



Dear customers,

In order to comply with all regulatory requirements and MDR medical device regulation (EU) 2017/745, h/p/cosmos performs regular PMS Post Market Surveillance, updated Clinical Evaluation Reports CER and ongoing Risk Management. In the latest CER file update 2 additional contra-indications have been found in the evaluation of clinical data and literature and a few recommendations have been made, which are incorporated in this addendum of the original instructions for use. Please read carefully, distribute to relevant staff and follow all safety information and warnings. Failure to comply may result in death or serious injury. All updated information on safety, Field Safety Notices FSN and FSCA Field Safety Corrective Actions can be found on the manufacturer's website under <https://www.hpcosmos.com/en/safety>
Updated manuals / IFU instructions for use can be downloaded: <https://www.hpcosmos.com/en/contact-support/media-downloads/manuals>

3 Intended Use (med) for medical treadmills

3.1 Intended Use / Indications / Target Population

h/p/cosmos medical treadmills are intended for walking or running* in place for

- Recreational fitness training (incl. athletes)
- Gait training (with or without body weight support)

h/p/cosmos medical treadmills can be used in combination with external devices for walking or running* in place as

- Stressing devices for neuromuscular and biomechanical measurements (e.g. EEG, EMG, motion analysis)
- Stressing devices for cardiovascular measurements (e.g. ECG)
- Stressing devices for cardiopulmonary measurements (e.g. ergospirometry)

* Devices marked with an "r" or "rs" like "h/p/cosmos saturn 250/75 r" are intended for applications with wheels as well.

Applications with wheels include cycling, roller skiing, wheelchair applications, etc...

Caution: In which ever mode, function, program, test or feature, the treadmill does not provide any kind of medical treatment proposal nor medical assessment with analysis.

The treadmill is purely used as a stressing device and training equipment.

Prescribed fall prevention device for any application where falling might cause an unacceptable risk such as

- while performing sprints, high speed training or max. endurance tests
- while training on running surfaces wider than 65 cm
- for children (<14 years)
- for subjects with all kind of disabilities, impairments (visual, hearing, balance, etc.), activity limitations and participation restrictions
- for subjects with recent hip replacement, intracorporal probes, osteoporosis, etc.
- during reverse belt rotation at speeds higher than 5 km/h.
- It is not allowed to run with the back to the crossbar or to the UserTerminal to prevent from collision.
- during all use with wheels (cycling, wheelchair, inline-skating or roller-ski) for the "r" models

The subject of a medical application is not necessarily a patient.

Therefore these instructions for use will use the term "subject" for patients as well as for athletes under test.

h/p/cosmos medical treadmills may be operated with healthy subjects as well.

For applications with healthy subjects, please apply the instructions for use for sports devices, available at www.hpcosmos.com



Prescribed fall prevention device (e.g. [safety arch](#) [cos10170xx] with [chest belt](#) [cos14903-xx] and [rope](#) [cos10670xx] or [fall prevention system for ceiling mount](#) [cos15866xx] or [airwalk ap](#) [cos30028] unweighting device) for any application where falling might cause an unacceptable risk such as osteoporosis, high speed or special applications, applications with persons not able to jump off the running surface, such as children, subjects with all kind of disabilities, impairments (visual, hearing, balance, etc.).

A [rip-cord device](#) (pull cord/safety lanyard) with magnet clip [cos101699xx] is NOT a fall prevention device and cannot prevent from falling.

It is impossible to list all indications, target population (age, gender, weight range, height range) and target user groups for treadmill training and treadmill testing, since the indications, target population and target user groups most likely correspond to recommendations for walking and/or running overground.

The treadmill does not provide recommendations for treatment and target population.

It is important to notice that the decision to use the devices with their potential risks and complications for diagnosis, rehabilitation or therapy of a particular patient is the essential responsibility of the medical operator.

The clinical user's judgment, on the other hand, must be based on current knowledge in medical science and the specific situation of the patient.

The indications, target population and target user groups for treadmill testing and treatment have to be decided by the medical doctor and primarily have to be derived from international accepted guidelines.

Examples: 2020 ESC Guidelines on Sports Cardiology and Exercise in Patients with Cardiovascular Disease

ESC European Society of Cardiology Clinical Practice Guidelines

<https://academic.oup.com/eurheartj/article/42/1/17/5898937>

ACC/AHA Guidelines for Exercise Testing.

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines
(Committee on Exercise Testing)

<https://www.jacc.org/doi/pdf/10.1016/s0735-1097%2897%2900150-2>

American Academy of Family Physicians Foundation

Physical Therapy and Rehabilitation Journal

Robotic-Assisted, Body-Weight–Supported Treadmill Training (BWSTT) in Individuals Following Motor Incomplete Spinal Cord Injury

<https://academic.oup.com/ptj/article/85/1/52/2805006>

The NEW ENGLAND JOURNAL of MEDICINE

Body-Weight–Supported Treadmill Rehabilitation after Stroke

<https://www.ctsi.ucla.edu/education/files/view/training/docs/dobkin-NEJM-BWSTT-after-stroke.pdf>

3.2 Intended operator for medical treadmills

- 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 and under the permanent observation of the intended operator. This means the operation of the device remains the responsibility of the intended operator at all times, taking the physical and mental condition of the subject into account.

The intended operator has to be within permanently reach (patient area = 1.5m radius).



3.3 Intended location for medical treadmills

- 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 intended to be moved after installation by professional staff.

3.4 Intended duration / exercise stop criteria for medical treadmills

- Depending on the prescription of the medical doctor
- WARNING! Heart rate monitoring systems may be inaccurate.
- Incorrect or over exercising may result in serious injury or death.
- If you feel faint or dizzy stop exercising immediately and consult a medical doctor.
- Further exercise test stop criteria see guidelines for various treadmill exercise and treadmill tests.

Sources:

<http://leitlinien.dgk.org> (German Cardiac Society)

www.acc.org (American College of Cardiology Foundation)

www.americanheart.org (American Heart Association)

http://my.americanheart.org/idc/groups/ahaecc-internal/@wcm/@sop/documents/downloadable/ucm_423807.pdf

3.5 Contraindications for medical treadmills

Absolute contraindications

(have to be excluded before the treadmill is used)

- Acute myocardial infarction (within 2 days)
- 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 extremities
- 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
- uncontrolled heart failure
- dissecting aneurysm



- recent aortic surgery and ECG abnormalities, such as abnormal ST-segment response (horizontal, planar or downsloping depression of >1 mm, T-wave elevation of > 1 mm in leads without Q-waves, and Twavechanges such as inversion and pseudo-normalization when an inverted T-wave becomes upright.

Relative contraindications

(The application may be started if the possible benefits exceed the risks.

The decision has to be made by the medical doctor before the treadmill is used)

- 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
- Anaemia
- Physical and/or mental disabilities leading to inability to exercise adequately
- Partially invasive medical devices (probes, infusions, catheters, external fixators, etc.)



4 Intended Use (sport) for sports and fitness treadmills

4.1 Intended use / Indications

- h/p/cosmos sports treadmills are intended for walking or running* in place.
- Do not use h/p/cosmos sports treadmills for medical applications.

* Devices marked with an “r” or “rs” like “h/p/cosmos saturn 250/75 r” are intended for applications with wheels as well. Applications with wheels include cycling, roller skiing, wheelchair applications, etc...

Caution: In which ever mode, function, program, test or feature, the treadmill does not provide any kind of medical treatment proposal nor medical assessment with analysis. The treadmill is purely used as a stressing device and training equipment.

Prescribed fall prevention device for any application where falling might cause an unacceptable risk such as

- while performing sprints, high speed training or max. endurance tests
- while training on running surfaces wider than 65 cm
- for children (<14 years)
- for subjects with all kind of disabilities, impairments (visual, hearing, balance, etc.), activity limitations and participation restrictions
- for subjects with recent hip replacement, intracorporal probes, osteoporosis, etc.
- during reverse belt rotation at speeds higher than 5 km/h.
- during all use with wheels (cycling, wheelchair, inline-skating or roller-ski) for the “r” models



Prescribed fall prevention device (e.g. [safety arch](#) [cos10170xx] with [chest belt](#) [cos14903-xx] and [rope](#) [cos10670xx] or [fall prevention system for ceiling mount](#) [cos15866xx] or [airwalk ap](#) [cos30028] unweighting device) for any application where falling might cause an unacceptable risk such as osteoporosis, high speed or special applications, applications with persons not able to jump off the running surface, such as children, subjects with all kind of disabilities, impairments (visual, hearing, balance, etc.).

A [rip-cord device](#) (pull cord/safety lanyard) with magnet clip [cos101699xx] is NOT a fall prevention device and cannot prevent from falling.

4.2 Intended operator (sport) for sports and fitness treadmills

- Adult persons carefully trained according to these instructions for use.
- A professional supervisor has to be in the same room.

4.3 Intended location (sport) for sports and fitness treadmills

- 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 intended to be moved after installation by professional staff.

4.4 Intended duration / exercise stop criteria

- Depending on the condition of the subject
- Exclude overloading or overstressing of the subject.
- WARNING! Heart rate monitoring systems may be inaccurate.
- Incorrect or over exercising may result in serious injury or death.
- If you feel faint or dizzy stop exercising immediately and consult a medical doctor.
- Further exercise test stop criteria see guidelines for various treadmill exercise and treadmill tests.



4.5 Contraindications

(have to be excluded before the treadmill is used)

- Acute myocardial infarction (within 2 days)
- 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 extremities
- 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
- uncontrolled heart failure
- dissecting aneurysm
- recent aortic surgery and ECG abnormalities, such as abnormal ST-segment response (horizontal, planar or downsloping depression of >1 mm, T-wave elevation of > 1 mm in leads without Q-waves, and Twavechanges such as inversion
and pseudo-normalization when an inverted T-wave becomes upright.
- 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
- Partially invasive medical devices (probes, infusions, catheters, external fixators, etc.)
- Cardiac pacemaker
- Visual impairment (vision < 30% acc. to WHO)

Sources:

<http://leitlinien.dgk.org> (German Cardiac Society)

www.acc.org (American College of Cardiology Foundation)

www.americanheart.org (American Heart Association)

http://my.americanheart.org/idc/groups/ahaecc-internal/@wcm/@sop/documents/downloadable/ucm_423807.pdf



5 Safety (med) for medical treadmills

- h/p/cosmos medical treadmills may be operated with healthy subjects as well.
- The safety notes, warnings and precautions have to be pointed out to every user and operator and displayed within sight of the running machine.
- Additional and latest safety notes and warnings see: <https://www.hpcosmos.com/en/safety>
- Any serious incident in relation to the device has to be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established as well as to EUDAMED database based on MDR.

5.1 Safety information – Forbidden use

Obey the following danger, warning and caution statements strictly 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.
- If you feel faint or dizzy stop exercising immediately and consult a medical doctor.
- Further exercise test stop criteria see guidelines for various treadmill exercise and treadmill tests.
- Exclude overloading or overstraining 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 anaesthetics.
- 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.

* Devices marked with an “r” or “rs” like “h/p/cosmos saturn 250/75 r” are intended for applications with wheels as well. Applications with wheels include cycling, roller skiing, wheelchair applications, etc.

** Devices supplied with the special “running belt for ski and spike applications” (see “Annex III (Accessories)”) are intended for application with spikes or studs as well.



- 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.
- Always the latest command will be executed, regardless of whether it came via interface or from the UserTerminal during one of the four modes. Only stop command has higher priority and cannot be overwritten.
- 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, shoes, clothing and humidity, in order to prevent electrostatic charge and 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 h/p/cosmos 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 h/p/cosmos 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 h/p/cosmos 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.
- Do not save personal data (names, address, etc.) or patient data (indications, etc.) on the UserTerminal, for example in file names or profile names.



6 Safety (sport) for sports treadmills

- h/p/cosmos sports treadmills are intended for walking or running* in place.
- Do not use h/p/cosmos sports treadmills for medical applications.
- The safety notes, warnings and precautions have to be pointed out to every user and operator and displayed within sight of the running machine.
- Additional and latest safety notes and warnings see: <https://www.hpcosmos.com/en/safety>
- Any serious incident in relation to the device has to be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or subject is established.

6.1 Safety information – Forbidden use

Obey the following danger, warning and caution statements strictly 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.)
- Only carefully trained staff is allowed to use the device.
- Do not use the device with children <14 years.
- Exclude access of unsupervised children (< 14 years) onto or near any parts of the device (incl. accessories, packaging, lubrication and service material).
- 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.
- If you feel faint or dizzy stop exercising immediately and consult a medical doctor.
- Further exercise test stop criteria see guidelines for various treadmill exercise and treadmill tests.
- Exclude overloading or overstressing of the subject.
- The subject has to be checked by a medical doctor before using the device.
- 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.
- Neither subject nor operator must be under the influence of alcohol, drugs or anaesthetics.
- 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 athletic or other appropriate shoes.
- Do not use high heels, spikes, studs, sandals, etc. **
- 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 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.
- Always the latest command will be executed, regardless of whether it came via interface or from the UserTerminal during one of the four modes. Only stop command has higher priority and cannot be overwritten.



- 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, shoes, clothing and humidity, in order to prevent electrostatic charge and 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.
- Animals must not be in the same room with the device.
- 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 h/p/cosmos 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 h/p/cosmos 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 h/p/cosmos 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.
- Do not save personal data (names, address, etc.) or patient data (indications, etc.) on the UserTerminal, for example in file names or profile names.

A well-structured installation, commissioning and instruction protocol including pictures, checklist and list of instructed operators is available for download: <https://www.hpcosmos.com/en/contact-support/media-downloads/manuals>



https://www.hpcosmos.com/sites/default/files/uploads/documents/20220204_cos15228-05_en_de_form_hpcosmos_commissioning_instruction_protocol.pdf