiar with the functions and features of this equipment for safe and reliable performance.

AVACEN Medical only provides reliable products to our customers.
Copyright Act protects this operational instruction and the product.

No part of this instruction and the product may be copied, reproduced, transmitted, or translated in any form without written permission from AVACEN Medical. This User Manual may contain printing or technical errors, which are subject to change without notice. Do not alter this device. Do not use this product other than for purposes described herein.

Requesting Service

- | |
|--|
| <ul style="list-style-type: none">■ All assembling, modifying, adjusting or repairing of this equipment shall be carried out only by the service personnel authorized by AVACEN Medical.■ Electrical connection or installation location must comply with relevant regulations. |
|--|

If repairing was done or attempted by unauthorized service personnel, anytime within the warranty period, the AVACEN Medical warranty will be voided.

When there is a problem with this device:

- Immediately contact AVACEN Medical or an authorized agency/franchise.
- Collect model name, product number and description of problem in advance, then contact AVACEN Medical or authorized agency/franchise.

How to Contact

AVACEN Medical 2365 Camino Vida Roble, Suite C Carlsbad, CA 92011	Phone: (888) 4-AVACEN (888-428-2236) Web: AVACEN.com Email: support@AVACEN.com
--	--

1.0 About User Manual

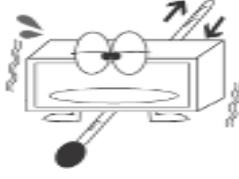
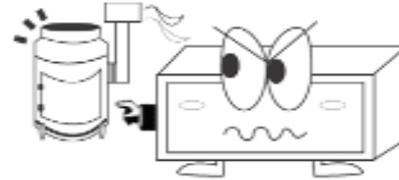
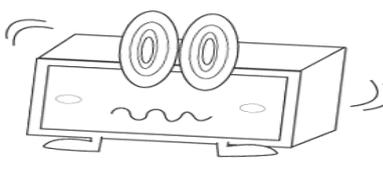
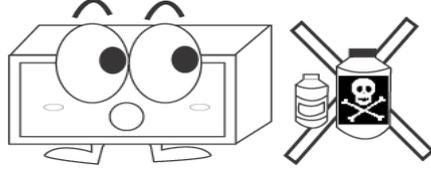
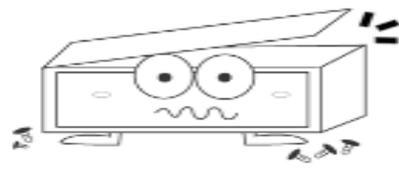
This manual contains the information needed to operate the AVACEN CSS and further provides the user health test results related to cardiovascular stress and screening.

Because the chapters in the manual are constructed so that each chapter can be used independently, some contents may appear in more than one chapter.

2.0 Notices and Precautions

2.1 Notice and Precautions for Use

Do not use or keep AVACEN CSS under circumstances described below:

 <p>Do not touch the power plug or equipment with wet hands.</p>	 <p>Do not expose AVACEN CSS directly to the sun.</p>
 <p>Do not place AVACEN CSS in an extremely hot or cold room.</p>	 <p>Do not place AVACEN CSS close to electric heaters.</p>
 <p>Do not place AVACEN CSS in an extremely damp place.</p>	 <p>Avoid shocks and vibrations.</p>
 <p>Do not place AVACEN CSS close to chemical substances and explosive gas.</p>	 <p>Do not disassemble AVACEN CSS. In this case, the product warranty will be voided.</p>

Operating Environment

- Temperature: 10°C - 40°C (50°F - 104°F)
- Humidity: 80% RH max @ 40°C (104°F)

2.2 Electrical Safety and Precautions

Check on the following before using the AVACEN CSS.

- Please make sure of the correct power voltage (100 – 240V AC) before using the AVACEN CSS.
- Please make sure the power cord and accessories are properly connected before turning on the power.

Classifications

Safety classification for electric shock	Class II
Protection degree of electric shock	Type BF

Warning

- **Do not connect the AVACEN CSS to other medical instruments when in use.**
- **Such connections may cause a leakage current.**

Note

- **Do not install AVACEN CSS close to an electric generator, x-ray device, broadcast device, or electric shifting cable to avoid electrical interference which may lead to invalid results.**
- **Keep out of the reach of children and pets to prevent them from electric shocks.**

2.3 Cleaning and Maintenance

It is recommended that the body of AVACEN CSS and accessories should always be maintained in a clean condition.

The warranty does not cover any damage caused by using any substances that may lead to product damages.

Use warm water or alcohol on a soft cloth to clean and remove dust. Never use thinner, ethylene or oxidized substances, which may cause product damage. Cables and accessories should be kept free of dust or dirt and be periodically wiped down with a warm water (40°C/104°F) soaked cloth. Never soak accessories in any liquids or detergents. Avoid all liquids coming in contact with the equipment and accessories.

2.4 Precautions

2.4.1 Prior to Measurement

Prior to the measurement, do not do anything that may cause sudden heart rate changes. Exercise, smoking, and certain medication may result in invalid measurement reports.

2.4.2 Preparation before Measurement

Patients should be in a relaxed state during the measurement.

2.4.3 Preparation on Measurement Day

Do not smoke, drink alcohol or take drugs that can irritate the autonomic nervous system.

If possible, remove nail polish on left index finger fingernail before measurement. If it is not possible to remove nail polish, position the left index finger on an angle and attempt to get an accurate test.

Relax for 15-20 minutes before measurement.

2.4.4 During the Measurement

Patients should not move or speak during the measurement or cross legs. Breathe normally.

2.4.5 Why you may get a different result when testing multiple times

In general, a healthy person has a large change in heart rate, and conversely, a person with a disease (diabetes, myocardial infarction, arteriosclerosis, obesity, etc.) or an elderly person has less change in heart rate.

In other words, a large change in heart rate means that the autonomic nervous system functions well and that the resistance to stress is good, thus lowering the incidence risk of stress-related diseases.

The cycle of heartbeat affects the autonomic nervous system (Sinoatrial Node).

Repeated testing and the effects of internal and external environmental factors (mental stress, emotional changes, breathing, blood pressure, body temperature or hormones, etc.) can significantly change the results value.

People with diseases or elderly people are not able to respond immediately to changes in internal and external environments. Therefore, the heart rate variation (HRV) value is small in the continuous measurement, but the difference for a healthy person is larger due to quick responses to the changes of internal and external environments.

In addition, since vital signs are very sensitive, the following points should be carefully taken for the measurement.

If possible, remove nail polish on left index finger fingernail before measurement. If it is not possible to remove nail polish, position the left index finger on an angle and attempt to get an accurate test.

If there is a lot of variation, it is recommended to calculate the average after 2 to 3 measurements.

Testing Tips

- ① If measuring after exercise, you should measure after a minimum of 10 minutes of rest.
- ② Do not move, talk or cross your legs during testing.
- ③ Maintain the most comfortable and normal breathing pattern. (Coughing, sneezing, sighing, yawning, and abdominal breathing are discouraged during the measurement)
- ④ Avoid drinking alcohol 8 hours before testing, and smoking or drinking coffee 3 hours before testing.
- ⑤ When measuring, do not apply pressure on sensor probe finger.
- ⑥ The proper temperature should be maintained. (Room temperature 22 - 25°C or 71 - 77°F)
Higher room temperature causes expansion of the peripheral blood vessels, resulting in higher wave height. Lower temperature causes contraction of blood vessels, resulting in lower wave height.
In particular, measurement with a cold finger may fail to produce accurate results.
- ⑦ Measure with the left index finger (measurement standard).
- ⑧ Nail polish must be removed for the measurement (a cause of measurement error).
- ⑨ There is a difference between the results in the morning and afternoon, but the measurement in the morning is recommended for periodic testing.
- ⑩ In case of hypertension, high fever or tachycardia, the result value tends to get better because of rapid blood flow in arteries. Even after drinking, the result value tends to get better due to increased blood flow.
- ⑪ In the case of arrhythmia, heart disease or asthma, the result value is unreliable.

The entire CSS solution is intended to be a stand-alone system. It is recommended that no additional 3rd party software be installed on the computer and that the system be used only for the intended purpose of measuring arterial health and evaluating the autonomous nervous system.

3.0 Overview

3.1 Purpose of Using the AVACEN CSS CPU

AVACEN CSS CPU measures heart rate variability (HRV) in a given time period and analyzes the variability to determine one's overall health status and autonomic nervous system activity.

Throughout the measurement, the levels of physical/mental stress, autonomic nervous system balance and vascular aging are evaluated.

3.2 Product Contents

Parts and items are provided as follows:

- | | |
|------------------------------------|--------|
| ① CSS CPU | : 1 pc |
| ② Operation Manual | : 1 ea |
| ③ Power Adapter | : 1 ea |
| ④ Power Cable | : 1 ea |
| ⑤ Photoplethysmography (PPG) Probe | : 1 ea |
| ⑥ USB to RS-232 Cable | : 1 ea |
| ⑦ Windows 11 Laptop & Accessories | : 1 ea |
| ⑧ Printer & Accessories | : 1 ea |
| ⑨ Carrying Bag | : 1 ea |

3.3 CSS Descriptions

● Back



- ① RS-232 Serial Port
- ② Power Adapter Inlet
- ③ Photoplethysmography (PPG) Probe Port

● Right Side



- ④ Power On/Off

4.0 Cable Connections

4.1 AVACEN CSS Connections

- Connect RS232 cable to the back of CSS CPU.
- Connect PPG sensor to the connection port of the CSS CPU.
- Insert barrel end of power adapter into the power terminal of CSS CPU. Plug one end of power cord into power adapter, and other side into electrical outlet.
- Check that the light on the power switch is on.



4.2 Printer Connections

- Insert USB Type B connector to back of printer.
- Plug in AC cable to back of printer. Plug the other end of power cable into electrical outlet.



4.3 Laptop Connections

- Insert USB Type C connector to Laptop for printer.
- Insert USB Type A connector to Laptop for CSS CPU.
- Insert barrel end of power adapter into laptop. Plug one end of power cord into power adapter, and other side into electrical outlet.



5.0 Method of Measurement

5.1 Advice for Users Using AVACEN CSS

- Do not move or talk or cross your legs during the measurement.
- Do not exercise, and relax for about 10 minutes prior to taking a measurement.
- Do not strain and then take a regular breath. Refrain from slowly breathing during the measurement.
- Keep the height of the probe level with the heart.
- The measurement should be taken with eyes open.
- Consult with a doctor in case of arrhythmia or cardiac disease.
- Measuring in the morning is recommended
- Refrain from smoking, taking drugs or drinking coffee 3 hours prior to the measurement.
- Refrain from drinking alcohol the day before taking measurement.
- Refrain from wearing accessories (ring, watch, nail polish) that may interfere with accurate measurement.
- Avoid taking measurement after a meal.
- Measurement should be taken in a quiet, comfortable room (room temp. 22 - 26°C or 71 - 77° F)

5.2 Direction for Use

5.2.1 Main screen



- ① Press Setup () button to see setup screen.
- ② You can set or change language, test time, reference type, username and phone number.
- ③ Press Exit () button to stop the program.
- ④ Press Arterial Health Measurement () button or Stress Measurement () button to see User information screen and take measurement.

5.2.2 SETUP Screen

→ Setup

Language **ENGLISH**

Test Time **1min**

Reference Type **WEST**

User Name

Telephone

Print Image COM Check

COMPORT = COM3

Printer Excel Cancel Save

① **SAVE and CANCEL button**

- Press  **Save** button to save input information, and move it to the main screen.

- Press  **Cancel** button to go back to main screen without saving the input information.

② **Language**

- Select language in the combo box.

- If you changed language, press SAVE button and then restart the AVACEN CSS program.

③ **Measurement time**

- Select 1 min, 3 min or 5 min in the combo box.

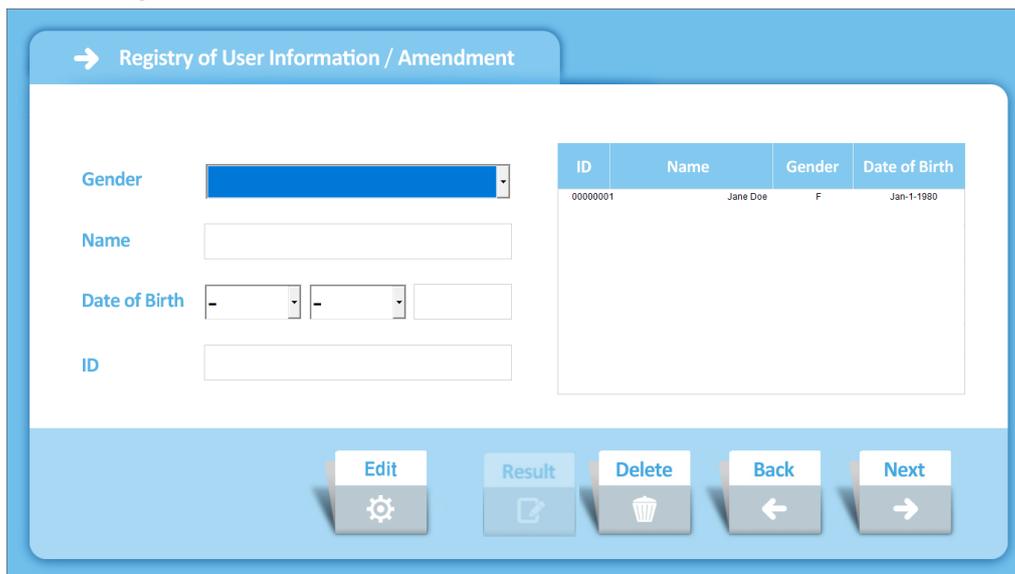
④ **Reference Type**

- Select ASIA for Korean, Japanese, Chinese, etc. or WEST for western peoples USA, EU, Middle East, etc.

⑤ **Facility name and Phone number**

- In order to print a facility name and telephone number, input the name of facility and telephone number.

5.2.3 User Registration / Edit



① Buttons



- When you press “NEXT” button () after filling in all personal information (Gender, Name, Date of Birth, ID), this personal information will be automatically registered and move to the measurement screen. You complete all fields at this time.

In other words, “Next” button also has a “Registration” function by itself.



- If the selected patient already has the measuring data, RESULT button () will activate. Press result button to see the results on the screen.



- If you press DELETE () button after selecting user information from the list, all the information will be deleted. Pay special attention to the DELETE button.



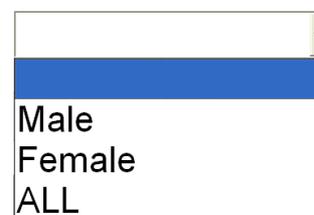
- If you press BACK () button, it moves to main screen.



- If you press NEXT () button after selecting User information, it moves to measurement screen.

② Entering new patient's information

- Enter information on Gender / Name / Date of Birth / ID information.
- Select birth Day and Month from the combo box by clicking the day and month from the list. Enter 4-digit year of birth.
- For the gender, you can select four categories as shown to the right.



- a) The user's initial screen is a condition that does not select any gender. This status is in condition of clearing all users' information. If the user inserts the information and later clicks on the white area of this box, all information will be deleted.

b) To register the user's name, select "Male" or "Female." If you want to see all of male and female without registration, you can select the white blank or "ALL".

③ **Recalling a previous user information**

- Input gender.
- Input name.
- A patient's information will appear on the list, which is identical to the information that has been inputted.
- Select desired information from the list. (although if all a patient's information has not been inputted, select one in case of a corresponding patient's information from the list)
- Press the NEXT button to see the measuring screen.
- If the selected patient already has the measuring data, press the result button to get the results on the screen.

④ **Deleting a previous user information**

- Select gender and input the name.
- Patients with matching information will be displayed in the list.
- Select desired user from the list.
- Press DELETE button.
- If "Do you want to delete the selected information?" is shown, press "Yes" button.

⑤ **Editing the user information which is already registered**

- Select the username on the user's list at the right side to edit it.
- Edit the user information on the left.
- Click "Edit" button.
- If the message "Do you want to edit the user data?", click "Yes".

5.2.4 Measurement

- ① Place photoplethysmography (PPG) probe on finger before pressing NEXT button after inputting or selecting User.
- ② Wearing method of PPG probe:

Grasp sides of finger cover and gently lift.

Insert left index finger deeply into the PPG probe and let finger cover close atop finger.



③ Place hands on the table comfortably, relax and then press NEXT button.

④ From the measurement screen, press the START button (), and the measurement will begin with a voice comment and the appearance of waveforms on the screen.



⑤ Do not move or speak while measuring.

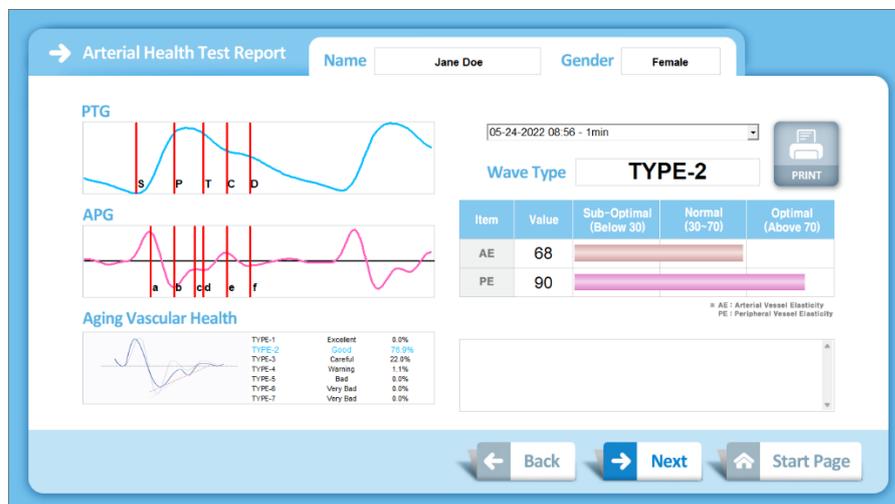
⑥ Press the STOP button or remove the PPG probe from your index finger if you want to stop the measurement. The program will automatically revert to the previous screen seconds after removal of the PPG probe.

⑦ The report screen will be shown after the measurement is finished.

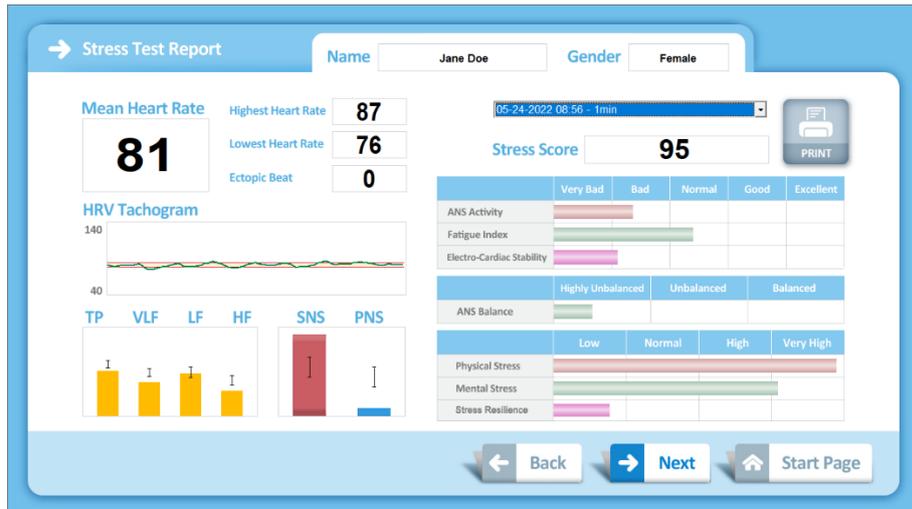
5.2.5 Report Screen

5.2.5.1 Measurement Time and Report

- The report screen will be shown after the measurement is finished.



<<Arterial Health Test Report>>



<<Stress Test Report>>

- You can print the HRV Report, APG Report and/or History Chart by pressing the PRINT button on the screen.

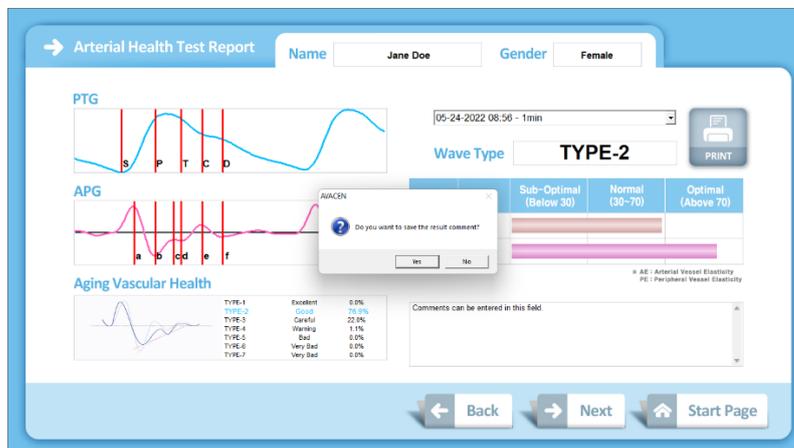


<<APG History>>



<<HRV History>>

- You can insert a comment on the Arterial Health Test Report. Click the “NEXT” or “BACK” button until you arrive at this report. Enter comments in the space provided. After pressing “NEXT,” a message box to save the comment will be displayed. When you click “YES”, the comments will be saved with the report.



- After completing the measurement, the result will be saved in an EXCEL format file at the following location:

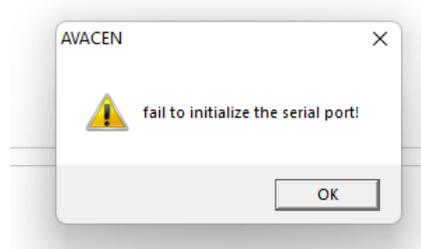
C:\AVACEN MEDICAL\Share\

The file format/name is as follows:

ID_Name_Date_HRV.xls/ID_Name_Date_APG.xls.

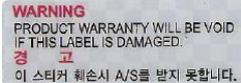
6.0 AVACEN CSS Troubleshooting

- ① The waveform does not show during preview.
 - Check the connection between the probe and main body.
 - Check the test time on the environment setup window.
- ② Do not measure while operating the printer. The equipment collects the data in real time; if the printer is in use during measurement, this could result in system resource irregularities.
- ③ Do not operate any other equipment while you are using AVACEN CSS. This may impact real-time data acquisition.
- ④ During measurement, if the window below appears on the screen after clicking “START”:



- Check if the power switch on the CSS is turned to the “ON” position and that the light is illuminated.
 - Check that the connections between the laptop and the CSS are fully inserted and secure.
- ⑤ Troubleshooting
 - Read the directions below if the equipment is improperly operating:
 - In case of not being able to turn on the power - Check whether AC is properly connected. Check connecting switch conditions.
 - If the waveforms are not present or are too small to see on the screen try re-seating finger in the sensor. Improper finger position in the probe can result in inaccurate results.

PRODUCT WARRANTY

- This product has passed strict inspection and testing.
- AVACEN Medical warrants that **operational defects or product defects will be repaired free of charge for 1-year from the date of purchase**. During 1 year from the date of purchase, reasonable repair fees may be charged if the repair requires extra costs caused by unusual wear and tear.
- This warranty must be represented to the authorized agency when a repair is required.
- This warranty shall only apply to operational defects or product defects under the circumstances of proper usage. Warnings and precautions stated in this manual must be observed.
- The repair service does not cover any surface damages or defects which do not affect proper operation of the system.
- The warranty will not apply to damage resulting from tampering with or tearing off the WARNING sticker () from main set.
- AVACEN Medical shall not be liable for direct, indirect, incidental or consequential harm related to the use of the equipment.

AVACEN medical®