# Some relevant safety features and measurements for control of medical treadmills
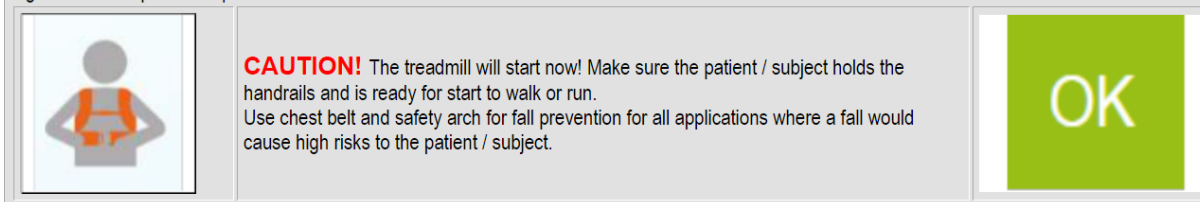
| no. | safety feature | info / download | to do |
|---|---|---|---|
| 1. | **checksum** in interface communication | QA and RA agreement page 1 article b2) | test procedure with interface communication logfile, assessment and release document. |
| 2. | **acknowledgement** in interface communication | QA and RA agreement page 1 article b2) | test procedure with interface communication logfile, assessment and release document |
| 3. | **failsafe** in interface communication | QA and RA agreement page 1 article b3) | test procedure with interface communication logfile, assessment and release document |
| 4. | **status** communication | see [10A] ControlStatus of coscom v4 | test procedure with interface communication logfile, assessment and release document |
| 5. | **initialisation / request control** and confirm ready for start (at least for all newly designed models) | confirmation on treadmill if treadmill has UserTerminal or alternatively confirmation on ECG. See [7B] coscom v4 | test procedure with interface communication logfile, assessment and release document |
| 6. | **design, validation and maintenance based on IEC 62304** certified along with the IEC 60601-1 standard by DAkkS accredited laboratory. | regulatory requirements based on MDR (EU) 2017/745 e.g. Article 10 and Section 3 of Annex I, Article 22 and others | *done for treadmill.* see certification by DAkkS accredited laboratory. CB / IEC 60601-1 certificate from TÜV Süd |
| 7. | **design, validation and maintenance based on ISO 14971 including PMS**, certified along with the IEC 60601-1 standard by DAkkS accredited laboratory. | regulatory requirements based on MDR (EU) 2017/745 ANNEX I 17.2., ANNEX III, Article 22 and others | *done for treadmill.* see certification by DAkkS accredited laboratory. CB / IEC 60601-1 certificate from TÜV Süd |
| 8. | **PMS; quality assurance and regulatory affairs agreement** between the involved parties: manufacturer of ECG and manufacturer of treadmills. | regulatory requirements based on MDR (EU) 2017/745 Articles 22, 83, risk management. QA and RA agreement page 1 respective articles | update: see sample QA and RA agreement with release document template. download |
| 9. | **fall prevention system** (e.g. safety arch with harness & chest belt) for all subjects/patients, where a fall would pose an unacceptable risk. | based on risk management according to ISO 14971 | *done for treadmill.* see risk management and warnings in IFU. e.g. page 11 of manual |

Figure 13: Example for "request control" confirmation:



**CAUTION!** The treadmill will start now! Make sure the patient / subject holds the handrails and is ready for start to walk or run.
Use chest belt and safety arch for fall prevention for all applications where a fall would cause high risks to the patient / subject.

OK

Some relevant links:
http://www.coscom.org/coscom_v4/20211111_cos100115v4_hpcosmos_coscom_v4_interface_protocol_treadmills_ergometers_admin_OP.pdf
http://www.coscom.org/coscom_v4/20210924_hpcosmos_coscom_v4_QA_RA_sample.docx
http://www.coscom.org/coscom_v4/20211201_regulatory_requirements_coscom_v4_interface_protocol_treadmill_control_hpcosmos.pdf
https://www.hpcosmos.com/sites/default/files/uploads/documents/20170120_h_p_cosmos_cb_certificate_iec_60601-1_product_family_150-50_lc.pdf
https://www.hpcosmos.com/de/aktuelles/interface-control-treadmills-risks-non-compliance-safety-features

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