**quality assurance & regulatory affairs agreement | coscom® v3 | coscom® v4**

regarding; medical device regulation MDR (EU) 2017/745,

standards EN 62304 / IEC 62304 (Life Cycle Requirements for Medical Device Software / Medical Device Software Life Cycle Processes)

and standards EN 14971 / ISO 14971 (Risk Management of Medical Products)

between: h/p/cosmos sports & medical gmbh, Am Sportplatz 8, DE 83365 Nussdorf-Traunstein / Germany eMail: r&d@hpcosmos.com

and: xxxxx

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| --- | --- | --- |
| responsibilities/ task/ subject | contact person @ xxxxx  | contact person @ **h/p/cosmos** |
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For staying in compliance with safety related issues, the MDR (EU) 2017/745 on the interface communications and linkage of medical devices both parties agree to:

1. inform each other in writing before each party makes amendments on interface and/or software which can have safety related impact on the treadmill control. The same clause applies for other safety related parts & components.
2. perform & exchange tests & test protocols on interface and/or software which can have safety related impact on the treadmill and/or ergometer control.

**b1)** With electronic data logger all commands between the systems (treadmill/ergometer and host equipment/software) via coscom v3 or coscom v4 protocol are saved and documentation will be exchanged and analyzed, verified, validated and archived by both parties.

**b2)** Checksum and Acknowledgement have to be implemented in the interface protocol accordingly.

**b3)** Error simulation on failsafe function (timeout simulation of broken interface cable or PC failure or software crash) and with “status communication” of stop button pressed on the treadmill have to be made.

**b4)** If “stop” button was pressed on the treadmill and/or ergometer, also the load protocol on the host PC-Software or system has to stop and must not continue to send speed or elevation commands automatically. See [implementation notes](http://www.coscom.org/coscom_v3/Downloads/20120103_cos100115_h-p-cosmos_coscom_v3_treadmill_ecg_device_control_example.pdf) v3 or [v4](https://www.coscom.org/coscom_v4/20240418_cos100115v4_hpcosmos_coscom_v4_interface_protocol_treadmills_ergometers_admin_OP.pdf) on [http://www.coscom.org](http://www.coscom.org/)

1. have internal documented and implemented bug-fixing process for medical device software maintenance during entire software life-cycle.
2. observe and inform each other in case of any amendment in the risk management status and/or regulatory affairs status, adverse event reporting and/or notifiable incident status and/or clinical data and post market surveillance (PMS) status.
3. exchange and report any kind of information of clinical studies, data and assessments that are related to h/p/cosmos devices as part of a market surveillance process. Both parties are obliged to set up internal procedures in order to assure the bi-directional reporting system for such a complaint handling and vigilance reporting and the exchange of market surveillance data related to the coscom interface control functions, features and safety.
4. Vigilance system: exchange and report any malfunction or deterioration in the characteristics and/or performance of the h/p/cosmos device (including a report about the incident and serial number of the device) within 10 days (or earlier if applicable in some countries), as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health.
5. record the serial numbers and end users names & addresses of all h/p/cosmos machines sold to customers & save those for at least 15 years or over the life time of the respective product. This is for organizing mailings in the unlikely event of product recalls or field corrective actions or warning messages.
6. allow access for the responsible notified bodies and authorities to quality and safety and regulatory affairs related documents and to the premises also for audits and unannounced audits where applicable.
7. archive quality and safety related documents for at least 15 years or for the expected lifetime of the product plus 5 years.
8. inform each other in case of any changes of scope or invalidity on the quality assurance certification (eg. EC or ISO 13485 certificates)
9. note: medical treadmills, used also for stress testing, are risk class IIb active diagnostic and active therapeutic devices based on MDR.
10. note: connecting two or more medical devices will create a medical system and have to be treated and documented as a new medical device/system also via risk assessment and management process accordingly.

These agreement clauses cover their sports and/or medical devices and software where both parties are involved. The archiving and information clauses are valid even after termination of an active sales and purchase co-operation.

place, date: place, date:

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signature host device (ECG, PC, CPET, etc.) manufacturer signature: h/p/cosmos sports & medical gmbh

name & function: name & function:

**coscom® safety test confirmation and official release document**

Following tests & test protocols on interface and/or software which can have safety related impact on the treadmill and/or ergometer control have been perform & exchanged between the parties.

b1) With electronic data logger all commands between the systems (treadmill/ergometer and host equipment/software) via coscom v3 or coscom v4 protocol have been saved and documented and have been exchanged and analyzed, verified, validated and archived by both parties.

b2) Checksum and Acknowledgement have been implemented in the interface protocol accordingly.

b3) Error simulation on failsafe function (timeout simulation of broken interface cable or PC failure or software crash) and with “status communication” of stop button pressed on the treadmill have been performed.

b4) If “stop” button was pressed on the treadmill and/or ergometer, also the load protocol on the host PC-Software or system has stopped and did not continue to send speed or elevation commands automatically. See implementation notes v3 or v4 on [www.coscom.org](http://www.coscom.org)

Preferably, also the device IDs (if possible with serial numbers) and software / firmware versions are communicated in the coscom interface communication and are logged at the start of the log-file for valid test documentations.

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| --- | --- |
| coscom implementation document: | <https://www.coscom.org/coscom_v4/20240418_cos100115v4_hpcosmos_coscom_v4_interface_protocol_treadmills_ergometers_admin_OP.pdf>  |
| (or alternatively) implemented coscom .DLL | <http://www.coscom.org/coscom_v4/20210212_cos100115-v4_hpcosmos_coscom_v4_dll_V1.1.0.0.zip> |
| comments |  |

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| --- | --- | --- |
| **manufacturer of host device (ECG, PC, CPET, software, etc.):** |  | **treadmill / ergometer manufacturer:** |
| company logo |  |  | xibologo |
| company name |  |  | h/p/cosmos sports & medical gmbh |
| name of test person |  |  |  |
| eMail of test person |  |  |  |
| device made in |  |  | Germany |
| company website |  |  | [www.hpcosmos.com](http://www.hpcosmos.com) |
| notified body |  |  | CE0123 TÜV Süd Product Service GmbH (Munich, Germany) |
| date of test / file |  |  |  |
| file name of log file |  |  |  |
| device type |  |  | treadmill with MCU5; treadmill with MCU6; MCU5 simulator; MCU6 simulator; torqualizer ergometer; discovery ladder(please delete non-applicable devices) |
| device model name |  |  |  |
| device article number |  |  |  |
| device **basic UDI-DI** |  |  |  |
| device **UDI-DI** |  |  |  |
| device **UDI-PI** (incl. ser.-no.) |  |  |  |
| device serial no. |  |  |  |
| software name |  |  |  |
| software version |  |  |  |
| software release date |  |  |  |
| coscom version |  |  |  |
| coscom communication stack |  |  |  |
| coscom communication stack version and release date |  |  |  |
| interface COM-port |  |  |  |
| interface connection cable |  |  |  |
| interface adapter / converter / dongle (e.g. USB-RS232) |  |  |  |
| pictures of test environment |  |  |  |

**Herewith both parties declare, that the**

1. necessary safety features and functions for the interface communication and / or device control have been implemented;
2. assessment of the tests and protocols did not indicate any safety related concern;
3. risk management for medical devices covers the theoretically possible event of malfunction of the interface communication;
4. PMS Post Market Surveillance has been implemented accordingly;
5. company logos and company names may be used in each other party’s manuals, websites, documentations and instructions for use to inform customers, dealers, technicians and relevant regulatory bodies about the compatibilities of the systems.

Thus, the compatibility via interface communication and device control through above mentioned configuration is herewith released:

place, date: place, date:

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signature host device (ECG, PC, CPET, etc.) manufacturer signature: h/p/cosmos sports & medical gmbh

name & function: name & function:

 read all relevant h/p/cosmos treadmill manuals – IFU instructions for use 

<https://www.hpcosmos.com/en/contact-support/media-downloads/manuals>

**Test procedure example for generating logfile:**

**- Perform all tests WITHOUT SUBJECT, so make sure no person is standing on the treadmill deck while performing these tests.**

- The log files should contain the data traffic in both directions (preferably with time stamp).

- The log file should contain a header with data and time, the relevant device descriptions, software versions and if possible including serial numbers.

- Perform tests with treadmill MCU5 UserTerminal and MCU6 UserTerminal. See also [www.coscom.org](http://www.coscom.org) for details.

<https://www.coscom.org/coscom_v4/20211111_cos100115v4_hpcosmos_coscom_v4_interface_protocol_treadmills_ergometers_admin_OP.pdf>

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| --- | --- | --- | --- | --- | --- | --- |
| # | Test procedure | What is tested | Expected target result / observation | Observed result | Assessment. Result file (data log file) and remarks | pass/fail |
|  | Power on the treadmill and make sure that interface connections are working correctly. If unsure or if there are troubles to connect, use h/p/cosmos para control software and test with para control first.<https://www.hpcosmos.com/en/products/software-measuring-technology>  | * correct setup
 |  |  |  |  |
|  | Make sure the treadmill setup is ready and1. allows interface control
2. correct interface protocol (e.g. coscom v4) on the treadmill is selected. See Option 20 with MCU5
3. the correct baudrate (19.200 bps for coscom v4) is selected on the treadmill and the host device (e.g. ECG device)
 | * correct setup, for example coscom v4 on MCU6
*
 |  |  |  |  |
|  | Start software on the host device (e.g. ECG device) and establish connection from the host device to the treadmill. | * Is the device information fetched (serial number, MCU5 or MCU6 treadmill...)?
* Is the checksum implemented?
 |  |  |  |  |
|  | 1. **Start load profile on the host device** (e.g. ECG device) and check if treadmill is reacting accordingly
2. Adjust and **change speed on the host device** (e.g. ECG device) and check if treadmill is reacting accordingly
3. Adjust and **change elevation on the host device** (e.g. ECG device) and check if treadmill is reacting accordingly
4. Operate the system for at least 10 minutes
5. End the load profile **on the host device** (e.g. ECG device) and check if treadmill is reacting accordingly.
 | * General communication (query of values or events), also over a longer period of a few minutes
* Is a request control function implemented. Example
* Setting speed and elevation/inclination/slope
* "Request Control" mechanism
* Basic failsafe implementation
 | a) treadmill should start after a “request control” command has been confirmed either on the treadmill display or on the host device (e.g. ECG)Either on treadmill or on host control equipment a warning before start and request control should be implemented and work. |  |  |  |
|  | 1. **Start load profile on the host device** (e.g. ECG device) and check if treadmill is reacting accordingly
2. Adjust and **change speed on the TREADMILL** **keyboard** and check if treadmill is reacting accordingly
3. Adjust and **change elevation on the TREADMILL** **keyboard** and check if treadmill is reacting accordingly
4. Operate the system for at least 10 minutes
5. End the load profile on the **TREADMILL keyboard** with **normal STOP button** (not the emergency button!) and check if treadmill is reacting accordingly.
 | * General communication (query of values or events), also over a longer period of a few minutes
* Setting speed and elevation/inclination/slope
* "Request Control" mechanism
* Basic failsafe implementation
 | a) treadmill should start after a “request control” command has been confirmed either on the treadmill display or on the host device (e.g. ECG)b) and c) depending on philosophy and risk management of host device manufacturer treadmill reacts with speed and elevation change or such changes are deactivated.d) no adverse event takes placee) treadmill shall stop. Host device realized the STOP stage. treadmill should not re-start automatically.Check on host device screen and with data logger if the load profile on the host device (e.g. ECG) is also ended through the normal treadmill STOP button (status communication!) and make sure that the host device does not re-start the treadmill belt automatically. |  |  |  |
|  | 1. Start load profile on the host device (e.g. ECG device) and check if treadmill is reacting accordingly
2. **Press Emergency-STOP button on the treadmill** and check if treadmill is reacting accordingly.
 | * Correct behavior during fail safe and status communication.
* Correct behavior in the event of an emergency stop
 | a) treadmill should start after a “request control” command has been confirmed either on the treadmill display or on the host device (e.g. ECG)b) treadmill shall stop. Host device realized the STOP stage. treadmill should not re-start automatically.Check on host device screen and with data logger if the load profile on the host device (e.g. ECG) is also ended through the normal treadmill STOP button (status communication!) and make sure that the host device does not re-start the treadmill belt automatically. |  |  |  |
|  | a) Start load profile on the host device (e.g. ECG device) and check if treadmill is reacting accordingly**b) Pull safety lanyard Emergency-STOP on the treadmill** and check if treadmill is reacting accordingly. | * Correct behavior during fail safe and status communication.

- Correct behavior in the event of an emergency stop | a) treadmill should start after a “request control” command has been confirmed either on the treadmill display or on the host device (e.g. ECG)b) treadmill shall stop. Host device realized the STOP stage. treadmill should not re-start automatically.Check on host device screen and with data logger if the load profile on the host device (e.g. ECG) is also ended through the normal treadmill STOP button (status communication!) and make sure that the host device does not re-start the treadmill belt automatically. |  |  |  |
|  | a) Start load profile on the host device (e.g. ECG device) and check if treadmill is reacting accordingly**b) Trigger quick-stop on the treadmill if available, e.g. by pulling rope of safety arch on the treadmill and/or activating light barriers on capture zones of oversize treadmills venus/saturn models** and check if treadmill is reacting accordingly. | * Correct behavior during fail safe and status communication.
* Correct behavior in the event of a quick-stop
 | a) treadmill should start after a “request control” command has been confirmed either on the treadmill display or on the host device (e.g. ECG)b) treadmill shall stop. Host device realized the STOP stage. treadmill should not re-start automatically.Check on host device screen and with data logger if the load profile on the host device (e.g. ECG) is also ended through the normal treadmill STOP button (status communication!) and make sure that the host device does not re-start the treadmill belt automatically. |  |  |  |
|  | a) Start load profile on the host device (e.g. ECG device) and check if treadmill is reacting accordingly**b) Active Cool-Down Function on the treadmill keyboard and wait until STOP of the treadmill** and check if treadmill is reacting accordingly. | * Correct behavior during fail safe and status communication.
* Correct behavior in the event of a quick-stop
 | a) treadmill should start after a “request control” command has been confirmed either on the treadmill display or on the host device (e.g. ECG)b) treadmill shall stop. Host device realized the STOP stage. treadmill should not re-start automatically.Check on host device screen and with data logger if the load profile on the host device (e.g. ECG) is also ended through the normal treadmill STOP button (status communication!) and make sure that the host device does not re-start the treadmill belt automatically. |  |  |  |
|  | 1. Start load profile on the host device (e.g. ECG device) and check if treadmill is reacting accordingly
2. **Pull plug of interface connection cable on the treadmill** or on the host device and check if treadmill is stopping automatically within 1 or 2 seconds.
 | * Treadmill stops as failsafe is triggered.
* Correct status communication!
* Check if the load profile on the host device (e.g. ECG) is also ended through the failsafe function and make sure that the host device does not re-start the treadmill belt automatically once the interface cable is plugged in again.
 | a) treadmill should start after a “request control” command has been confirmed either on the treadmill display or on the host device (e.g. ECG)b) treadmill shall stop automatically after 1 to max. 5 seconds due to failsafe timeout. Host device realized the STOP stage. treadmill should not re-start automatically.Check on host device screen and with data logger if the load profile on the host device (e.g. ECG) is also ended through the normal treadmill STOP button (status communication!) and make sure that the host device does not re-start the treadmill belt automatically. |  |  |  |
|  | Define profile with 0 km/h steps (e.g. for lactate testing) | * Check behavior of treadmill and software
* Treadmill – software communication shall not interrupt and cause a new “request control”
 |  |  |  |  |
|  | Trigger pull-stop events – magnetic ripcord (safety lanyard), safety arch, additional stop buttons in arm support, etc. | * Treadmill shall stop
* Software shall notify and behave correct
 |  |  |  |  |
|  | Check necessary implementation for data protection, cybersecurity, risk management and other regulatory compliance | * All regulatory compliance needs to be assessed and documented in relevant technical documentation, e.g. encryption of data transmission or no encryption required.
 |  |  |  |  |
|  | Evaluate logfiles  | * check if all relevant safety features have been implemented
 |  |  |  |  |
|  | others, if applicable,such as RFID / NFC / FTMS identification and communication, messages, bi-directional heart rate transmission (heart rate source from external ECG and displayed on treadmill), etc. |  |  |  |  |  |