



Informal document No. 9

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for Wheelchairs and Seating*

**30 JUNE 2003**

**GRSG (Ad-hoc) Group**

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On 1 April 2003  
MDA joined with  
MCA (Medicines Controls Agency)  
to become the MHRA  
(Medicines and Healthcare products  
Regulatory Agency)  
MHRA is an Executive Agency of the  
Department of Health

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The MHRA (Devices) is the primary source of expertise within the UK Department of Health for matters relating to the safety, quality and performance of all medical devices.

Also on behalf of the UK Secretary of State for Health MHRA (Devices) is the UK Competent Authority for the European Medical Devices Directive (CE marking).

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## Major areas of MHRA (Devices) workload:-

- Adverse Incident Investigations
- Advice & Guidance
- European Affairs
- Standards Activity
- Product Evaluation

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There are over 1,000,000 wheelchair users in the UK and thousands of vehicle journeys are completed every day with few reported problems.

However, a small number of injuries and fatalities have been reported.

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MHRA has attempted to raise awareness and understanding for all concerned by producing two guidance documents on the Safe Transportation of Wheelchairs.

- Guidance on the Safe Transportation of Wheelchairs MDA DB 2001(03) June 2001
- Guidance on the Safe Use of Wheelchairs and Vehicle-mounted Passenger Lifts MDA DB 2003(03) March 2003

The documents are available as a download from MHRA website [www.mhra.gov.uk](http://www.mhra.gov.uk) and in paper form from MHRA.

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- The UK Medical Device Regulations 2002  
SI No 618
  - The Disability Discrimination Act 1995
  - European Union Directives on Vehicle  
Construction
  - Manual Handling Regulations
  - International Standards

All have implications for wheelchair users, carers, prescribers, transport providers, vehicle and equipment manufacturers/suppliers.

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In general the safety of wheelchair users in vehicles should compare with other vehicle users.

When a wheelchair user is travelling in a vehicle where other seated passengers have an occupant restraint and/or headrest then an occupant restraint and/or headrest should be provided for the wheelchair user.

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As part of their CE marking process manufacturers of wheelchairs must:

1. Undertake a risk analysis.
2. Ensure that the device meets all the requirements of the relevant directives.
3. Make a declaration of conformity.

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## **RISKS/HAZARDS EXAMPLES (Wheelchairs)**

Start with a description of the intended user

Then identify **ALL** intended usage

Risks/hazards both from and to :-

User, environment, construction materials, transport, maintenance/repairs, electrical safety, fire retardency, biocompatibility, hygiene, any other potential hazards

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## MINIMISE OR REMOVE RISKS

Consider:-

Specification/design of equipment

Instructions/Warnings

Labelling

Training

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In some cases standards can be used by manufacturers to show how they have reduced risks and met some of the essential requirements of the Medical Device Regulations.

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For transportation elements of their risk management, many wheelchair and seating manufacturers look towards the available issued (or draft) standards.

Standards (or draft standards) are available for the dynamic impact testing of,

- wheelchairs
- wheelchair tie down and occupant restraint systems (WTORS)
- seating units

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ISO 7176 Part 19

(issued) - Wheeled Mobility Devices for Use in Motor Vehicles

ISO 10542 Parts 1 to 5

Wheelchair Tie-down and Occupant Restraint Systems (WTORS)

(issued) Part 1 General Requirements

(issued) Part 2 Four Point Strap Type Tie-downs

(draft) Part 3 Docking Tie-down Systems

(draft) Part 4 Clamping Tie-down Systems

(draft) Part 5 WTORS for Specific Wheelchairs

ISO 16840 Part 4

(draft) Wheelchair Seating for Use in Motor Vehicles

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## ALL THESE STANDARDS INCLUDE

- A forward facing impact simulation at 48km/h @ 20g.
- A lap and diagonal belt restraint for the wheelchair occupant with an above shoulder 'B' pillar mounting or guide.
- A tie-down system for the wheelchair.
- Pass/fail criteria and design/labelling for the equipment itself.

NOTE: Only ISO 10542 Part 5 specifically includes children at this time.

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The standards concentrate on equipment pass/fail, dummy movement and the possibility of contact with the vehicle structure or other vehicle passengers.

They do not at present include any form of injury level measurement for a wheelchair user.

The wheelchair could pass whilst the dummy occupant had been subject to high impact loading as confirmed by some of the TRL and other test results in this subject.

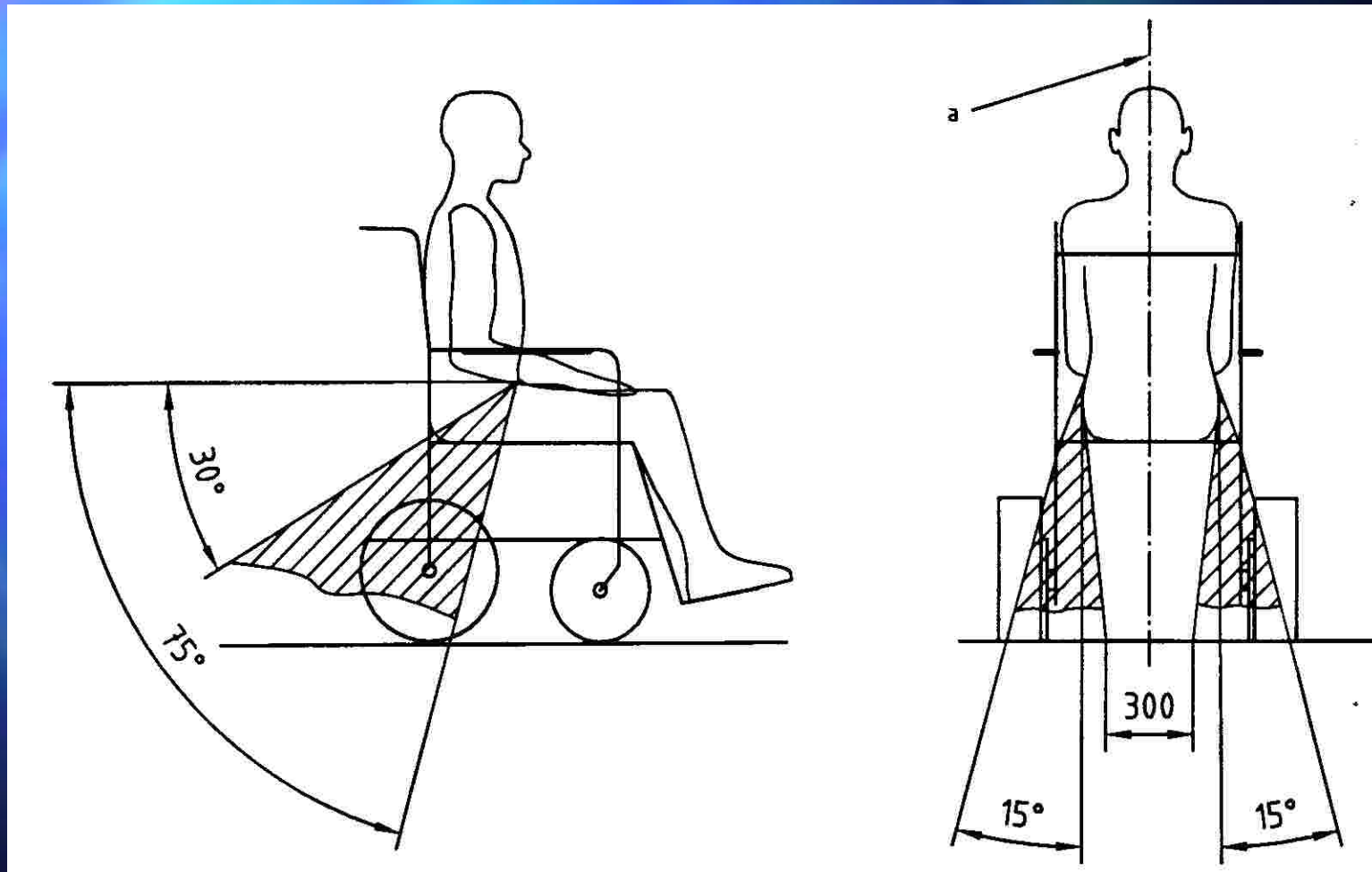
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## Occupant restraints provided by the WTORS manufacturer shall:

- have both pelvic and upper torso belts designed to apply forces to the occupant's skeletal regions
- function independently of the wheelchair, such that the restraint belts anchor to either the vehicle or wheelchair tiedown components so that occupant-restraint loads are not transmitted through the wheelchair
- have belt restraints that can be adjusted in length without the use of tools

## Range of required angles for pelvic belts and locations of pelvic belt anchor points

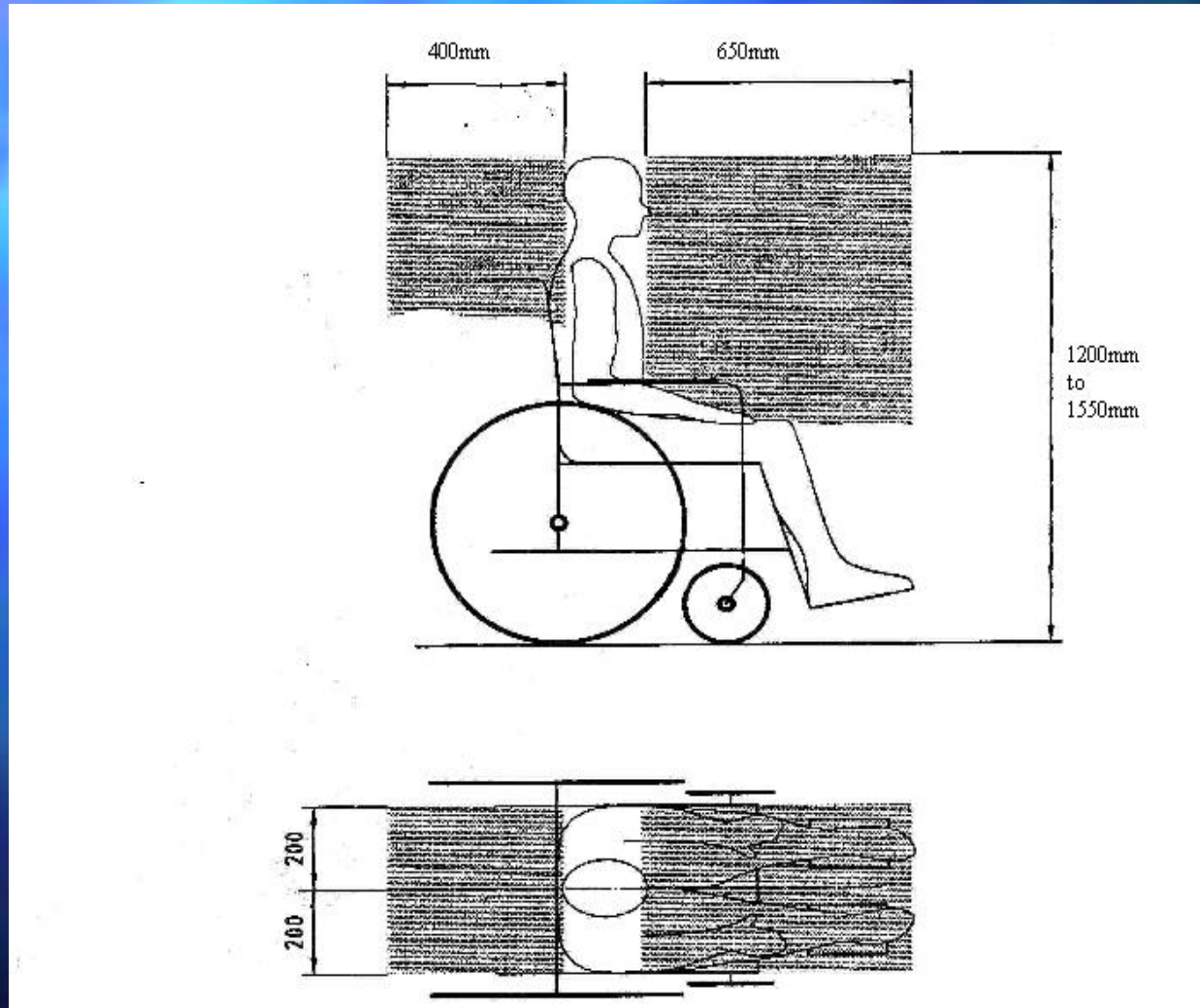


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If occupant restraints include structural components for the attachment of upper anchorages or guides for upper torso belts, locations for the upper anchor points shall be provided that are:

- adjustable in height so they can be positioned at or above the shoulder level of the intended user(s), or that are
- located at least 100mm above the wheelchair ground plane

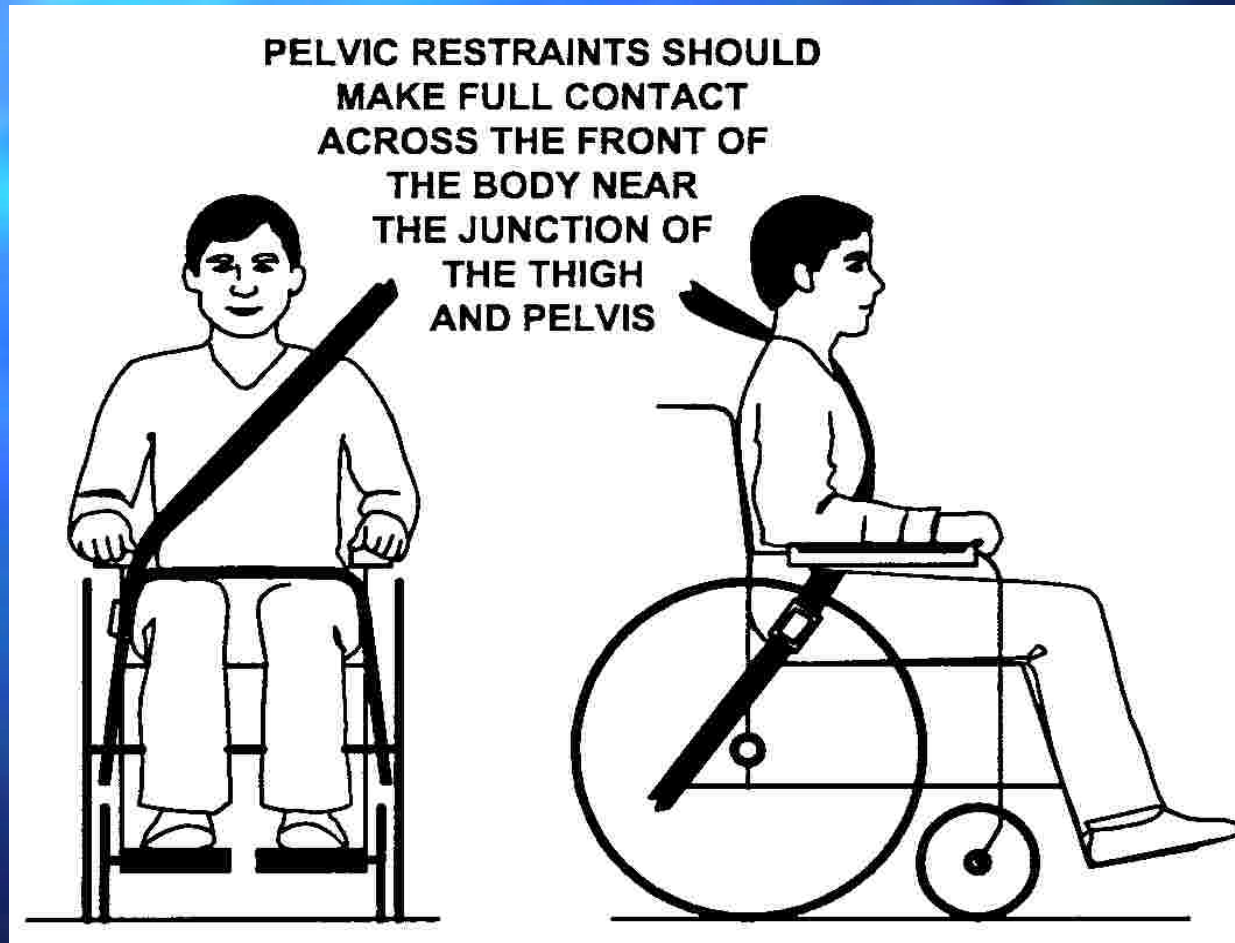
## Clear zones for wheelchair seated occupants



## Example of warning label illustrating improper positioning of occupant restraint belts



## Illustration of proper belt fit



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The vast majority of wheelchairs and WTORS now being sold in the UK have been tested against these standards.

Older wheelchairs have not been tested, but reports received so far do not reveal any major problem trends in the field when used with appropriate WTORS.

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Lack of a “Test Certificate” for a wheelchair based on one of these standards does not mean it is totally unsafe in all situations.

Conversely

A Test Certificate does not mean it is totally safe for the wheelchair user in all situations.

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The wheelchair manufacturer should give information on:

- suitability for use in vehicles transport
- any limitations
- if suitable should give information on how to transport it safely

Also the WTORS manufacturer should give information on:

- compatibility
  - how to use safely
  - any limitations in use
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# FUTURE

- The standards are still evolving.
- The inclusion of children into these standards will start soon (only 10542 Part 5 includes children at the moment).
- Rear facing in a frontal impact and forward facing in a rear impact are also under consideration. (Incorporating information obtained so far from provisional ISO Working Group tests plus the TRL research work.)
- Rear facing will probably be covered by a WTORS standard.

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Adverse incidents concerning wheelchair users should be reported to MHRA.

Incidents can be reported on-line or by completing paper copies of adverse incident forms obtained from our web page at:

**[www.mhra.gov.uk](http://www.mhra.gov.uk)**

All adverse incident reports are registered on the MHRA (Devices) database for investigation or trending.

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## Instructions for downloading safety warnings or guidance from [www.mhra.gov.uk](http://www.mhra.gov.uk)

- go to Devices
- go to publications/safety warnings
- choose Device Bulletins to download further copies of the Device Bulletins
- choose Safety Notices to download earlier Safety Warnings
- choose Device Alerts for Safety Warnings after December 2002)

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**Old MDA Web page**  
**[www.medical-devices.gov.uk](http://www.medical-devices.gov.uk)**

**New MHRA Web page**  
**[www.mhra.gov.uk](http://www.mhra.gov.uk)**

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