

To whom it may concern

h/p/cosmos sports & medical running-machines (treadmill-ergometers).

MDD medical device directive. Safety standards.

Dear valued customers,

Over 18 years of experience in the production of treadmill-ergometers and complex systems with accessories and special options have made h/p/cosmos the absolute treadmill specialist. We consider ourselves as the “market leader in technology and safety” amongst all treadmill manufacturers. Safety has a very high priority for us – above all because we know from experience what kind of accidents can occur and which consequences might result from these accidents.

On the one hand a treadmill is a very effective instrument in rehabilitation, therapy and diagnostics. However, like in many areas of daily life (i.e. all kinds of traffic, may it be by car, train or bus or the handling of electrical machine tools etc.) the use of a treadmill involves dangers which can be minimized by abiding strictly to safety procedures, but can never be fully ruled out. As a manufacturer it is h/p/cosmos' duty, and as the distributor or end-user/operator of the running machine it is your duty, to minimize those dangers as far as possible.

In medical applications many additional risks (patients with pacemakers, ECG lead and electrode connections to the skin, health and physical limitations, high workloads during stress tests, medication, etc.) have to be considered. Therefore medical treadmills with interface and interactive heart rate based load controls are classified as risk class IIb medical devices. They have specific additional design characteristics compared to fitness treadmills, and can only be sold and serviced by authorized and certified distributors. h/p/cosmos has the responsibility to ensure that the systems are correctly installed (with usage instruction) and maintained. Therefore we have implemented a medical device observation and reporting system based on the statutory obligations contained in, Guideline 93/42 EEC, MDD (medical device directive), ISO9001 and EN13485 standard and our internal safety policy and risk management system. This is of utmost importance and all our distributors must sign a contract that they will comply with these important international rules for medical devices, particularly for class IIb devices and their respective statutory requirements.

h/p/cosmos fulfils its duty in different ways:

- All medical treadmill-ergometer device-families have to undergo an internal product-type examination as well as external tests performed by the respective examination institutes such as the TUV Product Service in Munich / Germany or the EMC laboratory. Our medical treadmill-ergometers meet the norms and guidelines stipulated for the medical application area such as the **CE** 0123, MDD, EU guideline 93/42 EEC for medical products, IEC EN 60601-1 (VDE 0750), VDE 0751, IEC EN 60601-1-2 (EMC), IEC EN 60601-1-4, EN 957-1, EN 957-6.
- All h/p/cosmos medical treadmill-ergometers must undergo a 24-hour non-stop test after production with strict safety tests, high-voltage-tests and electrical as well as mechanical safety-checks. All tests are recorded, checked by a second independent employee and filed. h/p/cosmos treadmills have to pass the checks 100% without exception.

date

January 24, 2006

our email

sales@h-p-cosmos.com

your ref.

your message

your phone-no.

your fax-no.

your email

your address-no.

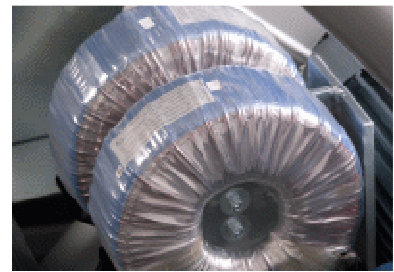
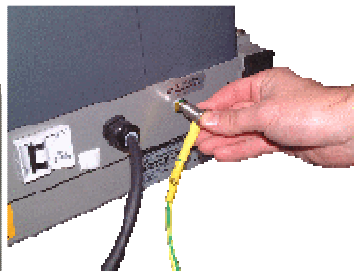
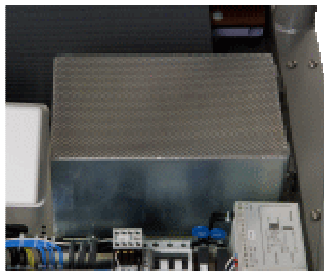
h/p/cosmos sports & medical gmbh

Am Sportplatz 8
DE 83365 Nussdorf-Traunstein
Germany

phone +49 / 86 69 / 86 42 0
fax +49 / 86 69 / 86 42 49

email@h-p-cosmos.com
www.h-p-cosmos.com

President Franz Harrer
HRB-Nr. 7563 Traunstein



- All medical h/p/cosmos treadmill-ergometers have an Emergency Off Switch (current off with mains disconnection, not only the “standard software controlled emergency stop button”), power supply with increased voltage resistance, electrical installation and wiring according to IEC 601-1, a potential equalization pin and a potential equalization transformer.
- h/p/cosmos has a quality management and risk management system according to ISO 9001:2000 & ISO 13485 as well as medical device observation and incident reporting system.
- In the course of maintenance work h/p/cosmos technicians or authorised service personnel check the electrical safety of the treadmill together with all safety relevant details and measure the accuracy of speed and elevation of the treadmills at the customer's premises.
- h/p/cosmos trains all relevant service technicians and sales personnel as medical device consultants with respective certification.
- The user manuals of h/p/cosmos treadmills contain all important information and safety advice as well as maintenance instructions and user regulations. The treadmills have a label with the date of the next safety check /maintenance.
- h/p/cosmos offers numerous options and accessories such a safety arch with harness for fall prevention, chest belt with automatic stop, arm supports or the unweighting system h/p/cosmos airwalk, which increase safety for the patient during the use of a treadmill-ergometer. <http://www.h-p-cosmos.com/en/safety/index.htm>

Therefore we take it as our responsibility to inform our partners and customers about the background and necessity only to use medical products in the medical application field. Statutory requirements only permit us to supply medically classified equipment for medical applications. However we ask you to ensure that your customers ONLY use medical products for applications stated under § 1 of the MDD (Medical Device Directive COUNCIL DIRECTIVE 93/42/EEC of 14th June 1993 concerning medical devices):

Medical Device Directive Article 1 Definitions, scope 2 a.)

“medical device” means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: Diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for any injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

The use of a product not released for medical use by the manufacturer in a medical application can result in increased risks for the patients and for the operator – especially in the case of an accident on the treadmill ergometer. In this case all parties involved (your insurance company, your professional association, possibly patients lawyers and courts) will question negligence and liability. Therefore the use of a sports device for medical purposes bears increased risks for the distributor, customer, operator, end user and last but not least the patient. Despite that some of the above mentioned laws and guidelines are only binding within the European Union, the patient's needs, the risks and the required safety procedures are the same all over the world. We ask all parties involved to help in improving safety.

With cosmic regards

h/p/cosmos sports & medical gmbh

Franz Harrer

President

reply to h/p/cosmos Germany by fax: +49 / 86 69 / 86 42 49

Herewith we confirm the receipt and the understanding of the distributor's and the user's duties for using medical devices for medical application based on MDD (Medical Device Directive COUNCIL DIRECTIVE 93/42/EEC of 14th June 1993 concerning medical devices). We will not use sports and fitness treadmills for medical applications.

place, date, name and occupation in block capitals

stamp and signature of distributor

place, date, name and occupation in block capitals

stamp and signature of customer (operator / end-user)