User and Service Manual
Cardiomed Treadmills

CardioMed Treadmills

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CE MD

Last Version: April 2023

Because the running machine is a motor-driven device, you must pay special attention to the mentioned safety regulations. If proper notice is taken of the safety regulations, the operation of our running machines is nearly without risk. Neglect of the safety regulations could result in dangerous situations and accidents with serious injury or death. Therefore please read this operating and service manual and the danger precautions in full before taking the device into operation.

Some simple maintenance and monitoring (no repair work!), as described, can easily be done or even have to be done by yourself. All kinds of installation and repair work and most maintenance work are to be performed only by trained and authorized technicians who have been certified by **Cardiomed Treadmills**. The following symbols will indicate which work can be done by the customer and which work has to be done only by authorized technicians:

	The customer/user should perform this maintenance and monitoring work. Some safety checks or monitoring (for examples harnesses and ropes, running belt condition and position, etc.) have to be performed on daily basis. It is not expedient to contract certified technicians for such maintenance work. However, where it is practical, all maintenance and monitoring work marked with this symbol can also be performed by certified technicians.
	All installation, maintenance, repair and monitoring work marked with this symbol must only be performed by trained and authorized technicians who have been certified by Cardiomed Europe. Customers/users must not perform these kinds of tasks and work.

We recommend calling our competent service team or entering into a maintenance contract for a routine service at an interval of 6 or 12 months for standard machines and standard applications. A form for registration of your institution and device is included in the delivery. In order to be able to supply you with the latest technical information and service, it is important for you to fill out the form. Therefore, please fill out the form for registration immediately and send it back via fax, email or mail.

This operating and service manual as a firm part of the delivery has to be accessible to the user at any time. It has been written with great care. Should you, however, still find any details which do not correspond with your device, please notify us so that we can correct any mistakes as soon as possible. Subject to alterations without prior notice.
Errors and omissions excepted. E & OE.

Content

1.1 Description

A running machine (also called “treadmill”) is an exercise device for running or walking while staying in one place. The running machines are stationary treadmills which are used for training and testing, simulating adjustable speeds and various adjustable elevations (also called “slope” or “inclination”). The medical versions can also be used for diagnostics and therapy applications. The machine provides a moving platform with a wide conveyor belt and an electric motor. The belt moves to the rear allowing a person to walk or run an equal, and necessarily opposite, velocity. The rate at which the belt moves is the rate of walking or running. Thus, the speed of running may be controlled and measured.
CMT are treadmills designed for medical purposes as well as for use in gyms and sports centers. They are unique devices for the improvement and preservation of physical performance and can be used for verification of the cardio vascular system.

The patient (for sports devices called “subject”) is asked to follow the speed of the belt and keep his position on the deck. By walking and/or running, the physical condition of the patient can be analyzed through a treadmill stress test protocol and additional ECG or VO2max. (metabolic cart) diagnostic device. In physiotherapy and neurologic application the patient can be additionally secured and un-weighted with a body weight support system and the gait can be analyzed and corrected under safe and reproducible conditions.

Duration of use of the medical versions is approx. 5 to 25 minutes per patient per day, depending on the prescription of the doctor, the condition of the patient and depending on the standardized or individual load protocol (for example BRUCE protocol).

The following materials are used: mainly powder coated steel tubes for the frame, conventional rubber or PVC for the running belt, conventional frequency inverter and drive motor for belt speed control, conventional electric and electronic components and conventional plastic parts.

Contact with the body occurs through walking shoes on the running belt, through hand palms on handrail grips when the patient holds the handrail and through fingers if the patient is allowed to press keyboard and/or emergency stop on the handrail of the device. There is no physical contact to organs, tissues or body fluids.

In medical diagnostics and therapy, the recommended and right endurance dose of the load parameter (speed, elevation, distance, heart rate, body weight support, motion support, etc.) and specific application is decided and supervised by the doctor. A number of training profiles and standardized protocols e.g. Bruce, Naught on, Cooper, Ellestad A, Gardner, etc. are available, but the treadmill does not calculate medical parameters, nor does it perform medical diagnoses or medical evaluation. Finally, it does not give recommendations for treatment.

1.2 Device Components

1] User Terminal
[2] pull cord safety stop actuator
[3] emergency stop button (mushroom style)
[5] handrail crossbar (front)
[6] handrails (side)
[7] motor hood/cover
[8] tread plate with slip resistant surface
[9] running surface (gliding plate/deck)
[10] running belt *
[11] rollers (behind the belt)
[12] roller cover
[13] base frame
[14] elevation element

* **applied parts** based on definition in IEC 60601-1

1.3 Safety Equipment

For any use with patients or other subjects for whom a fall would constitute a serious accident (for example after hip replacement operations, patients with neurologic problems, patients connected to invasive probes, maximum load tests, running at high speeds, running side wards, co-ordination training, etc.) or injuries, a fall prevention system such as safety arch with chest belt system and stop-function or an unweighting system is obligatory. The chest belt secures the subject and prevents falling forward. The chest belt system is connected via a pull rope with the emergency stop at the crossbar of the safety arch. If more than approx. 8 kg / 17.6 lbs traction pulls on the harness, the switch stops the running belt immediately. The length of the harness is individually adjustable. The running belt is stopped in the moment of falling.

Unweighting systems as an accessory can be used for body weight support of the patient, in case the patient should not bear his full body weight on his legs.

CAUTION! The big and highly visible emergency stop button is standard on all models and is placed on the handrail. An additional emergency stop button can be retro-fitted at all running machines. It can, for example, be duplicated on the opposite handrail. conforms with the norm EN 957-6: “The push-button type or pull cord safety stop actuator shall be in a reachable position in front of the user and in an area of ± 180 mm parallel to the centre line of the running surface. If the push-button type safety stop actuator is outside this area, it shall be duplicated on the opposite side except when a pullcord actuator is provided.” can supply a second and additional emergency stop button.

On all medical treadmills the emergency stop push button is simultaneously an emergency off button. That means by pushing this button the power supply of the device is cut off.

2. Intended use / indications, contraindications, risks & forbidden use

2.1 Intended use

Medical treadmills are intended for endurance training, recreational fitness training and gait training. In combination with external devices medical treadmills are intended as loading devices for EMG and ECG measuring, ergospirometry as well as diagnosis and prognosis of cardiovascular diseases by stress tests.

By combining medical treadmill with external devices, a medical electrical system (ME-System) is created.

Medical treadmills may be operated only in medical facilities by medical staff.

Medical treadmills must not be operated in home environment. The correct loading for a patient on the treadmill must be prescribed by a medical doctor. The treadmill manufacturer cannot make any declaration or recommendation.

The following table gives an overview over the intended applications and the corresponding minimum safety equipment.

A not restricted patient is defined as a patient able to grap the handrail and jump off the running belt in case of emergency.

A restricted patient is defined as a patient not able to grap the handrail and jump off the running belt in case of emergency.

2.1.1 Intended operator

Medical staff only

- that has been carefully trained according to these instructions for use
- that is working according to the prescription of the medical doctor, where applicable and necessary
- The subject is not the intended operator.

But the intended operator is authorized to allow the subject to control the device according to the instructions of the intended operator and under the permanent observation of the intended operator.

This means the operation of the device always remains the responsibility of the intended operator, taking the physical and
mental condition of the subject into account.
The intended operator has to be within reach of at least one emergency stop / off at all times.

2.1.2 Intended location

- Medical facilities only
- No use at home or in home healthcare environments (acc. to IEC 60601-1-11)
- No outdoor use
- No direct sunlight
- Sufficiently lighted for proper readability of warning, labels, displays and operation elements.
- Proper environmental conditions (see “Technical Data”)
- Stationary training equipment: Not moved during use

2.1.3 Intended duration
Depending on the prescription of the medical doctor

2.2 Contraindications

Contraindications must be excluded before the treadmill is used.
It makes sense to distinguish between absolute and relative contraindications. In case of relative contraindications, the application may be started if the possible benefits exceed the risks of application. The decision must be made by a medical doctor. In case of relative contraindications permanent observation of the patient by medical staff is obligatory.

Absolute contraindications:

- Acute myocardial infarction
- Instable angina pectoris
- Cardiac arrhythmia pathology and/or limited hemodynamics
- Symptomatic massive aortic stenosis
- Uncompensated / uncontrolled heart insufficiency
- Acute pulmonary embolism or pulmonary infarction
- Acute endocarditis, myocarditis, pericarditis
- Acute aortic dissection
- Acute coronary syndrome
- Acute phlebothrombosis of the lower extremitie
- Febrile infections
- Pregnancy
- Acute thrombosis
- Fresh wounds e.g. after surgery
- Acute fracture
- Damaged disc or traumatic disease of the spine
- Epilepsy
- Inflammations
- Acute migraine

Relative contraindications:

- Left main coronary stenosis
- Main artery disease
- Cardiac valve disease of moderate severity
- Known electrolyte imbalance
- Arterial hypertonia (RR > 200 mm Hg syst. > 110 mm Hg diast.)
- Tachyarrhythmia or bradyarrhythmia
- Hypertrophic cardiomyopathy and other forms of outflow tract obstruction
- Higher degree atrioventricular AV-blocking
- Anemia

- Physical and/or mental disabilities leading to inability to exercise adequately

Also see following guidelines:
Deutsche GesellschaftfürKardiologie – Herz- und Kreislaufforschunge.V.
(http://leitlinien.dgk.org).
American College of Cardiology Foundation - www.acc.org
American Heart Association - www.americanheart.org
http://my.americanheart.org/idc/groups/ahaecc-internal/@wcm/@sop/documents/downloadable/ucm_423807.pdf

Further contraindications may occur. This has to be evaluated by the responsible medical doctor.

2.3 Safety

CMT medical treadmills may be operated with healthy subjects as well.

For applications with healthy subjects, please apply the instructions for use for sports devices. The safety notes, warnings and precautions have to be pointed out to every user and operator and displayed within sight of the
running machine.

2.3.1 Safety information – Forbidden use

Obey the following danger, warning and caution statements stricktly in order to prevent serious injury or death!

- Prescribed fall prevention for any application where falling might cause an unacceptable risk (high speed or special applications,applications with subjects not able to jump off the running belt such as children, physically impaired, etc.)
- The automatic modes must only be performed on the prescription of the medical doctor.
- During stress tests a medical doctor has to be available at any time.
- Do not use the device with children <12 months.
- Exclude access of unsupervised children (< 14 years) onto or near any parts of the device (incl. accessories, packaging,lubrication and service material).
- In case of application with children (> 1, < 14 years) permanent observation of the subject by medical staff is obligatory.
- Animals must not be in the same room with the device.
- Only carefully trained medical staff is allowed to use the device.
- Do not use the safety harness on bare skin.
- WARNING! Heart rate monitoring systems may be inaccurate.
- Incorrect or over exercising may result in serious injury or death.
- Advice the subject If you feel faint or dizzy stop exercising immediately and consult a medical doctor.
- Exclude overloading or overstressing of the subject.
- The subject has to be checked by a medical doctor before using the device.
- A defibrillator must be present at any time.
- The intended operator has to be in reach of at least one emergency stop/off at any time.
- Obey all information given in these instructions for use.
- Do not use the device against the intended use.
- Do not use the device in case one or more of the listed contraindications prevail.
- In case of relative contraindications permanent observation of the subject by medical staff is obligatory.
- Neither subject nor operator must be under the influence of alcohol, drugs or anesthetics.
- Start the use of the treadmill with slow walking, especially for beginners.
- Make sure the space under the treadmill is free from persons, body parts or objects, especially when switching on (treadmill will lower during initialization) and when changing the elevation.
- Do not enter the device when running belt is rotating.
- Do not step on rear roller.

- Do not stand on or enter the running deck when device is in elevation (running belt might slip through due to gravity).
- Make sure no objects, sand, stones, liquids, towels, jewellery, cell phones, containers with liquid etc. can fall into the device or onto the running surface or underneath the running belt
- Do not enter the device without appropriate shoes without high heels, spikes or studs. *
- Do not use the device with wheels (bikes, wheelchairs, inline skates, etc.). **

  Do not turn around, walk sideways or backwards; do not jump on or off the running belt while it is in motion.
- Do not touch the running belt while it is in motion (besides contact with feet).
- Do not lean on the UserTerminal - do not apply pressure to the displays - press keys softly.
- Ensure assist mean, accessories, cables etc. do not extend into the running area.
- Do not insert any object (especially no metal objects such as a pin or a wire) into any gap or any outlet on the device.
- Do not touch the subject and external electrical devices at the same time.
- Be aware that electromagnetic interferences may cause a fail-safe mode, the running belt will stop with a pre-defined deceleration ramp. WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- WARNING: Do not use portable high frequency communication devices in the subject environment (see “position of subject and user”). Disregard can cause loss of performance.
- Free standing equipment has to be installed on a stable and levelled base.
- Choose proper floor, clothing and humidity, in order to prevent electrostatic discharge (also see technical data).
- Do not use the device without instruction by authorized personnel acc. to the instruction protocol.
- Regard safety area behind device of 2.0 m x width of treadmill.
- Operator and subject have to be aware of automatic load changes during profile, cardio and test mode.
- Unmeant trapping hazards: Take off ties, scarfs or other clothes that may be trapped. Secure long hair and ribbons during maintenance and training in order to prevent being captured in trapping zones.
- Perform a daily visual inspection (see chapter “maintenance”).
- Obey the maintenance intervals claimed in chapter “maintenance”.
- Obey the competences claimed in chapter “maintenance”.
- A second person has to be present during maintenance.
- In case of any visible or assumed defects or malfunctions (of the device, accessories, software, etc.), unplug device, exclude reconnection, mark clearly and inform Cardiomed service personnel via telephone and writing.
- In case of any visible or assumed wear and tear (of the device, accessories, labels, etc.), unplug device, exclude reconnection, mark clearly and inform Cardiomed service personnel via telephone and writing. Do not change or remove any labels!
- In case of any fluid entering into the device, unplug device, exclude reconnection, mark clearly and inform Cardiomed service personnel via telephone and writing.
- Do not modify the device, configurations, accessories or software in any way.
- Do not connect any devices, accessories or software, not listed in “accessories / compatible devices”.
- Disinfect the device before and after every treatment.
- Disconnect the device and all accessories from mains power supply before cleaning or disinfection.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."

WARNING: a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and MODEL OR TYPE REFERENCE). -> RS232 3M CABLE

WARNING: Use of accessories, transducers and cables 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."

"**WARNING**: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Cardiomed Treadmill, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

2.4 Risks

In the event of overload of the patient due to wrong application and/or wrong assessment and/or unexpected problems, the following risks, problems and injuries may occur. Risks are reduced by correct load dosing (according to the clinical picture and condition of the patient). Especially for ergometry (stress-test) application, the patient is subject to additional risk since the test is designed to stress the patient until cardiovascular problems may occur. The risk remains even in the presence of trained, medical staff and even when medical equipment and a defibrillator for reanimation are available. The higher risk cannot be reduced even with the knowledge of contraindications. Neither can loading capacity nor cognition restrictions be excluded by contraindications.

The risk of falling and consequential injuries is reduced by the safety equipment and application of a fall prevention system.

Residual risk / Side effects (med)

After risk reduction most risks are "acceptable". Only a few risks remain "widely acceptable". There are residual risks, such as falling of a person resulting in skin abrasions, bruises, fractures or in worst case even death.

These risks may occur during use as well as when entering or leaving the device and during stand-still in elevation.

Furthermore there is residual risk such as unintended overload of the subject caused by wrong operation, wrong assessment, or wrong application of the operator and also incorrect data transfer (e.g. electromagnetic interferences, software failure, etc.). Even the best software and hardware safety concepts can never completely rule out a failure of software or hardware and thereby a theoretically possible overloading of the subject.

Since the treadmill is an electrically operated device, an electric shock, which might result in death can never be ruled out, although the design and verification is according to the relevant standards for electrical safety of medical devices, an electric shock, which can result in death, can never be ruled out completely.

The residual risk of strangulation and trapping of clthes / shoes / fingers / hair or other body parts in the elevation system, belt reentry zones or other moving parts can not be excluded as well. These risks are reduced by safety information within the IFU.

It cannot be excluded that unintended or forbidden use might cause further not yet regarded risks and that already regarded risks might have been estimated incorrectly. It can also not be excluded that the daily use of the medical product might show further risks.

For medical applications such as ergometry, diagnostics and therapy there are alternatives to treadmill application such as bicycle ergometry (without natural gait movement) or overground gait therapy (secured only by the therapist), etc. the benefit of treadmill training in contrast to these alternatives is clearly outweighing the residual risk of falling or overload with the known consequences.

In this risk analysis the "present state" of the device has been evaluated.

Having carried out the evaluation and validation of the product, the risk of appearance of a not acceptable risk is very low.

The device (it´s construction, it´s function as well as the intended application) does - under normal conditions - not represent any unjustifiable risk for the subject, the user, the operator or third persons. However, the risk of injury or even death due to a malfunction of the treadmill is very low. In over 30 years of history and with more than 10,000 Cardiomed treadmills on the worldwide market, there has never been such a reported incident.

Remaining risks in ergometry / stress testing

Cardiac complications	**Frequency**
Morbidity	< 0.05 %
Lethal complications	0.03 – 0.04 %
Non-lethal complications	0.07 – 0.15 %
Acute MCI	0.035 – 0.1 %
Acute cardiac death	< 0.005 %
Ventricular tachyarrhythmia	0.05 % - 2.3 %
Supraventricular tachyarrhythmia - in case of known paroxysmalsupraventricular arrhythmia - atrial fibrillation, atrial flutter	3.4 – 15 % < 1 %
Ventricular extrasystoly	2 – 20 %
Supraventricular extrasystoly	4 – 24 %
Paroxysmal atrial fibrillation	0.8 %
Transient left bundle-branch block	0.4 %
Bradyarrhythmia Hypotony	3 – 9 %
Hypertensive blood pressure Regulation	n.s.

Ventricular rupture	n.s.
Papillary muscle rupture	n.s.
Non-cardiac complications	
Intracranial haemorrhagen	n.s.
Thromboembolic event	n.s.
Transient global amnesia	n.s.
Arthralgia	n.s.
Myalgia	n.s.
Low back pain	n.s.

n.s.: not specified

Problem & injure risk	Risk control
Due to overloading and/or fall : - Bruises - Sprains and torns - Skin abrasions - Injuries of the	- Note in instructions and warning labels on the User Terminal that the device may only be used under supervision by medical or therapeutic staff. - Proper loading dose must be prescribed by doctors or therapists as qualified personnel only. - Note in instructions and warning labels on the User Terminal that operating personnel must stay in permanent patient environment of 1.5 m. - Recommendation and application of weight support system and/or fall stop device, automatic shut-off of the running belt. - Comprehensive instruction of the patient before the start of treadmill therapy with an explanation that the drive of the running belt is very strong and does not stop automatically when the patient stops.

Overload of the cardiovascular system in extreme situations with cardiac arrest and death as possible worst case scenario.	▪ Note in user's manual that correct load dosing must be done by a medical doctor or therapist. ▪ Note that a defibrillator has to be kept on hand for reanimation. This is already standard in some countries. ▪ Integrated cardio mode, which reduces the load after reaching the recommended maximum heart rate and stops the treadmill in case of overload or breakdown of the heart rate measurement.

In case of correct load dosing (according to the clinical picture and condition of the patient) and intended use, the risks are comparable to the risks of walking / running on the ground: falling off the treadmill with skin abrasions, bruises, torn ligaments, fractures and in worst case fatal injury such as a broken neck.

Firefighting

Do not use liquid firefighting resources.
Use CO2.

2.5 Forbidden use

-All prohibitions in the chapter entitled "Safety precautions, safety regulations, prohibition and warnings".

-Do not modify the running machines and do not connect them to other equipment which is not explicitly declared as compatible by all involved manufactures.

-The running machine must not be used without carefully trained specialist staff and without the staff having been instructed on the safety regulations.

-The subject must interrupt the training immediately if he/she starts feeling sick or dizzy and should see a doctor.

-Subject with a cardiac pacemaker or who suffer from any kind of physical restriction must see a doctor before using the running machine and ask for permission.

-Animals are not allowed to use the running machine and must not get near to it (4 m safety zone).

-Unsupervised children (<14 years) are not allowed to use the running machine and must not get near to it (4m safety zone).

-Children, supervised by medical doctor or therapist, are to be secured by a fall prevention with chest belt system.

-Other use than the explicitly mentioned intended use.

-In the event of any detected and/or assumed malfunctions and/or defects or unreadable safety warning labels, the device has to be taken out of operation, clearly marked as such and disabled. The supplier and authorized service personnel have to be informed in writing.

-Under no circumstances should a subject/patient or other user be overloaded or overstressed.

-Under no circumstances should the device be used with increased risk, e.g. sprint or medical application with a high risk of falling, unless additional safety precautions and safety equipment such as safety arch with fall stop are used.

-The device must not be used if one or more of the listed contraindications prevail (see chapter entitled "Contraindications").

-It is prohibited to use wheels on the standard running machines. Thus, no cycles, wheelchairs, inline skates or roller skis are to be used.

-Never use running shoes or other shoes with spikes or studs on the standard running surface or running belt.

-Medical Treadmills must not be used in environmental conditions other than those specified in the chapter „Technical specifications" and "Environmental conditions" (e.g. in wet and humid areas, swimming pools, sauna, environmental chambers, high-pressure-, low-pressure, altitude- and oxygen-chambers, etc.).

-Do not jump onto the rotating running belt. Do not jump off the rotating running belt (not even forward). Do not stop moving or turn around on the rotating running belt. Never run side wards or backwards. Do not do anything which could interfere with your balance. Do not set too high loads (speed, elevation).

The listing of forbidden use may be incomplete and only lists the most important foreseeable misuse.

3. Safety notes, warnings, precautions

3.1 General

	**Important notes, warnings and precautions are marked with this sign. It also reminds you of concerns which have to be considered for measurements and connection with other devices.**

The safety instructions and danger warnings must be attached in the viewing area of the treadmill and each user must be stated on these safety rules and danger warnings.

- Reading the Instructions for use, the safety instructions and danger warnings is essential before using the device.
- These safety rules and danger warnings must be placed in the view area of the treadmill.
- Each operator and each user must be pointed out these safety rules and danger warnings.
- The disregard of the safety instructions and danger warnings, the unauthorized or improper use of the running device, the lack of or unauthorized maintenance, repair, or safety-technical control can injuries or in the worst case result in death. Continue to the device or its accessories may be damaged and any defect or other liability claims shall expire.
- Be error or damages of the treadmill suspected or detected or warnings that are unreadable, is to take the treadmill out of operation immediately and secure before further use.
- The immediate written notification of an authorized service agent is necessary.
- All maintenance substances and oils are to stay away from children, as not intended for human consumption.
- The manufacturer accepts no liability for persons, property damage or damage to property.
- The user must be in good physical and mental shape, to understand the contents of this manual and that execute different instructions according to.
- Before the use of the treadmill is highly recommended to check the State of health by a doctor. In patients with cardiac pacemakers and who are health limited, the consultation with a doctor and whose approval for the use of the treadmill is urgently needed.
- The device may be operated only on the instruction of a physician or a supervisory person. The use of the treadmill and its accessories is not permitted without a permit and without supervisor.
- Wrong running training as well as stress testing may constitute a health hazard.
- Any discomfort, dizziness or pain the training to cancel immediately and a doctor is looking.
- Neither the user nor the supervisor can be under the influence of drugs, alcohol or other drugs.

- Unattended children must not use the appliance and keep a minimum distance of 4 m for him.This minimum also applies to animals.
- No loose objects such as clothes, towels etc. should be placed on or on the treadmill. You could cause a hazard or a disability of the user.
- The safe installation and installation of all cables (power cord, interface cable, Earth potential balancing cable or similar) is required to avoid tripping sources.
- The least to be respected safety zone is directly behind the treadmill 2 m x 1 m (length x width). For treadmills with travel direction inversion, the security zone is both before and behind the machine to comply.
- The danger of indentation in the area of the lifting mechanism, as well as on the side and rear area of the running belt. Treadmills with reversal of rotation direction is an additional danger of indentation at the front of the treadmill and on the bonnet.
- The user should use the treadmill suitable clothing (fit) and sports and running shoes (no spikes / not barefoot) wear. Long hair is to ensure that the danger of the indentation in the running belt is bypassed in the event of a fall. For the same reason, tight-fitting clothes is the jewelry without long or similar bands, to acquire and to refrain from the use of devices such as wired headphones. The supervisor must alert the user in case of need to secure long hair or secure the user before fall, putting this on the chest strap that is connected to the safety bar.
- During the entire operation, the emergency stop button for the user and the Invigilator in terms of reach must be. Is recommended to use only the security guard with case stop using the reversing.
- The emergency-stop button should be activated only in case of danger.
- A sudden interruption of the running belt drive (E.g. by pressing the emergency stop button, power failure, etc.) can cause a sudden acceleration of the running belt with a slope due to the weight of the user and the gravity.
- Under no circumstances may be jumped onto the moving belt. The user must not stand on the running belt, turn around, sideways or backward.
- Upon entering the tread, and the descending is sure, not to enter the rear idler shaft. This can the belt put suddenly by the weight in motion - fall hazard!
- The setting of the load (speed, slope) must comply with the health and physical condition of the user and must be not too high.
- The barrel should be started with low speed and slowly be increased depending on the health status and condition of the user.
- The backup of the user via the safety bar with case protection line and chest harness is inevitable during sprints, off load tests, large surfaces or other increased risk.
- It may never ground in the running Belt w.
- warning that the use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Me equipment or Me system as replacement parts for internal components, may results in increased emissions or decreased immunity of the Me equipment or Me system

The treadmill does not have essential performance. Special training is not required for the people who will make the placement of the machine, however you must read carefully the instructions given in this manual.

3.2 Preparation of the patient / user

-It is strongly recommended to consult a doctor before using an exercise device.
-Subjects with a cardiac pacemaker or those who suffer from any kind of physical restriction must see their doctor and get permission before using the running machine.
-Animals are not allowed to use the running machine and must not go too near (4 m distance).
- It is prohibited to use the running machine under the influence of alcohol, drugs and/or anaesthetics.
-Training or therapy must always be performed with sports or running shoes (no spikes) and sports clothing. It must never be used with bare feet.

- Harnesses, chest belts, waist belts, patients' vests, forearm arm rests, leash and cuffs are not designed for direct skin or mucous membrane contact.

-There are dangerous capture areas/gaps on the elevation system as well as at the rear end and the sides of the running belt and rollers. Upon reverse belt rotation, there are dangerous capture areas/gaps at the motor hood and the front area as well. Make sure that nobody exposes body parts, hair, clothes, ties, towels or other parts to any dangerous capture areas/gaps.

-Subjects with long hair should use a hairnet and must be made aware of the danger that hair may be caught in the capture areas/gaps. at the rear end and the sides of the running belt, at the elevation system in case of reverse belt rotation: at the motor hood and the front area.

-Valuable articles such as watches, emblazonments, etc. must be removed before using the device, nor should they be stored in the near vicinity of the device.

- Never use shoes with spikes or studs on the standard running surface or running belt.

- In case of reverse belt rotation, always use the safety arch with chest belt system since the standard safety stop buttons and keyboard as well as standard handrails and front bar handrail might not be in reach when facing the running deck backwards. Furthermore a supervisor must be present.

3.3 Preparation of the running machine

-When the device is used daily, we recommend switching it on in the morning and leaving it in stand-by mode during the day.

- If the running machine is at an angle of elevation > 0 when switched on, it will automatically move to position zero by switching the device on. Please ensure that while driving down the elevation, no harm can be done to persons or objects under the running machine.

-The ON-/OFF intervals must not be shorter than 1-2 minutes (for models with 3-phase connection: 2-3 minutes). Otherwise it could lead to interferences and/or failure of the backup and/or data loss and/or data corruption. Too short switch on / switch off intervals lead to a deactivation of the inrush current limiter and result in an overload of the circuit fuse.

- Keep a safety zone of at least 2 m in length and the treadmills width behind the running machine and 1 x 1 m in front of the running machine. In case of reverse belt rotation, the frontal safety zone should be same size as the rear.

-The crossbar handrail, safety arch harness and/or safety stop pull cord type should always be positioned in a way that the subject can walk or run in the first (front) 40% and/or second (middle) 30% of the running surface length. When the subjects moves to the rear 30% of the running deck length, the safety arch harness and/or safety stop pull cord type triggers the stop function automatically.

-There must be a gap of at least 4 cm between the crossbar and the User Terminal due to the danger of bruising.

-It is not allowed to run with the back to the crossbar.

-The front handrail crossbar should be dismounted if a safety arch with chest belt system is installed and used.

-It is prohibited to use wheels on the running surface and belt. Thus, no cycles, wheelchairs, inline skates or roller skis are to be used.

-Treadmills which are not designed for cycling, wheelchairs, spikes or ski sticks, must not be used with those applications as this will result in serious damage to the treadmill.

-The bike or wheelchair brakes are to be deactivated (e.g. demount brake suspension) and the skate brakes

demounted during the exercise on the running machine. Remember to reactivate brakes before using this equipment outdoor again.

-The subject is to be secured by a safety arch with chest belt system for fall stop in the following cases:

-while performing sprints

-for max. endurance tests while training on running surfaces wider than 65 cm

-for children

-for subjects with all kind of disabilities, impairments (visual, hearing, balance, etc.), activity limitations and participation restrictions

-while running with shoes with spikes or studs during reverse belt rotation (or use the pull cord safety stop actuator)

- The safety arch with chest belt system must be checked for wear and damage before each use. In particular, the rope, harness and all links such as the snap hook and the rope brake are to be checked.

-All wear and tear parts of the system (rope, harness and all links such as snap hook and rope brake) are to be changed immediately in case of damage.

3.4 During treadmill exercise

-Use the medical running machines and accessories only under permanent supervision of your doctor or/and medical staff.

-Children are only allowed to use the running machine under constant supervision of a medical doctor or therapist and only when safeguarded by safety arch with chest belt system or an unweighting system.

- When using the treadmill for load tests, a medical doctor and a defibrillator are to be within reach at any time.

-Electrical equipment and a subject must never be touched by the doctor or trainer at the same time.

-The handrail crossbar should be dismounted if a safety arch with chest belt system is installed and used. Dismounting of the handrail crossbar allows more freedom of motion and is beneficial for applications where holding a front handrail crossbar is not part of the application.

-Use of the treadmill should be started with slow walking. After some minutes, the speed can be increased slowly according to the fitness level.

Never set too high loads (speed, acceleration, elevation, heart rate, duration, motion support, etc.) if the health and the condition of the subject/patient do not permit and a medical doctor has not authorized these loads. Disregard may cause injuries and dangerous health problems or even death. At high loads and identifiable risks, higher precautions are necessary. Under no circumstances should the test person/subject/patient be overloaded.

-The automatic operation of the running machine (modes profile, cardio, test, remote control via PC and peripheral devices) must not be employed if the health and condition of the test person / subject / patient does not permit and if a doctor has not authorized said operation. Disregarding this provision may lead to injuries, serious health problems and even death.

-For automatic operation, the subject/patient and supervisory staff have to appropriate exact knowledge of the expected loads before starting and anticipate an automatic load alternation (heart rate, speed, acceleration, deceleration, elevation and STOP) at any time. Higher precautions may be necessary. The treadmill belt will start moving automatically and the speed and elevation will be changed automatically after the automatic mode has been started. All users need to be familiar with the details and risks of these modes (e.g. the max. speed and elevation) so that there is no danger of encountering speeds which are too high and which may lead to injury.

- Do not use the cardio mode in case of detected or suspected interference of the wireless heart rate transmission.

-The subject must interrupt training immediately if he/she starts feeling sick, dizzy or feels pain. The patient should consult his/her doctor in this case.

-If the treadmill is being controlled via ECG, pay special attention to the ECG manufacturer's manual! The summary of clinical data and the risk management of **Cardiomed Treadmills** does NOT cover any measured parameters and/or vital

functions which are measured and/or detected by host devices (e.g. ECG, ergospirometry devices, EMG, etc.)
which are connected to the treadmill.

-WARNING: Heart rate monitoring systems can be inaccurate. Incorrect and/or forbidden use and/or overtraining can lead to serious injury or death. If the user feels faint, the training must be stopped immediately.

- If an irregular pulse is displayed in spite of flawless technical condition, please check the pulse manually or, when in doubt, consult the doctor. The battery power may be low.

- Do not jump onto the rotating running belt. Do not jump off the rotating running belt (not even towards the front).

- Do not stop moving or turn around on the rotating running belt. Never run side wards or backwards. Do not do anything which could interfere with your balance.

- The emergency stop must be within reach of the subject and the supervisory staff at all times.
- The emergency stop should only be used in an emergency, especially when there is a danger of falling. It is not to be used as a normal stop key.
- In any case of emergency, e.g. danger of stumbling and/or falling, etc: Grab the front crossbar and/or both side handrails and jump onto the foot rails (step platforms) with both feet. Press the emergency stop button immediately!
- If the treadmill is used with elevation function and the motor is switched off (e.g. by pressing the stop -button or the emergency stop button, power failure, etc.), the bodyweight of the subject and the force of gravity may cause an acceleration of the running belt. In this case, the user must not step on the rear roller when getting on or off the running surface; the gravity force might cause a movement of the running belt.

3.5 Emergency dismount

- Subject is conscious and aware of danger.
- Subject grabs the handrails
- Subject jumps off the running belt onto the foot rails
- Operator / subject hits the emergency off
- Subject is conscious but not aware of danger.
- Subject stumbles and falls into fall prevention device.
- Treadmill stops
- Operator / subject hits the emergency off
- Operator helps subject stand up again.
- Operator helps subject exit the device.
- Subject lost consciousness and is hanging in the fall prevention device.
- Hit the emergency off.
- Call a medical doctor.
- Call one or more persons, strong enough to carry the subject.
- Inform the third person that you will open the buckle of the safety harness
- Open the buckle of the safety harness.
- Subject will slide into the other person's arms.
- Render first aid.

3.6 Machine Care

	In case of any detected and/or assumed malfunctions and/or defects or unreadable safety labels, the device must be discontinued immediately. The device must be marked accordingly and its operation discontinued (e.g. by pulling the power plug and affixing a warning/defect label on the power plug). The supplier and authorized service personnel are to be informed in writing immediately.

-Damaged socket connections, wires and pressure control switches are to be replaced immediately by trained and authorised personnel.
- Fluid entering into the device is to be removed immediately by the authorized customer service and a safety check is to be performed.
- All wear and tear parts are to be replaced at least every two years or earlier if necessary due to first sign of wear and/or damage.

4 Operation

4.1 General

The normal position of the walking or running subject should be at the front 40% of the running deck length. As much as 70% of the front of the running deck length can be utilized. The rear 30% of the running belt length should not be used and should provide a buffer zone. Safety devices (pull cord safety actuator, safety arch with chest belt system and stop function, unweighting systems) should be adjusted so that the subject cannot use the rear 30% of the running deck length and the automatic stop function stops the running belt.

The patient/subject is placed onto the correct position on the treadmill. Before using the treadmill, the patient/subject has to be carefully instructed to follow the speed of the running belt and to keep his position, but not hold the handrails during exercise.

Healthy subjects should hold the handrails only in case of emergency or for weight relief. The patient is not allowed to jump or turn around on the rotating belt. Furthermore, he/she should be informed about emergency procedures. Depending on the prescribed or intended test or training, further devices may be necessary (e.g. heart rate transmitter, ECG or ergospirometry device). The doctor and/or the medical staff are to supervise the patient during the complete test or training. If the heart rate transmitter is used, adjust the belt length so that the belt fits tightly but is not confining. The belt should not loosen while exercising

Position of Subject and Operator

1) Position of subject (initial contact)

1a) Optimal position 40%, front

1b) Tolerated position 30%, middle running area

1c) Not tolerated position / buffer zone 30%, rear

2) Intended position of operator

The operator must be within reach of the emergency off at all times.

If the operator is not able to reach the emergency off button at the UserTerminal (body height, obstacles, etc.), the operator

must install an additional emergency stop within reach (see accessories).

3) Patient environment acc. to IEC 60601-1 device + 1.5 m

There must be no electrical devices within this area, which are not part of an ME-System with the device.

Do not touch the subject and external electrical devices at the same time.

4.2 Emergency Stop, stop buttons, stop functions and safety features

In case of emergency, e.g. danger of stumbling and/or falling, etc., grab the front crossbar and/or both side handrails and jump onto the foot rails (step platforms) with both feet.

The emergency stop button is to be pressed immediately!
CMT - 2058 is in compliance with the norm EN 957-6 and offers more safety features than required, as shown in the following tables.

	-Use the emergency stop only if in danger. -The emergency stop is not to be used as a normal stop key.

Type of stop	Function	Interface communication	How to restart
	-mushroom switch is hit -running belt & inclination system stop fast - machine is cut off from main power of drive motor and inclination system	**Interrupted** during cut-off from main power	-wait 1 minute -pull mushroom switch - push “ON” button at main power switch

5 Service manual

Some simple maintenance and monitoring (no repair work!), as described, can easily be done or even have to be done by yourself. All kind of installation and repair work as well as most maintenance work is to be carried out only by trained and authorized technicians who have been certified by **Cardiomed Treadmills**. The following symbols will indicate which work can be done by the customer and which work has to be done by authorized technicians:

	The customer / user should perform this maintenance and monitoring work. Some safety checks or monitoring (for examples of harnesses and ropes, running belt condition and position, etc.) have to be performed on a daily basis. For this reason it is not practical to contract certified technicians for such tasks. However, where it is practical, all maintenance and monitoring work marked with this symbol can also be performed by certified technicians.
	All installation, maintenance, repairs and monitoring work indicated with this symbol must only be performed by trained, authorized technicians who have been certified by Cardiomed Europe. Customers/users must not perform these kinds of tasks.

We recommend calling our competent service team or entering into a maintenance contract for a routine service at an interval of 6 or 12 months for standard machines and standard applications. A form for registration of your institution and device is included in the delivery. In order to be able to supply you with the latest technical information and service, it is important for you to fill out the form. Therefore please fill out the form for registration immediately and send it back.

5.1 Safety notes, warnings, precautions

5.1.1 Room conditions

- The bearing capacity of the floor and the height in the building has to be considered before installation.
- Install the device on a sturdy floor and take an adequate precaution to prevent the device from turning over. If the floor is not strong enough or the installation site is not adequate, this may result in injury from the device falling or tipping over.
- Keep a safety zone of at least 2 m in length and the treadmills width behind the running machine and 1 x 1 m in front of the running machine. In case of reverse belt rotation, the frontal safety zone should be same size as the rear.
- **Cardiomed Treadmills** devices must not be used outdoor and/or in environmental conditions other than those specified in the chapter "Environmental requirements", (e.g. outdoor, in wet and humid areas or a place where it is likely to be splashed by water or rain water, swimming pools, saunas, environmental chambers, high-pressure-, low-pressure, altitude- and oxygen-chambers, etc.). Deterioration of the insulation, current leakage or electric shock may result.
-The installation room has to meet the requirements of DIN and VDE installation directives.
-Never install the device in a flammable or volatile location. This may cause explosion or fire.
-Never install the device where acid or corrosive gases are present as current leakage or electric shock may result
due to corrosion.
- For high performance applications a 3-phase powered treadmill and 3-phase power supply is recommended

5.1.2 Transport and Installation

-The manufacturer does not assume liability for any damage, complaints or missing parts which are not reported immediately upon delivery on the packing list/delivery note.
-In order to ensure proper installation and safety, the manufacturer, an authorised service crew or an authorized dealer must always transport and install the devices.
-Failure to comply with the conditions listed in this operation and service manual and listed in the operation and service manuals of other respective devices which may be used in connection with this device, failure of performing recommended maintenance and safety inspection intervals, unauthorized maintenance or amendments of the design and/or performance and/or specifications and/or labeling of the devices shall absolve Cardiomed Europe from any responsibility for the safety, reliability and performance of this equipment.
-Always ground (earth) the device to prevent electric shock. If the power supply outlet is not grounded, it will be necessary to install a ground by qualified engineers.
-Never ground the device through a gas pipe, water main, telephone line or lightning rod. Such grounding may cause electric shock in the case of an incomplete circuit.
-Connect the device to a power source as indicated on the name plate (rating label) attached to the unit. Use of any other voltage or frequency other than that on the name plate may cause fire or electric shock or may cause other damages.
-Plug the running machines directly into the wall socket with a protection system. Each running machine should be connected to a separate circuit. The socket is to be marked with name and serial number of the running machine. The use of extension cables or a multiple plug socket is prohibited.
-An overload or voltage drop (even temporary) of more than 20 % of the mains voltage might cause malfunctions and/or defects and might totally switch-off the running machine. In the event of such high voltage drops or total power failure, the running machine switches off and the running belt stops. To start again, switch on the running machine at the main „ON" switch.
-When connecting treadmills to the multiple safety socket, there are no performance limitations to expect at low performance applications (walking, slow running). For high-performance applications (fast running, sprints, etc.,) the use of the multiple safety socket can result in performance limitations.
-For treadmills used in the medical field:
-All devices are to be connected via a potential compensation cable in „star connection" with the potential compensation bar.

-First connect the potential compensation (potential equalization) with the corresponding plug pin (next to the main switch on the front) and then connect the mains plug.

-During electric safety measurements and tests (leakage currents, etc.) the potential equalization cable has to be disconnected temporarily.

-Due to the very high electrical load of treadmills, do not connect more than one treadmill or other electrical device with high load to the multiple safety socket. Use a dedicated line only.

-After adjusting the running belt, the allen key must be pulled out of the screw immediately after usage due to risk of injury!

-There are dangerous capture areas/gaps at the elevation system as well as at the rear end and the sides of the running belt. At reverse belt rotation there is also danger at the motor hood and front area.

-It should be ensured that all cables (power connection, interface, potential equalization, etc.) and accessories are installed properly and safely and that nobody can stumble or fall over the cables and/or accessories.

-The connection of the gas pressure container has to be checked for MOT-admissibility

-Absorption, cleaning and disinfecting chemicals are to be kept in the appropriate reservoirs.

-All lubrication material and all other parts should be kept away from children and animals.

-Do not modify the running machines and do not connect to other equipment which is not explicitly declared compatible by all involved manufacturers.

-Only connect accessories, software and host equipment if it is confirmed as compatible by all manufacturers.

-It is not allowed to connect sports treadmills to medical devices such as ECG-systems.

-Connecting a running machine to a medical device results in a medical system. Only trained staff is authorized to perform this connection. Always use IEC 60601-1 approved potential isolation components. This medical system is to be connected via a potential balance cable with the provided connector bolt and bearing within the designated room.

-Do not insert metal objects such as a pin or a wire into any vent, gap or any outlet on the device. This may cause electric shock or injury by accidental contact with moving parts.

-Do not touch any electrical parts (such as power supply plug) or operate switches with a wet hand. This may cause electric shock.

-Never put containers with liquid on the device as this may cause electric shock or short circuit when the liquid is spilled.

-Never bind, process, or step on the power supply cord, or never damage or break the power supply plug. A broken supply cord or plug may cause fire or electric shock.

-Do not use the supply cord if its plug is loose. Such supply cord may cause fire or electric shock.

-When removing the plug from the power supply outlet, grip the power supply plug, not the cord. Pulling the cord may result in electric shock or fire by short circuit.

-Disconnect the power supply plug before moving the device. Take care not to damage the power cord. A damaged cord may cause electric shock or fire.

-Disconnect the power plug when the unit is not used for long periods. Keeping the connection may cause electric shock, current leakage, or fire due to the deterioration of insulation.

-If the device is to be stored unused in an unsupervised area for an extended period, ensure that children do not have access.

-Do not put packing plastic bags, plastic foils or other materials within reach of children as suffocation may result.

5.1.3 Maintenance and safety inspections

-Maintenance and repair of the devices (also opening of the device) have to be performed by service engineers authorized and certified by **Cardiomed Treadmills**, preferably within the scope of a maintenance contract. The installation by unqualified personnel may cause electric shock or fire or other damages or electric shock or injury due to a malfunction. Never disassemble, repair, or modify the device yourself.

-In case of any detected and/or assumed malfunction and/or defects and/or unreadable safety labels, the device is to be disengaged immediately. The device is to be marked and secured against operation and the supplier and authorized service personnel has to be informed in writing immediately.

-Before intervention in the device, switch the running machine off and pull the mains plug from the power supply.

-During all maintenance work and safety tests, ensure that no third parties are directly or indirectly in contact with the device under test and/or the technician performing the test. Keep a safety zone of 2 m radius clear.

-Due to environmental influences, interior climate and type of application (for example frequent short-run operation or infrequent long-run operation, etc.), the required automatic oil setting of the treadmill can deviate extensively from the factory setting.

-In case the required lubrication, quantity and quality is not assured due to lack of inspections by the user and/or lack of maintenance by authorized **Cardiomed Treadmills** service technicians, early damage to the running belt and running surface can occur and warranty will expire.

-In case of any maintenance work on the treadmill, ties have to be removed. The tie might be pulled in and the person wearing will be strangled.

5.2 Installation

5.2.1 Unpacking and packaging

Unscrew only the base of the package if you want to keep the package as it is.

When receiving the machine in a crate or unpacked, make sure the machine, the accessories and/or the packaging is not damaged. If you discover any damage and/or missing parts make a note on the packing-list / delivery note of the carrier. Inform **Cardiomed Treadmills** and your dealer immediately in writing about any damage and/or missing parts.

The manufacturer does not assume liability for any damage, complaints or missing parts which are not reported immediately upon delivery on the packing list/delivery note. Before unpacking the machine and accessories, read the instructions on the crate. Make sure that the machine, power connection cable or any optional equipment will not be damaged during unpacking. Pay special attention to small parts, so that you do not dispose of them or any instructions with the packaging. Within Germany, most devices are delivered and assembled by **Cardiomed Treadmills** directly or by an authorised forwarder. If delivered by Cardiomed Europe, the packaging will be removed and recycled.

If the running machine is delivered by a carrier, you can recycle the packaging yourself or send it back to the manufacturer (transportation to be paid by the customer). Often a recyclable transport tool, packaging material or a transport fuse (metal angle with screws) is included in the scope of delivery. In some cases, a credit note can be granted. Special packaging and/or carrier constructions must not be disposed unauthorized.

5.2.2 Storage

Store the devices at a temperature of – 20° ... + 50° C. All devices can be stored without power connection and without operation for a period of 6 – 9 months. After this period, batteries in the device may be discharged. Maintenance and/or a new setup/programming of the device by an authorized **Cardiomed Treadmills** technician may be necessary.

5.2.3 Environmental requirements / room configuration

The bearing capacity of floor and ceiling in the building must be higher than the weight of the machine. An authorized body of the operator must certify the bearing capacity for the **Cardiomed Treadmills** device.

Running machines are not to be used in medically utilized rooms with a danger of explosions or in easily inflammable atmospheres. The devices must not be installed near to e.g. an x-ray device, motors or transformers with high voltage connection, as the electric and magnetic interference can falsify measurements or even render them impossible. High

voltage lines must be avoided nearby the device. **Cardiomed Treadmills** electrical devices with mains connections must neither be used in wet and humid areas (e.g. swimming pools, saunas, etc.) nor in environmental chambers. If not stated otherwise in the delivery information, **Cardiomed Treadmills** devices are designed for operation in normal climatic surroundings:

Temperature: + 10° ... + 40°C

Relative humidity: 30 ... 70 % (non condensing!)

Air pressure: 700 ... 1060 mbar

Maximum operating altitude: approx. 10,000 feet (3000 m), without pressurization

The running machine should be protected from high humidity. Vents are not to be covered, as this would hinder the air circulation.

5.2.4 Mechanical installation

-Keep a safety zone of at least 2 m in length and the treadmills width behind the running machine and 1 x 1 m in front of the running machine. In case of reverse belt rotation, the frontal safety zone should be same size as the rear.

–The floor must be very solid, stable and firm. If the floor is bouncing, the treadmill will bounce too which can affect

running characteristics and energy consumption data and which can also create noise in stories underneath the floor.

-Put a gymnastic mat (or something similar) in front of and behind the running machine to protect the subject in the event of a fall. Place the device on a rubber mat as large as the device to protect the floor from dust and scratches, to ensure a firm stand and to reduce noise.

-The designated space for the running machine must allow even and horizontal positioning of the device.

-Models with levelling sockets (adjustable "feet") at the rear of the running machine have to be adjusted so that they have a firm stand to avoid noises such as knocking or rattling during the training. Check the weight load pressure on the leveling sockets (weight of the running machine at the rear), by trying to lift the frame off the ground at the rear of the running machine one side after the other. Thus, it can be determined whether the same load is on both sockets.

-The leveling sockets and the front wheels of the elevation system may cause a print in the flooring.

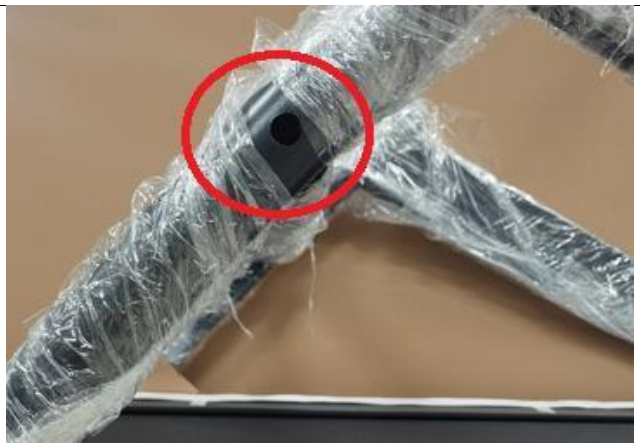
-For models with a running surface of 200 x 75 cm or larger, ensure that the floor is even and horizontal and that the entire base frame rests on the floor. The device is equipped with leveling sockets, but they should only be used in case of an uneven floor.

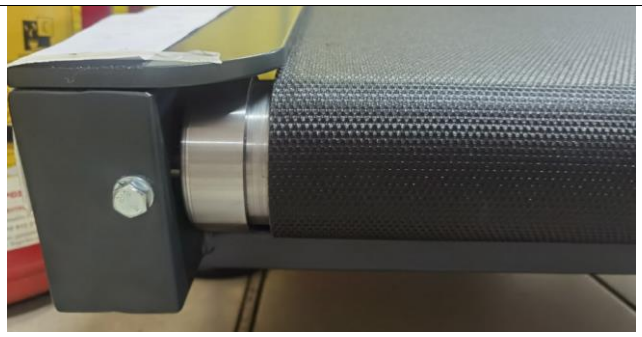
-After installation or change of location, check and, if necessary, adjust the running belt (see chapter 8.5 and 8.6 for

maintenance instructions), so that it is placed exactly in the middle of the two rollers.

-If the running machine has been installed safely and horizontally, it can be plugged in “Electrical installation“) and taken into operation.

-It is recommended to lubricate the running surface with 30 ml silicone oil before using it for the first time.

No.	Illustration	Description
1.		Unscrew lightly the screw insight the hole of the handrails. Not completely 
2.		Unscrew completely the screws of handrails in the front of the treadmill.
3.		Get up the handrail and screw them again
4.		Plug in the white cable. (right side in the front) It is for the emergency stop.

5.		Perfect alignment Otherwise, the conveyor belt may chop
6.		Adjust the tension on the belt if looseness is noticeable. The belt tends to hesitate or stick. NOTE: When running belt is too tight the edge of belt will curl causing premature running belt failure. For instructions go to chapter **6.6**

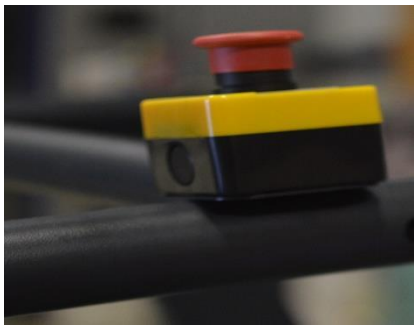
5.2.5 Electrical Installation

At a gradient, the treadmill when you turn automatically moves to the zero position. Before switching on the device is basically to check whether there is danger of injury by a lowering of the tread or that there are still no objects under the treadmill.

The treadmill should connect in an electrical system with type **C16 circuit breaker.**

The main switch is located on the front of the treadmill at ground level and can be switched on in accordance with the safety and danger notices. It takes a few seconds, until the unit is ready for use, because it performs a self-test right after power-on.

No.	Illustration	Description
1.		Plug the power cord of the running machine directly into the wall socket. The use of extension cables or multiple plug sockets is not allowed.

2.		Release all emergency stop buttons of the running machine.
3		The zero-level switch must be closed in order to start the treadmill
4.		Plug the USB/ Serial into the appropriate gate. Switch on the running machine by using the red switch in the Front Terminal. If the indicator does not flash up, please check the power supply, the expulsion fuse and the emergency stop.
5.		On the switch **SW1** (left to right) the third option is about kilometers or miles. Up for kilometers and down miles. The fourth option the operation in serial gate or USB. Up for serial and down for USB.

6.		If you have display, you could open it from the back in the left side. Then will be opened automatically in few seconds the cardiomed programm.

6 Maintenance and safety inspections

-Maintenance and repair of the devices (also opening the device) are to be performed only by service engineers authorized and certified by Cardiomed Europe, preferably within the scope of a maintenance contract.

- In case of a detected and/or assumed malfunction and/or defects and/or unreadable safety labels, the device is to be disengaged immediately. Mark the device and ensure that it cannot be operated. Inform the supplier and authorized service personnel in writing immediately.

-Disregarding warnings, notifications of intended and forbidden use, precautions as well as

unauthorized or lack of maintenance and/or regular safety checks may lead to injuries or death and/or can damage the device. Furthermore, it will result in loss of any liability and warranty.

-Before intervention in the device, for safety reasons, switch the running machine off and pull the mains plug.

-During all maintenance work and safety tests make sure that no third parties are directly or

indirectly in contact with the device under test and/or the technician performing the test. Keep a safety zone of 2 m radius clear.

6.1 Preventive maintenance

The **Cardiomed Treadmills** authorized service engineers are happy to help you in case problems occur.

Preventive maintenance can prevent future problems and is indispensable for the safety of technical devices. Therefore, ask our service department for an annual preventive maintenance contract, which is highly recommended by the manufacturer.

Some basic regular maintenance and regular safety checks as stipulated in the following chapters are obligatory!

Before cleaning the device turn the main power switch to OFF, and disconnect the treadmill from its power outlet. Never use wet cleaning materials near a power source: you could suffer an electrical shock.

To preserve the condition of your warranty, make sure that all repair procedures (other than normal maintenance) are performed by an authorized and qualifies service provider.

Use only Cardiomed's replacement parts. Using other parts may void your warranty and may cause your treadmill to malfunction.

Daily Maintenance

- Ensure that the treadmill is functioning properly.
- Visual inspection of treadmill and walking belt for damage and wear.

Weekly Maintenance

- Vacuum around and under the treadmill. Clean all exposed surfaces with a vacuum cleaner. Avoid moving the treadmill from its original position as moving it will compromise the original belt tracking setting.
- Check Running Belt Tension Adjustment
- Observe Running Belt Tracking Adjustment correct as required.

Monthly Maintenance

- Belt Cleaning and Inspection.

Semiannual Maintenance

- Evaluate the condition of the Running Deck and Running Belt.
- Running Belt / Drive Belt adjustment needs to be performed to assure proper belt alignment.
- Check Running Belt Tension Adjustment.
- Check Drive Belt Tension Adjustment.
- Clean and lubricate the treadmill elevation screw.

Belt Cleaning and Inspection

1. Turn treadmill main power switch ON.
2. Start treadmill at 0.5 MPH. With a damp small towel wipe excessive dirt from running belt keeping the towel in the center of the length of the treadmill. Avoid getting the towel near the rear roller.
3. When belt is clean stop treadmill.
4. Inspect running belt for tears or nicks. If damaged, replace the running belt.
5. Perform Running Belt Tracking Adjustment and Running Belt Tension Adjustment.

Running Belt Tension Adjustment

The running belt may stretch and loosen with regular use. This looseness is noticeable when the belt tends to hesitate or stick. Adjust the tension on the belt by following the procedure and referring to the illustration below.

1.Turn the treadmill’s power switch to ON.
2. Start treadmill and increase to 1.0 MPH
3. Start walking on the treadmill, grab side handrail and apply pressure with your foot to create resistance on running belt.
4. If running belt hesitates or slips on front drive roller, tighten both tension bolts ½ turn (Clockwise).
5. Repeat steps 2 thru 4 until running belt stops slipping.

NOTE: When running belt is too tight the edge of belt will curl causing premature running belt failure.

Running Deck Maintenance

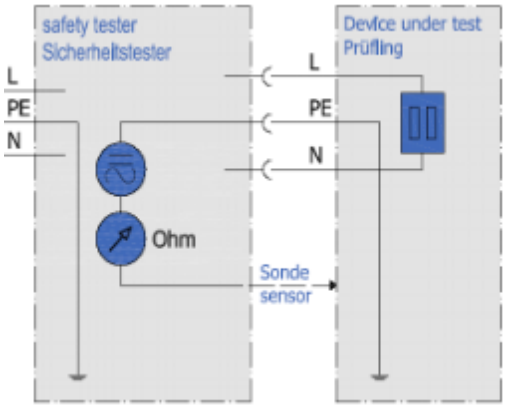
The running deck is maintenance–free and offers (2) running deck surfaces to double the life of ordinary treadmills.

NOTE: Do not use silicone sprays to wax your treadmill deck, Use silicon oil. Using silicone sprays will void the warranty. Such sprays can bring about surface changes that may result in hesitation or excessive belt slip.

If running deck surface becomes grooved due to wear, it can be renewed by flipping the deck to the opposite side.

Before switching the device on the user always has to check visually:
-the circuit cable
-plugs
-outlet socket
-circuit entry of the device
-accessories such as harnesses and cables where applicable and available

6.2 Immediate maintenance



Immediate maintenance is necessary if:

-the device has been under high mechanical stress (push, power supply cable and/or interface cable defect through driving over it or pulling it)
-fluid has entered the device
-cable and/or connector plug have been damaged
-coverings and/or safety warnings have fallen off / broken
- connections made of rubber show cracks (mainly the running belt and the drive belt)
-the running belt does not run concentrically
-the running belt is not well-lubricated
- a defect or malfunction of the device has been detected or is suspected.

Only a properly and regularly serviced device is safe.

6.3 Regular inspections / examinations

For use in sports and medical fields as well as for private, public and military applications, refer to the date on the inspection sticker on your device.

To keep the condition of the device in due order, examinations have to be performed regularly according to the local laws and requirements of your country .

For **Cardiomed Treadmills** sports and medical running machines, a maintenance interval respectively technical safety checks of one year have been set. These examinations are only to be performed by trained and authorized electricians.

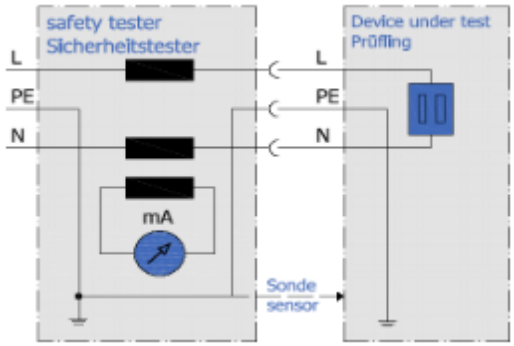
The main inspection sticker on the device (e.g. running machine) also certifies the inspection of the optional equipment and the accessories. However, inspection intervals for optional equipment and accessories may deviate significantly from inspection intervals of the main device. Read the manuals for details.

6.3.1 Visual inspections

-Carry out visual inspection for damages of device and complete accessories: internal space, engine compartment, connecting lead and the right position of the tensile relief and plug, ground wire connections, etc.

- Carry out visual inspection of mechanics and wear and tear parts: driving belt, tension roller, running belt, lifting element with fixing bolts, welding seams at the frame, tight fitting of all screws and nuts. Follow the appropriate maintenance list.

-Clean device and engine compartment/internal space. Remove dust and dirt from the cooler openings of the fan housing and the cooling air ducts of the drive motor, as well as from the ventilation slots and the cover of the perforated plate of the frequency inverter.
-Attach legible and complete hazard notes according to the instructions. Check the warning signs, protective covers, step platform, engine hood and plastic cover installation channel in the engine compartment for damage and replace if necessary.



-All protective resistance connectors which can be reached from the outside must be examined for their correct value and correct labelling.
-Check capture slot at the rear end and at reverse belt rotation in the front as well and adjust if necessary.
Capture slot has to be < 8 mm, according to regulation draft 60601-2-xx © IEC:200X 62D/479/NWIP 2003- 05-18 and according to EN 957-1. See chapter entitled “Test finger“, which has a diameter of 9.5 mm (+ 0.1) at the front.

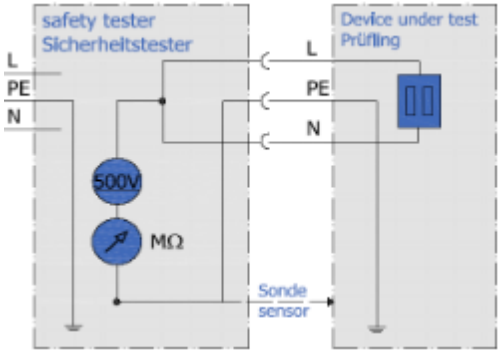
6.3.2 Isolation resistance (R_{ISO}) measurement

-Resistance between „bridged“ L+N and Protective Earth- Connection.
-Make sure that all isolations that are under stress of the mains voltage, are considered. All switches and contactors should be connected.
- The measurement is to be performed with measuring devices for the isolation resistance measurement according to VDE 0701/0702 (sports and fitness machines) or VDE 0751/IEC 60601-1 (medical devices).

6.3.3 Protective earth resistance (R_{PE}) measurement

-Resistance between housing and protective earth connection.
-The low resistance pass is to be controlled according to VDE 0701/0702 (sports and fitness machines) or VDE 0751/IEC 60601-1 (medical devices) by the protective resistance measurement with a measuring device for the protective earth resistance measurement.
The connecting lead is to be moved while measuring for at least 5 sec. If the resistance thus changes, it is highly probable that the cable or the connectors have been damaged. In this case the cable should be replaced and the device repaired immediately.

6.3.4 Equivalent (alternative) leakage current (I_{EDL}) measurement



-Impedance measurement, indicating the current in the
protective earth cable
-The measurement is to be performed by a measuring
device for leakage current measuring according to VDE
0701/0702 (sports and fitness machines) or VDE 0751/IEC 60601-1 (medical devices).
-The measurement is equivalent to the single fault earth
leakage current based on IEC 60601.

6.3.5 Leakage current measurement

direct method: measurement in PE - line

-The measurement is to be performed by a measuring device for leakage current measuring according to VDE 0701/0702 (sports and fitness machines) or VDE 0751/IEC 60601-1 (medical devices).

-The leakage current of the equipment is to be measured under operating conditions if - despite closed switching - not all isolations are considered

- Measurements must be made on both poles.

-The unit to be tested must be isolated against earth potential.

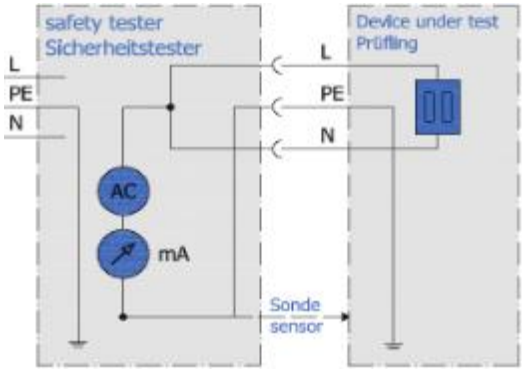
-The measurement is equivalent to the earth leakage current with grounded applied parts based on IEC 60601.

-During the direct method, the device being tested is temporarily without PE-connection. Especially devices without potential isolation transformer (sports devices) temporarily have a voltage of approx. 120 volts on the metal housing and frame parts. Do not touch the device being tested during this measurement!

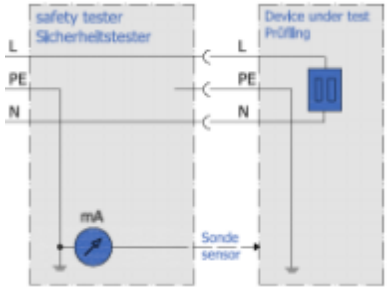
6.3.6 Electric safety tester and measurements

Picture: example for electric safety tester based on IEC 60601-1.

For all measurements read operation manuals of the measurement devices carefully and verify the values and intervals with the local guidelines and laws. An appropriate inspection record for all measurements and instructions is available at the manufacturers. See also detailed instructions and special protocol . Upon first installation at the customer's site and before first commissioning of the running machine, the "first measured values" have to be determined and recorded on the special protocol and marked as "first measured values". During each preventive maintenance and/or regular maintenance and/or after each repair of the device (even if it was only mechanical repair work!), all above-mentioned electric safety measurements and are to be performed again. All values have to be compared with the "first measured values" and permissible range of tolerance specified in VDE 0701/0702 (sports and fitness machines) or VDE 0751 / IEC 60601-1 (medical devices). In case the measured values are not within the permissible range of tolerance specified in VDE 0701/0702 (sports and fitness machines) or VDE 0751 / IEC 60601-1 (medical devices), the device must be repaired until the values are within the specified range of tolerance. In the event that the device cannot be repaired accordingly and immediately, it must be marked and secured against further operation. Inform the supplier and authorized service personnel in writing immediately.



6.3.7 Building installation: Electric checks, protective earth function, RCD, leakage current



The customer/operator has the duty to check the building installation (electrical installations and stationary installations) at regular intervals according to regulation BGV A3 of the professional association respectively the

stipulations of the legal accident insurance every four years, at their own response and expense, for the correct functioning and safety of the complete electrical building installation. For operating sites or special rooms such as

environmental / climate chamber, pressure chamber, installation with extraordinary hazards, the prescribed interval is one year or shorter, if applicable. All mentioned special installations are only available at extra charge and with special design!

Use ground wire plugs with tested ground wires only. Existent earth leakage current protection switches, so-called RCD (residual current operated protective device), at the building installation must be tested by the customer/operator on a monthly basis for proper functioning.

The testing procedure normally involves pressing a button at the RCD switch (not the "main handle"), thereby simulating an earth leakage current. The RCD switch will then shut down the electricity supply. These tests should be carried out by the customer/operator when the normal operation is not disturbed and all electrical devices and computers are switched off and nobody is endangered. The RCD switch test may cause a shutdown of the complete or partial power supply of the building, depending on the electricity circuit. It should be pointed out that these are not regulations, standards or safety checks specifically for Cardiomed running machines, but rather apply to all electrical devices and building installations worldwide, including all electrical devices with metal housing.

6.4 Lubrication of the running belt / running surface

Do not touch the running belt while it is in motion.
This maintenance must be supervised by a second person, who could press the emergency stop
button if necessary.

The lubrication level must be checked periodically by the user. For this procedure, unplug the running machine from the power supply, place a hand between the running belt and running surface to ensure that the surfaces are oiled and not dry. A special "lubrication test", utilizing a tissue [cos14379]) is available from **Cardiomed Treadmills** as an alternative way to check the lubrication level of the running belt and deck. The use of bikes, wheelchairs or skis on the running machine as well as environmental conditions will affect the lubrication interval! Running machines with automatic oiling systems must also be checked periodically by the user to ensure correct lubrication levels as the type and frequency of use can influence the amount of oil needed. (This can be compared to the need to check a car's engine oil periodically as oil usage depends on driving style and can vary dramatically). Cardiomed Europe should be contacted immediately if dry chafing noises are heard during use or oil is noticed on the running deck. An **Cardiomed Treadmills** authorized technical service engineer will then advise what corrective action needs to be taken. Use original **Cardiomed Treadmills** special oil only. The use of other oils or the failure to lubricate regularly may damage the running belt, running deck or the lubrication system and reduce warranty and liability. **Cardiomed Treadmills** recommends a maintenance contract with an authorized **Cardiomed Treadmills** service partner. Routine maintenance does not reduce the necessity to regularly control the lubrication levels. Regular maintenance and maintenance of the correct lubrication levels greatly prolong the life of the running belt and running deck!

6.5 Control and tightening of the running belt

The belt may loosen after a while or if it has been adjusted wrongly. In this case a backlash occurs between the driving

shaft and the belt, i.e. when weight is applied to the belt by stepping on it, the belt slows down. The belt tension should be checked as follows:

- Visually inspect the surface for cracks. In case of a crack replace running belt immediately.
- Open the motor hood at the front. Take care that nobody gets his hands into the motor.
- Press the "START/Enter" key for manual mode and select a speed of 1 to 1.5 km/h.

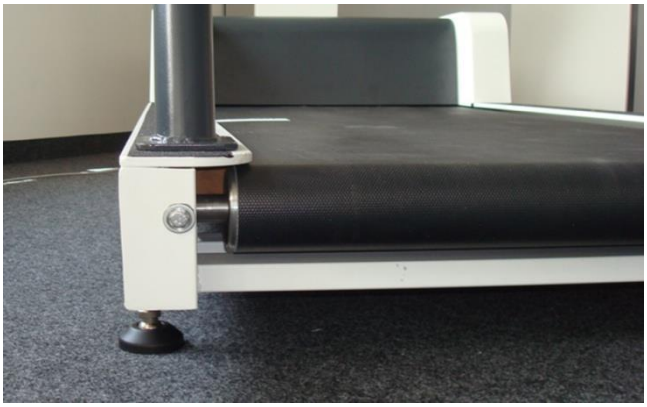
-Stand on the running belt. Hold on to the side handrails with both hands and try to block the rotation of the running belt by
stemming yourself against the belt with your feet. If necessary, 2 people can do this.
-Try to block the movement of the running belt for max. 10
seconds. The driving shaft and the motor shaft should not be turning during that time. Otherwise the running belt has to be tightened (or the driving belt).

6.6 Adjustment (centring) of the running belt

-Attention: Dangerous gap/capture area at the tail shaft at the back of the device (belt re-entryzone). Take care that long hair and loose clothing are not caught in the gap of the tail shaft.
-For safety reasons, the adjustment procedure must be attended by a second person who can immediately press the emergency stop button in an emergency.
-Switch off the running machine and pull the mains plug before intervening.
-In case of any maintenance work on the treadmill, ties have to be removed. The tie might be pulled in and the person wearing will be strangled.

If necessary, lubricate the running belt before adjusting it. Lubrication may have impact on the centering of the belt. Adjust the running belt while the device is in operation with the help of the left trimming screw of the running machine. Use the enclosed hex socket (8 mm). Operate the running machine at 12 km/h without elevation. Monitor the running belt for at least 2 minutes. It should be in a centre position on the rear roller (tail shaft).

If this is not the case, please do the following:
-Move the running belt to the right by turning the LEFT trimming screw to the right.
-Move the running belt to the left by turning the LEFT trimming screw to the left.
-If the discrepancy is only minor, the screw should only be turned max. ¼ turn; in the case of major discrepancies turn the screw max. ½ turn.
-Observe the running belt after each alteration for at least 2 minutes. For control purposes, operate the running machine at 5 km/h and 20 km/h.
-The adjustment procedure is finished if the running belt stays in the centre of the rear roller (tail shaft) after having been operated at a speed of 12 km/h for at least 4 min.
-Uphill run and other running styles may lead to locomotion of the running belt. +/- 2 cm are to be considered as a tolerance zone. As long as the running belt returns to the centre at a speed of 12 km/h, it must not be readjusted. The running belt will remain in the adjusted position for a period of months if it has been adjusted correctly.
-During "reverse belt rotation" (downhill run), a re-adjustment of the belt position (centering) is required.
-By evenly turning the left and right trimming screws to the right, the running belt can be tightened if necessary.



Note: Verify that the white stripe from the running belt is in side the guide in the axe.

6.7 Checking the tension of the driving belt with the "slipping-test"

The "slipping-test" can detect if the drive belt has too low tension. The "frequency-test" must be used (see next point) to exclude too high tension. The driving belt tension is checked as the running belt tension:

- Block the running belt at a speed of 1 - 1.5 km/h.
- Ensure that there is no backlash between the motor shaft and the driving belt.
- Ensure that the tension at the bottom run (see picture) is between 98 Hz and 103 Hz (frequency at oscillation).
- The noise at higher speeds and the correct course on the pinion should be considered.

6.8 Side step platforms: check for non-slipping

Each running machine has an anti-skid area on both sides next to the running surface. These step platforms offer safe footing if it is necessary to suddenly leave the running surface. Check the anti-skid areas at regular intervals and replace them at signs of wear and tear.

6.9 Hygiene and cleansing

- For safety reasons, switch off the device and pull the plug before cleansing, disinfecting and before opening.
- Pay attention to the safety notes, warnings and precautions of the running machine, the accessories and the disinfectant.

The Cardiomed's Treadmill devices are neither sterile nor can they be sterilized.

Pay attention to the operating instructions of the respective devices and accessories. Chemicals needed for application or cleansing should be stored in appropriate reservoirs so as not to confuse them. The surfaces of the treadmill can be cleaned with a light moistened cloth. Before use of cleaning and disinfection substances, always test the compatibility of the substance at poorly visible places. In the event that patients with communicable diseases use the treadmill, the treadmill must be disinfected at the discretion of the doctor or medical stuff before and after the treatment. This must also be done when a communicable disease is merely presumed.

6.9.1 Cleansing of outside and applied parts

Spray contact surfaces, impact, wipe and rub off. Spray disinfectant onto a tissue and rub clean any surfaces that may be contaminated. Always follow the manual of the disinfectant

manufacturer, especially the safety warning and regulations regarding disposal.It is recommended to be used a product with this Composition:

Active ingredients: Glutaral 50 mg/g,

benzyl-C12-18-alkyldimethyl-ammonium chlorides 30 mg/g,
didecyldimethylammonium chloride 30 mg/g.

The cleaning product is supplied as a concentrate. Completely wet the parts of medical devices and other washable surfaces with an adequate amount of solution. To remove disinfectant residues from sensitive plastic surfaces of medical devices, wipe surfaces with a cloth soaked in water (at least drinking water quality) after the exposure time. Please follow the manufacturer's instructions. maintenance disinfection of hard surfaces incl. virudal efficacy: 0.5% 1 hour exposure time Rinse cleaning equipment well with water. Contact between aldehyde-based and amine-based products must be avoided. Therefore – especially if work has previously been carried out with an amine-based product – an intermediate cleaning must be carried out before using for the first time.

Use disinfectants safely. Always read the label and product information before use.

6.9.2 Cleaning of the interior

The interior should be cleaned every 6 months. The fans inside the machine and the moving running belt accumulate dust and sweat. For this reason frequent interior cleaning is highly recommended for all treadmill models.

Depending on your model, lift up the motor hood or remove bellow from upper frame. Clean the interior of the running machine by removing dirt with the help of a vacuum cleaner. Pay special attention to the ventilation net of the drive motor and the cover of the frequency inverter. For devices with an external control unit, the internal space of the control unit must be cleaned as well.

7 Trouble shooting

In case of a detected and/or assumed malfunction and/or defects or unreadable safety warning label, disengage the device immediately and mark it as such. Furthermore, secure the device against further operation and inform the supplier and authorised service personnel in writing.

7.1 Mechanical noise problems

If knocking or rattling noises are heard during training, please check if the machine has a firm stand and follow exactly the advice given in the chapter "Mechanical installation". Most often false adjustment of the leveling sockets (adjustable "feet") at the rear of the running machine is responsible for the knocking sound.

7.2 Running belt adjustment problems

If the tension of the running belt is not correct, it is difficult to keep the position of the belt centered. The belt should be readjusted every time it is used in reverse direction mode. Check and follow exactly the advice in the chapter entitled "Control and tightening of the running belt".

7.3 Fuses

The treadmill are equipped with an expulsion fuse in the interior of the device/frontal section below the hood, depending on the model.
An authorized person has to unscrew the front panel and turn on the fuses.

7.4 Electrostatic discharge

If the user moves around the devices, they can become electrostatically charged with up to several thousand volts. If the user then touches a metal piece, keys or display, there may be an electrostatic discharge between the user and the device. Such discharge may interfere with the operation of the device. Generally, electrostatic discharges are without harm for the user as well as for the device, but can be quite unpleasant. The main causes for electrostatic discharges are the choice of clothes, the shoe soles and the movement. Very dry air and many light fittings can also lead to the same effect. We recommend that you try different clothes or shoes, humidify the air in the room, and switch off some of the lights.
Please inform the manufacturer of such interference.

7.5 Sources of interference

The device should not be installed near e.g. an x-ray device, motor or transformer with high connection power, as the electric and magnetic interference may falsify measurements. Very strong sources of interference (e.g. above the limit specified by EMT) may influence the functioning of the device. Avoid high-tension power lines and electrical devices without **CE**-sign and without a certificate of compliance for electromagnetic tolerance.
Pay special attention to the advice and data in the chapter 8 entitled “Technical data” / “Electromagnetic compatibility (EMC) and immunity: Guidance and manufacturer's declaration”.

7.6 Voltage on the device housing / electric shock

Open (interrupted) earth wire / ground
If the earth wire (ground) is not connected (for example due to defect in the building installation), a voltage will be on the metal frame via the „Y-anti-interference capacitor. This is very common with almost all electrical equipment with metal housing and EMC-fault clearance filters if the earth wire and/or contactor at the wall socket [1] in the building or at any other part of the AC-power line/feeder is open [2]. In this case, a voltage of approximately 110 V runs via the capacitor of the EMC-fault clearance filter (to be found in the device) between housing and earth. There is a voltage [5] of approx. 110 V AC between frame [3] and grounding [4 via the capacitors of the incorporated EMC filters, e.g via the floor or heating radiator system or other grounded parts or machines.

If a medical device (with potential isolation transformer) is flawless the current flow will remain nearly unnoticed when bare metal parts (for example screws) are touched.

⚠	Disengage the device immediately, unplug it and secure it against new start-up. Order an authorised electrician to repair the contactor circuit in the building or/and on the device.

Read and follow the directives and information concerning the check of ground-wire terminals and functions in the chapters on installation, maintenance and safety checks of this operating and service manual.

7.7 RS232 interface

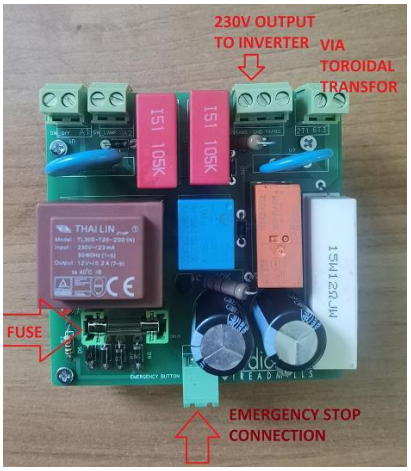
The most common causes for problems with the RS232 interface are
-Wrong connection cable between the running machine and the periphery.
-Connection to the wrong COM port of the treadmill or the periphery.
-Another program, running on the external PC, is blocking the COM-port where the treadmill is connected.
-Technical defects of the connection cable or male/female connector.
-False setting of protocols/driver at running machine or periphery (ECG, PC, ergospirometry).
-False setting of COM port at periphery (ECG, PC, ergospirometry).

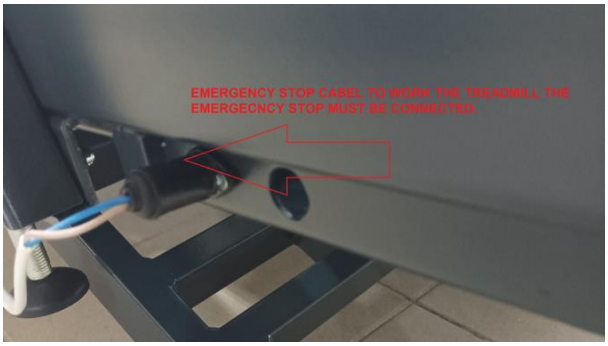
7.7.1 Troubleshooting and testing of the RS232 interface

-Loop-back test: For testing the RS232 of the running machine, a special RS232 test plug including testing instruction is available from the manufacturer.
- If you install the software of a stress test on an external PC, you can control the running machine. If it works, you know the running machine, the RS232 interface connection cable and the RS232 interface card of the PC are working well.

7.8 General Check for troubleshooting- Step by Step

1. **EMERGENCY STOP**
   Please check if the appropriate cable is connected to the external plug of emergency stop below the handle.
   If it is necessary check inside the treadmill the connection in the small PCB board.



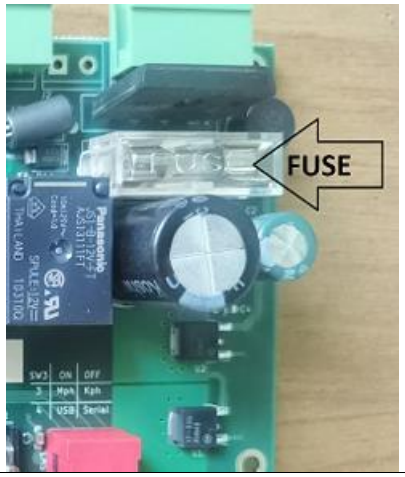


2. FUSES:

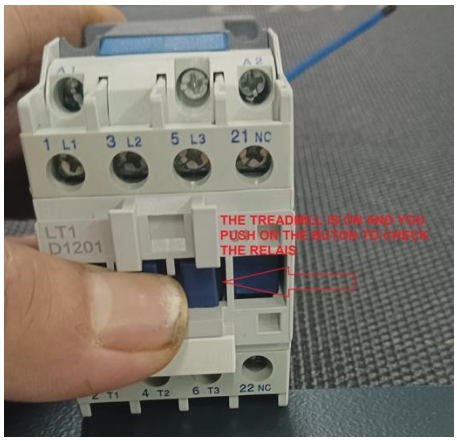
In order to check the external fuse, you have to unscrew the plug in the front.

MODEL	POWER	FUSE - TYPE6X30
CMT 2058	230V/115V	15A/20A
CMT 2263	230V/115V	15A/20A
CMT 2673	230V/115V	15A/25A
CMT 3078	230V/115V	20A/25A

Power supply board fuse 3,1 A type 5X20	

Main board fuse 5A type 5X20	

3. **RELAIS:** If the treadmill's power button is on and it is not inverter, please check the inner contactor, open slightly up the cup and press like the second photo.



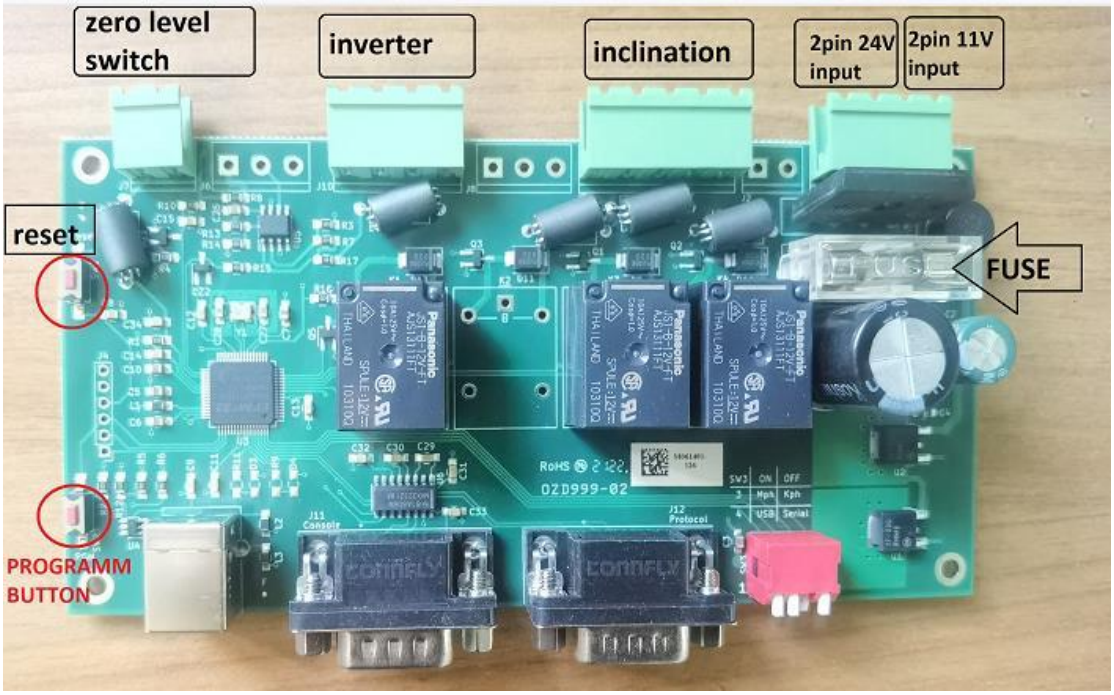
If the inverter is working, the relay should be changed.

4. **MAINBOARD:** If all the components are working well, but the treadmill is not , the main cause is in the mainboard.

INCLINTION CHECK:

In order to check the inclination, please check the following:

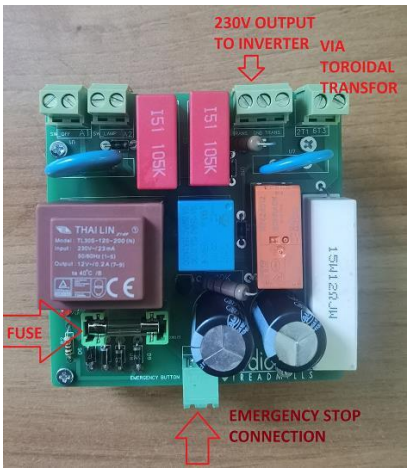
1. The fuse in the mainboard 5A (type 5x20)
2. The connection of the inclination motor to mainboard
3. The connection of the zero-level switch to mainboard
4. Power supply for inclination motor pass through the main board (24V input). Check in the cable are appropriate installed.



The zero-level switch must be closed in order to start the treadmill

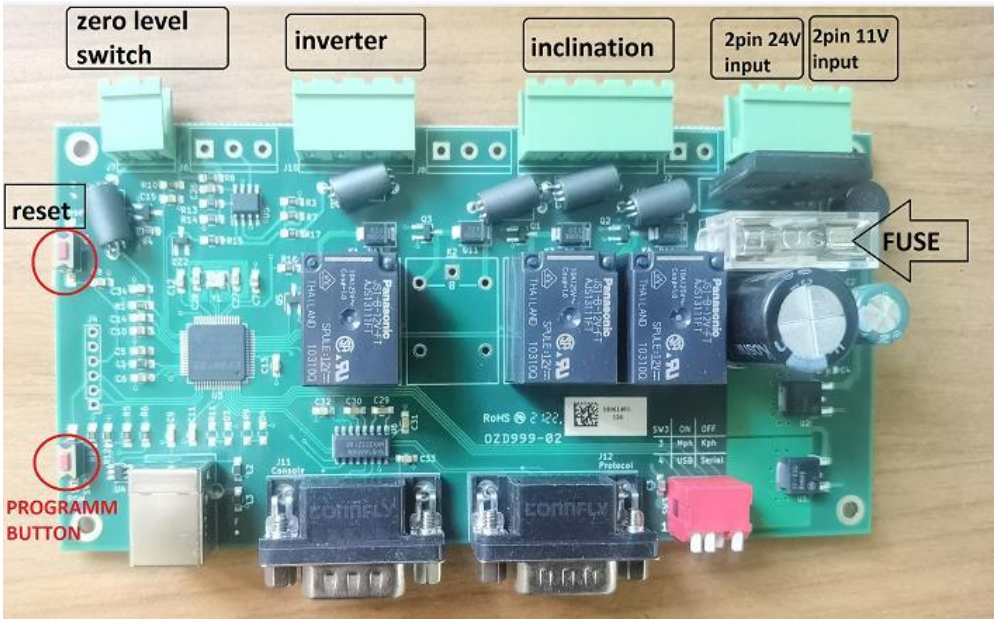
RUNNING CHECK

1. The inverter has power through the relay and the small board, from the toroidal transformer.



2. If the treadmill is on, the inverter should be working.

3. Please check if all are connected well.



8 Technical data

8.1 Running machines

	CMT - 2058	CMT - 2263
Speed	0 to 25 km/h (0.2-25)	0 to 25 km/h (0.2-25)
Slope	0-25%	0-25%
Reversal of rotation direction	Optional,-25 to 0%	Optional,-25 to 0%
Tread	150 x 51 cm	160 x 56 cm
Maximum load on surface	200 kg	200 kg
Motor	AC 230V 50 Hz 11A (3 phases) 2. 2kW	AC 230V 50 Hz 11A (3 phases) 2.2kW
Interfaces	2 x RS232, USB	2 x RS232, USB
Frame size	203 x 70 x 120 cm	213 x 75 x 120 cm
Unit weight	165 kg	195 kg
Emergency stop	Standard, Stop button	Standard, Stop button
Heart rate	Optional	Optional
Entry ramp	Optional	Optional
Anti slip strips	Standard	Standard
Short handrails	Standard Height: 900 mm	Standard Height: 900mm
Long handrails	Optional	Optional
Safety handle and safety leash	Optional	Optional

Environmental conditions		
Operation: - Temperature - Relative air humidity(non-condensing) - Air pressure	15 to 40 ^{0}C 30 to 90% 70 to 100 kPa	15 to 40 ^{0}C 30 to 90% 70 to 100 kPa
Storage: - Temperature - Relative air humidity(non-condensing) - Air pressure	-20 to 70 ^{0}C 10 to 95% 50 to 100 kPa	-20 to 70 ^{0}C 10 to 95% 50 to 100 kPa

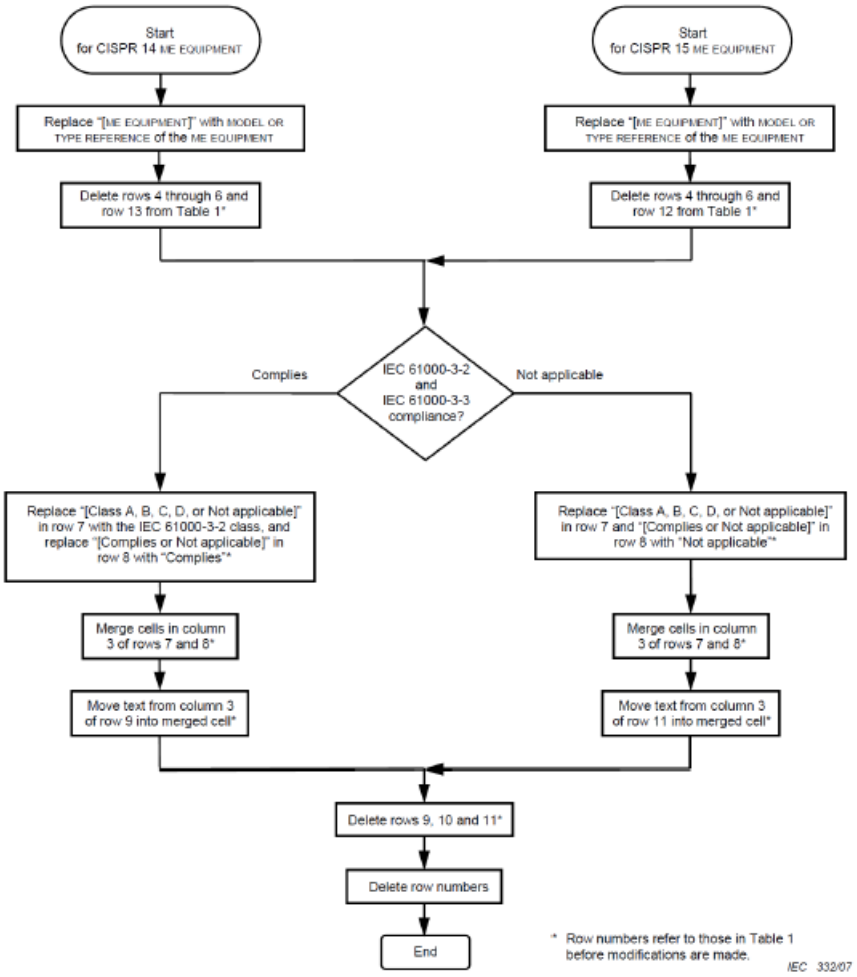
Safety standardsCLASS SA, EN ISO 957.1 / EN, ISO 957.6 CE 0653

8.2 Electromagnetic compatibility (EMC) and immunity

8.2.1 Guidance and manufacturer's declaration

Guidance and manufacturer's declaration - electromagnetic emissions		
The running machine is intended for use in the electromagnetic environment specified below. The customer or the user of the running machine should assure that it is used in such an environment.		
Emissions test	**Compliance**	Electromagnetic environment — guidance
RF emissions CISPR11	Group 1 Class B	The running machine uses RF energy only for its internal function. Therefore, its RF emissions are low and are not very likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Group 1 Class B	The running machine is suitable for use in all establishments including domestic 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	Not applicable	
Voltage fluctuations/	Not applicable	

Guidance and manufacturer's declaration – electromagnetic emissions		
The [ME EQUIPMENT or ME SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [ME EQUIPMENT or ME SYSTEM] should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The [ME EQUIPMENT or ME 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	Group 2	The [ME EQUIPMENT or ME SYSTEM] must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class [A or B]	
Harmonic emissions IEC 61000-3-2	[Class A, B, C, D, or Not applicable]	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	[Complies or Not applicable]	
	[See 5.2.2.1 c) and Figure 1]	The [ME EQUIPMENT or ME 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.
	[See 5.2.2.1 c) and Figure 1]	The [ME EQUIPMENT or ME SYSTEM] is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning**: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM] or shielding the location.
	[See 5.2.2.1 c) and Figure 1]	The [ME EQUIPMENT or ME SYSTEM] is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 14-1	Complies	The [ME EQUIPMENT] is not suitable for interconnection with other equipment.
RF emissions CISPR 15	Complies	The [ME EQUIPMENT] is not suitable for interconnection with other equipment.


Start
for CISPR 14 ME EQUIPMENT
Start
for CISPR 15 ME EQUIPMENT
Replace "[ME EQUIPMENT]" with MODEL OR TYPE REFERENCE of the ME EQUIPMENT
Replace "[ME EQUIPMENT]" with MODEL OR TYPE REFERENCE of the ME EQUIPMENT
Delete rows 4 through 6 and row 13 from Table 1*
Delete rows 4 through 6 and row 12 from Table 1*
IEC 61000-3-2 and IEC 61000-3-3 compliance?
Complies
Not applicable
Replace "[Class A, B, C, D, or Not applicable]" in row 7 with the IEC 61000-3-2 class, and replace "[Complies or Not applicable]" in row 8 with "Complies"*
Replace "[Class A, B, C, D, or Not applicable]" in row 7 and "[Complies or Not applicable]" in row 8 with "Not applicable"*
Merge cells in column 3 of rows 7 and 8*
Merge cells in column 3 of rows 7 and 8*
Move text from column 3 of row 9 into merged cell*
Move text from column 3 of row 11 into merged cell*
Delete rows 9, 10 and 11*
Delete row numbers
End
* Row numbers refer to those in Table 1 before modifications are made.
IEC 332/07

Guidance and manufacturer's declaration - electromagnetic immunity (for all equipment and systems)			
The running machine is intended for use in the electromagnetic environment specified below. The customer or the user of the running machine 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power 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	<5 % *U*T (>95 % dip in *U*T) for 0.5 cycle	<5 % *U*T (>95 % dip in *U*T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the running machine requires continued operation during power mains interruptions, it is recommended that the running machine be powered from an uninterruptible power supply or a battery. Caution! Running machines require high capacity UPS because of high capacity motor drive.
	40 % *U*T (60 % dip in *U*T) for 5 cycles	40 % *U*T (60 % dip in *U*T) for 5 cycles	
	70 % *U*T (30 % dip in *U*T) for 25 cycles	70 % *U*T (30 % dip in *U*T) for 25 cycles	
	70 % *U*T (30 % dip in *U*T)	70 % *U*T (30 % dip in *U*T)	

Guidance and manufacturer's declaration -electromagnetic immunity

The running machine is intended for use in the electromagnetic environment specified below. The customer or the user of the running machine should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the running machine, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.17\ 1/V * \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 Vrm	$d = 1.17\ m/V * \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.33\ m/V * \sqrt{P}$ for 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey. a should be less than the compliance level in each frequency range.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations.

Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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

Recommended separation distances between portable and mobile RF communications equipment and the running machine

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

Rated maximum output power of transmitter (in Watt)	Separation distance (in meters) according to frequency of transmitter		
	150 kHz to 80 MHz *d = 1.17 1/V * √P*	80 MHz to 800 MHz *d = 1.17 m/V * √P*	800 MHz to 2.5 GHz *d = 2.33 m/V * √P*
0.01W	0.12 m	0.12 m	0.23m
0.1W	0.37 m	0.37 m	0.74m
1W	1.17m	1.17m	2.33m
10W	3.70m	3.70m	7.37m
100W	11.7m	11.7m	23.3m

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

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all

8.3 Compatible Devices

Manufacturer	Medical Product	Intended Use
AMEDTEC GMBH	ECG PRO	ECG
BTL	BTL CARDIOPOINT ERGO	Stress Test
CARDIOLINE	CUBE	Stress Test
CARDIONICS SA	CARDIOPLUG I/II	ECG
CORTEX GMBH	META CONTROL 3000 ERGOSPIROMETRY	ECG Ergospirometry
COSMED SRL	QUARK C12 X STRESS TEST, Ergospirometry FITMATE MED	Stress Test, Ergospirometry
CUSTO MED GMBH	CUSTO CARDIO 200	ECG
EDAN	SE-1515	ECG

GANSHORN GMBH	POWECUBE ERGO	Ergospirometry
GE	CARDISOFT	ECG
INNOMED	CARDIO PC/E	ECG
LABTECH LTD	EC-12S	Stress Test
MEDSET GMBH	CARDIOLIGHT	ECG
MORTARA	Q-STRESS	Stress Test
NEUROSOFT LTD	POLYSPECTRUM TM	ECG
NORAV	1200W	Stress Test, ECG
PROGETTI SRL	PG STRESS	Stress Test
PULSE BIOMEDICAL	QRS CRD	ECG, Stress Test
SCHILLER	CARDIOVIT CS200	ECG, Stress Test
SEIVA SRO	PARAKTIK ERGOLOG	ECG

8.4 Economic life time

The economic life time of the product is considered to be 20 years with normal usage and application, provided that after 10 years all electrical parts and components are renewed (if damaged or extremely heavily used possibly earlier) and the recommended maintenance intervals are kept. Every maintenance and repair work is to be carried out by authorized **Cardiomed Treadmills** technicians. A shorter life time may be expected for wear and tear parts.

Liability and Warranty

Following will cause loss of liability and warranty and may result in serious injury or death or damage to the device:

- Use other than explicitly mentioned as intended use
- Unauthorized maintenance or lack of maintenance, safety checks or repairs
- Unauthorized modifications or extensions
- Unauthorized installation, commissioning or instruction
- Use of any unauthorized or non-original **Cardiomed Treadmills** parts, spare parts, consumables, sensors or detectors
- Disregard of safety information (danger, warning and caution statements)
- Any unauthorized modifications to the device, software, configurations and accessories
- Connection of accessories, software or devices, not listed in “accessories / compatible devices”

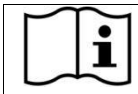
The “safety information – forbidden use” list does not claim to be exhaustive and may be extended during market phase (post market surveillance).

Expected Lifetime

- Obey the maintenance intervals claimed in chapter “maintenance”.
- Obey the competences claimed in chapter “maintenance”.
- The expected lifetime of the entire device is 10 years, provided, that all maintenance intervals are maintained.
- wear and tear parts are replaced by **Cardiomed Treadmills** service personnel during applicable maintenance intervals and/or earlier at the first sign of wear and tea

Annex

Used Symbols

	The instruction manual is to be observed. It is an integral part of the medical device and to be kept.
	Warnings, alerts or warnings
	Dangerous electrical voltage
	AC
	Protective conductor
	Grounding
	Equipotential bonding
	The device must be disposed of properly and legally compliant (according to the currently valid electrical old device regulation). Definitely not, the device must be carried to the normal household waste.

WARRANTY

The manufacturer declares that the product under maximum load has been tested and with the technical data and functions within manufacturing tolerances.

The manufacturer guarantees:

A. 3 years on frame and color
B. 1 year for electronic and mechanical parts

The warranty includes replacement of problematic parts. It does not apply for the running belt.

The guarantee refers to damage caused by improper use of the product, nor for damage resulting from failure to follow of the maintenance instructions.

Appendix A

Maintenance Log

Serial number #..... Date Purchased.....

Purchased From.....Phone.....

Date	Hours	Service Completed	Cost