



d.o.o. Ajdovščina, Vipavska cesta 4i, 5270 Ajdovščina,
TEL 000386 (0)5/3689 330, FAX 00386(0)5/3663 805,

TRR 04751-0000200307, ID S179828612, E-MAIL: info@timo.si

FIELD SAFETY NOTICE

To whom it may concern

Medical device: Shower trolleys
Product affected: Shower trolleys - electrical (type: 155030)
Date of announcement: 26.2.2014
Types of action: Changes to Instruction for use and maintenance
Warning label on residual risk for the incorrect position of the castors

BACKGROUND FOR SAFETY NOTICE

A problem can occur with the shower trolley under the following circumstances:

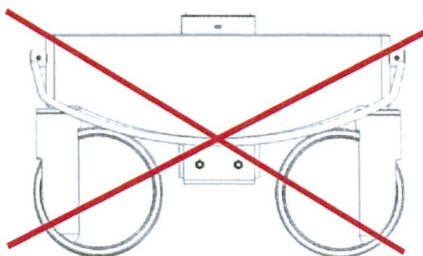
- the mattress platform of shower trolley is in highest position, and
- the castors are blocked in the incorrect position i.e. inwards the mattress platform, and
- patient is lying on his side close to the side rails and nurse is holding him/her while bathing and care.

The risk of shower trolley overturning may be present.

One case of near-miss incident was reported to happen in home for elderly people in Finland. Although no one has been injured in the reported incident and not all circumstances of the incident was clarified, we have analyzed the reported incident with all seriousness. Such incident has never happened so far with our shower trolleys.

The outcome of our analysis was:

- The deemed instability of shower trolley happened while moving patient from/to the trolley by supporting nurses and the castors of the trolley were either unblocked or blocked in inward position (i.e. incorrect position) and the side (dynamic) fatigue was exerted during patient handling process.
- The likelihood of occurrence of risk is considered to be higher with shower trolley type 155030 with castors of diameter 200 mm and less possible for shower trolley with castors diameter 125 mm.
- The existing Instructions for use and maintenance of the shower trolley do not include precise information on safe and unsafe practices of patient handling process and not emphasize the functions of overturning preventions. Therefore we decided to:
 - add the warning label shown below to the instruction for use and maintenance
 - to fix the warning label for the incorrect position of the blocked castors on the base of shower trolley.



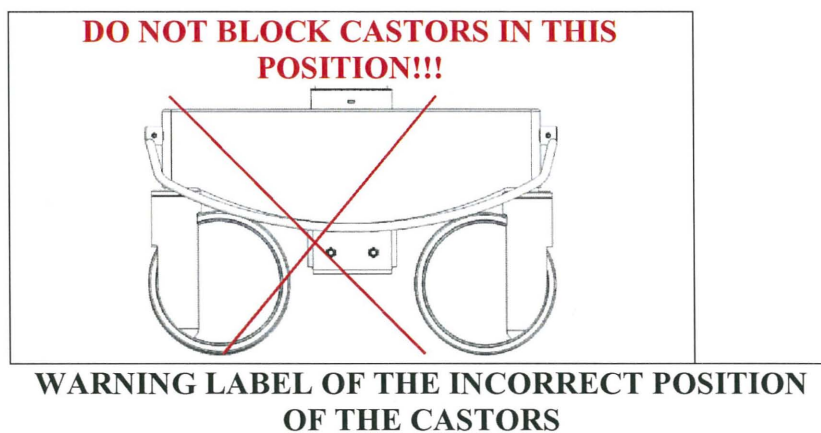
INCORRECT POSITION OF THE CASTOR DURING PATIENT HANDLING PROCESS

ADVICES FOR USERS

Users are asked to take note of the following warning in the instruction for use and maintenance as also of the warning label of the incorrect position of the castors, that are placed on the base of shower trolley at foot brake pedal.

Before you start with the care and bathing of patient in shower trolley, you must be sure that castors are blocked in correct position. The correct position of castors are shown on picture 14 (parallel with mattress platform) or shown on picture 15 (oriented outwards the mattress platform).

It is not allowed that castors are blocked in the incorrect position as it is shown on picture 16 (oriented inwards the mattress platform). Namely, in case the mattress platform of shower trolley is in highest position and patient is lying on his/her side close on the side rails and nurse is holding him/her while bathing and care, there is a risk that the shower trolley can be overturned, because of the instability caused by potential overload on side rails while handling the patient bathing and care in the trolley. As a result, the shower trolley can be overturned and cause injury to the patient or staff.

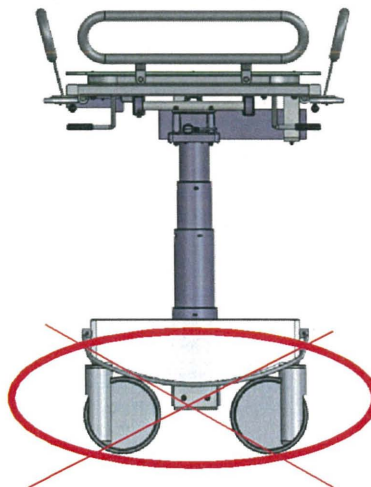


WARNING IN THE INSTRUCTION FOR USE AND MAINTENANCE:

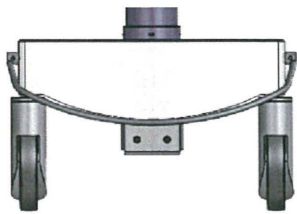


ATTENTION!! Make sure that castors are blocked in correct position before patient handling!

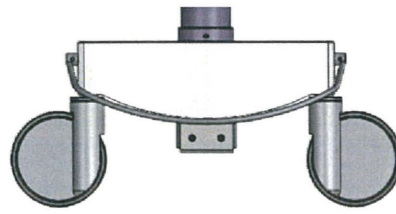
Never block the castors inwards the mattress platform as it is shown on picture 16 – risk of trolley overturning!



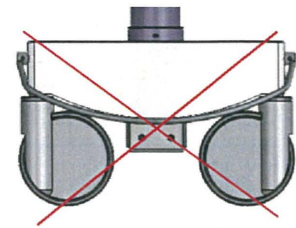
picture 16



picture 14



picture 15



picture 16



Timo shower trolleys can be indentified by the TIMO logo on the base of the product.



CIRCULATING THIS FIELD SAFETY NOTICE

This field safety notice must be sent to all staff in concern in your organisation, and to any representatives of the organisations that have been using product that may be affected by the above mentioned risk. Please fill in (and photocopy where necessary) the attached confirmation form and sent it to your local retailer or the manufacturer within 30 days.

CONTACT INFORMATION

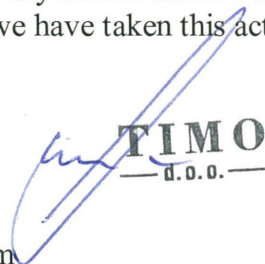
For more information, contact your local retailer or the manufacturer.

Retailer	Manufacturer
J.B. CARE A/S	Timo d.o.o. Ajdovščina
Jan Bjerregaard	Vipavska cesta 4i
Stokagervej 27 hal 3	5270 Ajdovščina
8240 Riskov	Slovenija
Tel. 70 27 27 66	Tel: +386(0)53689330
	Fax: +386(0)53663805
jan@jbcare.dk	e-mail: info@timo.si

The appropriate authorizaties have been informed abouth this safety notice.

We apologise for any inconvenience caused by this safety notice and hope that you understand why we have taken this action.

Zvonko Ličen,
Director



ATTACHED:
confirmation form



Podjetje je vpisano v sodni register pri okrožnem sodišču v Novi Gorici, št. reg. v pisa 1/01977/00, osnovni kapital 219.496,00 EUR



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CONFIRMATION

I hereby confirm that _____, (organisation)
has received the important safety notice from TIMO d.o.o. Ajdovščina dated 26.02.2014 and
circulated it as instructed.

(Name, title)

(location, date)

Please send by e-mail, fax or post this page to:

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ISO 9001
Q-1245



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