Guidance on the Stability of Wheelchairs
1 Executive summary

The MHRA continues to receive adverse incident reports where users or carers have been injured or have died as a result of wheelchairs tipping in use. The reports cover all types of wheelchairs with or without supportive seating, including buggies for children with impaired mobility, non-powered wheelchairs, powered wheelchairs and powered scooters.

This Device Bulletin has been prepared in consultation with interested parties to give guidance to users, carers, health services, healthcare professionals, manufacturers and others involved in the provision and use of wheelchairs, seating and accessories.

This document identifies a wide variety of issues affecting wheelchair stability and gives guidance on reducing or removing the risks whilst trying to maintain independent mobility for an individual wheelchair user. It includes:

- what is meant by ‘stability’ or ‘instability’ where wheelchair users are concerned;
- major factors affecting the stability of powered or non-powered wheelchairs;
- risk management;
- points to consider before purchase or prescription;
- manufacturers’ testing and information for users, carers and prescribers;
- how to report incidents to the MHRA.
2 Introduction

Our investigations of adverse incidents have found that there is a lack of understanding of the potential effects of the use of wheelchairs on slopes, ramps or uneven ground. We have also found a lack of understanding of reduced stability due to:

- movement of the user;
- effects of the addition of accessories or other equipment;
- inappropriate adjustments or modifications to the wheelchair.

In some cases these issues are further compounded by the effects of the local environment such as:

- hills;
- slopes;
- ramps;
- sloping pavements;
- dropped kerbs.

This gives rise to difficulties for all concerned in equating the usage angles stated in the wheelchair manufacturer's literature into practical terms that a user, carer or prescriber can easily recognise, understand and use.

Furthermore different body proportions of a wheelchair user affect stability for example:

- lower limb wasting or amputation;
- increased upper torso mass;
- upper torso height;
- obesity.

Asymmetrical body positions or fixed joints such as hips or knees, or extensor spasm may also affect stability.

Approximately 51% of stability-related incidents reported to the MHRA were concerned with rearward stability, 39% involved forwards stability and 10% involved sideways stability.
In the past, the use of extended wheelbases by moving the rear wheel mountings rearwards was frequently used as a means to increase stability. Whilst this was appropriate in some cases it really only concentrated on rearwards stability. The increased rearwards stability could then cause problems to users and carers in normal use such as self-propelling or negotiating kerbs and steps if the amount of increase was not carefully matched to the requirements and capabilities of the user and carer.

When individual stability tests are being carried out before purchase or prescription they are mainly static tests against a simple pass/fail criteria. This may not represent real life usage including the effects of the environment in all cases.

The following sections incorporate guidance on all aspects of stability. This includes forwards, rearwards and sideways stability when the wheelchair is moving or stationary. All aspects should be considered during prescription processes, before a purchase is made or before any accessories or other equipment are added to a wheelchair. Similarly the capability of the user, their physical shape and mass should be included.

For simplicity most of the figures in this document have been based on a non-powered wheelchair outline but the principles apply to manual and powered wheelchairs, buggies and powered scooters.
3 Stability and instability for wheelchairs and users

3.1 Stability/stable

Generally, for a wheelchair to remain stable it must be upright on its wheels with the combined centre of mass of the wheelchair and the user being within the wheelbase of the wheelchair as shown in Figures 1 and 2.

Note: on all figures the red circle denotes the approximate centre of mass for the user and wheelchair combined. The red arrow represents the direction of the force due to gravity, which always acts vertically downwards. If the line of action of the force remains between the points of contact (POC) of the wheels with the floor then the wheelchair will be stable (see also Figure 2).

Figure 1 Stable (side view)
In a similar manner sideways stability also depends on the position of the centre of gravity of the wheelchair and user (see Figure 2). If the line of action of the force (red arrow) remains between the points of contact (POC) with the ground then it will be stable.

![Figure 2 Stable (front view)](image)

Note: if castor assemblies rotate, the POC will change for these wheels and may reduce the stability of the wheelchair for the same slope.

### 3.2 Instability/unstable

This section outlines general information concerning instability. Section 4 builds on this and highlights the major factors that reduce stability and may in some cases lead to instability.

**Downhill slope or ramp**

A wheelchair can be stable when forward facing on a downhill slope or ramp (see Figure 3). If used on a steeper slope the wheelchair may roll due to ineffective braking or, if the line of action of the force due to gravity moves close to the point of contact (POC) of the front castors, the wheelchair may slide. If the force due to gravity moves past the POC it will tip forwards (see Figure 4).

Sliding may occur whether the brakes are operated or not. Due to the slide the user may lose control until the wheelchair arrives at the bottom of the slope or ramp.
Uphill on slope or ramp
A wheelchair can also be stable when facing forward on an uphill slope or ramp (see Figure 5). However if used on a steeper slope, the line of action of the force due to gravity moves to the rear of the POC of the rear wheel and the wheelchair will tip rearwards (see Figure 6).
Crossing a slope or ramp
A wheelchair can be stable facing across a slope or ramp (see Figure 7). If crossing a steeper slope, the line of action of the force due to gravity may move to the point of contact (POC) of the lower wheels. The wheelchair will slew (turn sideways) to travel down the slope or slide sideways or, in extreme cases, tip sideways (see Figure 8).

This action may cause the castor assemblies to rotate and further assist the wheelchair to turn down the slope or tip

Figure 7 Stable on slope

Figure 8 Unstable (slope too steep)
4 Major factors that affect stability

4.1 Cushions

Raising the user higher in the wheelchair by the addition of a seat cushion or a seat board etc. onto a standard wheelchair base will raise the centre of gravity and subsequently reduce the angle of slope or ramp on which a wheelchair can remain stable. The forwards, rearwards and sideways stability will all be affected as a result. Figures 9 and 10 show the rearward effect. The sideways and forwards effects will be similar to those shown in Figures 11, 13, 15 and 17.

In some cases seat cushions or seating units can be secured lower within the wheelchair frame itself, which may not raise the centre of gravity to produce instability. Castors can also be outrigged to widen and/or lengthen the wheelbase and in some cases the rear wheel position can be moved rearwards to lengthen the wheelbase (see section 4.6).

If a backrest cushion only is added then rearwards stability will be improved but forward stability will be decreased. The addition of a seat and backrest cushion can have similar effects to that of a seating unit (see section 4.2).
4.2 Seating units

Seating units fitted into wheelchairs, tilting seating units (tilt-in-space) or reclining backrest wheelchairs can have similar effects on stability to the addition of cushions (see section 4.1). However, some seating units also move the user upwards and possibly forwards or rearwards within the wheelchair compared to the original wheelchair seating position. This will further affect stability in all directions. The effects are similar to those covered in sections 3.2 and 4.1.

![Diagram of instability with seating unit](image)

**Figure 11** Unstable forwards with seating unit

To reduce these problems a seating unit may be able to be secured lower within the wheelchair frame without compromising good leg and foot position. The wheelchair base could be fitted with appropriate castor outrigger brackets and/or with the rear wheels positioned further rearwards than standard to widen and/or lengthen the wheelbase. Rather than modify basic wheelchairs, some seating manufacturers offer their own wheelbase units that have been designed to address many, if not all of these aspects.
4.3 Accessories

The attachment of accessories such as trays, communication aids, elevating leg rests etc. to the front of the wheelchair or carrying shopping bags or luggage on the user’s knee will move the combined centre of gravity of the user and wheelchair forwards. Forwards stability is reduced (see Figures 12 and 13) and may lead to sliding or, in extreme cases, tipping.

![Figure 12 Stable without tray](image1)
![Figure 13 Unstable with tray](image2)

The attachment of accessories or other items such as shopping bags, ventilators or oxygen cylinders to the rear of the wheelchair will move the combined centre of gravity of the user and wheelchair rearwards. This may not cause major problems when on level ground but as the wheelchair moves onto a slope the accessories will affect the stability and may increase the effect if they swing further rearwards. Rearwards stability is reduced and may result in instability leading to tipping (see Figures 14 and 15).
Even a small additional mass can considerably reduce the stability. In general accessories should be carried as low as possible within the wheelbase of the wheelchair. Any addition of accessories will require a risk assessment (see section 5) to be carried out including all effects on stability and the overall carrying capacity of the wheelchair. If the mountings are adjustable or can swing then the risk assessment should consider the potential worst case configuration.

Accessories or other items such as shopping bags, communication aids or tray supports are sometimes fixed or carried to the side of a wheelchair. Such additions or mountings that are made to swing away from the front of the user to the side of the wheelchair to aid transfers or feeding will move the combined centre of gravity of the user and wheelchair to one side. Hence sideways stability is reduced and may lead to instability on a slope leading to slewing (turning sideways) or tipping (compare Figures 16 and 17).

Movement of an accessory etc. can also, in extreme cases, lead to tipping of a wheelchair on the level especially during occupant transfers.
Trays and other attachments should be small and as close to the occupant as possible to reduce the effects. Any fitment of accessories will require a risk assessment (see section 5) to be carried out. The user must be made aware of any increased limitations. Movable fixings such as swing to the side communication aid supports require considerations of risk in all positions of maximum movement and adjustment with the wheelchair occupied and unoccupied.

4.4 Anti-tip devices

Anti-tip devices can be added to the front or rear of some wheelchairs to give a physical restriction to the amount of tipping that can occur. It is essential that any anti-tip device will have sufficient strength to function correctly when the wheelchair is carrying its maximum user mass on the steepest intended slope. Where anti-tip devices are removable (e.g. to reduce overall size for storage) it is essential that they are refitted before the wheelchair is used by the occupant. To remove the possibility of this action being missed it would be beneficial for the anti-tip device to be permanently attached to the wheelchair.
4.5 User body movement affecting stability

User body movement can reduce or improve stability.

4.5.1 User body movement reducing stability

The stability forwards, rearwards and sideways can be reduced by the user moving their upper body or by the user extending their arm to reach for other equipment, operate switches or to lean out from the wheelchair to pick up something. See Figures 18, 19, 20 and 21.

**Figure 18** Stable

**Figure 19** Unstable
Users should be informed about the risks and offered information concerning other assistive devices such as an appropriate height table or a grab stick to reduce the need to move the upper body whilst reaching. This may also involve referring the user to other suppliers or service providers.
Other body movement such as extensor spasm or pushing rearwards with the feet on the floor during foot propelling can reduce rearwards stability and lead to instability (see Figure 22). Occupants who are subject to significant involuntary postural changes or sudden spasms, should be assessed for appropriate posture management. Some users may benefit from special calf straps or heel loops to stop feet moving backwards behind the foot supports. Posture belts (hip/pelvic belts) may also be used to stop a user slipping down in the wheelchair seat. More complex solutions may be required in some cases. In all these cases the user would benefit from a multi-disciplinary assessment where all elements can be considered to arrive at the most appropriate outcome.

Figure 22 Potentially unstable.
4.5.2 User body movement improving stability

Users should also be made aware that appropriate body movement, where they are able to, could improve stability in some circumstances.

![Figure 23 Improved stability rearwards](image1)

![Figure 24 Improved stability sideways](image2)

Whilst a forwards movement of the user’s upper body may cause instability on level ground (see Figure 21) or when facing downhill, a forwards movement (see Figure 23) when moving up a slope will considerably improve the stability of the wheelchair as it moves up the slope. In a similar manner leaning the upper body towards the uphill side (see Figure 24) when moving across a slope can improve sideways stability.

Some active users have developed their skills to balance their wheelchairs on the rear wheels to aid manoeuvrability. This position is maintained by a combination of balance, body position and arm movement. Training and practice is generally required to achieve this level of skill (also see section 4.6).

Information and, where appropriate, training should be given to users and carers before use of a wheelchair, stressing both the positive and negative aspects of body movements where stability is concerned.
4.6 Adjusting rear wheel position

To improve rearwards stability some wheelchairs have the option of moving the rear axle mount backwards. This could be as a part of an adjustable mounting or due to the frame being modified by the manufacturer to place a fixed rear wheel mounting further rearwards than standard. This option is known generally as Rear Wheels Set Back (RWSB).

This extension of the wheelbase rearwards (compare Figures 25 and 26) can improve the rearward stability considerably. However, this can cause problems to users who self-propel because the rear wheels have been moved rearwards in relation to their arms and shoulders. Also in some cases, longer wheelbases can cause problems to users and carers who have to negotiate steps or kerbs and require the wheelchair to tip to climb the kerb. The choice of the amount of RWSB is therefore critical in striking the appropriate compromise between the risk of instability rearwards and the need for the wheelchair to be able to be propelled or tipped easily to negotiate steps etc.

![Figure 25 Short wheelbase](image1)
![Figure 26 Longer wheelbase](image2)

Also some rear wheels can be moved forwards to give improved propelling and balance position for an active user. However the shortening of a wheelbase will reduce stability and may be inappropriate for the safety of some users.
4.7 Effect of propulsion by motor or hand

4.7.1 Operation and adjustment of controls for powered wheelchairs

Sudden movement of the control input device from one direction to the opposite direction (e.g. forwards to reverse, reverse to forwards or side to side) can lead to instability or sliding if the wheelchair is already on a slope or has accessories or attachments and is nearing its maximum level of stability (see Figures 27, 28 and 29).

This situation can be further exaggerated if the control unit itself has been programmed to provide fast acceleration or rapid response for directional changes. Also, if the user does not have adequate support for their arm whilst operating the control, sudden movement of the control input device may occur.

Controls should be adjusted and programmed for their user to ensure that the position, response for acceleration and directional change is appropriate taking into account the capability of the user, the expected usage and environment. Also training should be given to the user where necessary in the safe operation of the controls which should include the potential for invoking instability both up, down and across slopes or when the wheelchair has been fitted with accessories etc. as described in earlier sections.

Figure 27 Unstable up slope

Figure 28 Unstable down slope
4.7.2 Hand propulsion of non-powered wheelchairs

When moving uphill the rearwards stability will be significantly reduced due to the propelling action of the user. Furthermore stopping the wheels from rotating whilst travelling down a slope may lead to sliding and loss of control (see Figures 30 and 31).

Users should take care when hand propelling up or down slopes so that tipping or sliding does not occur. The chances of tipping and sliding can be reduced if appropriate body movement is used (see section 4.5.2)
4.8 Brakes

In some cases, the wheelchair will slide down a slope with its brakes applied or tip if it is nearing its limit of stability (see Figures 28 and 29). Users and carers should be fully familiar with the method of correct operation of all the brakes on their wheelchair and the braking characteristics of their wheelchair.

Uneven braking characteristics on service brakes can lead to adverse steering effects and possibly result in a slide or tip (see Figures 28, 29 and 31). Regular servicing and maintenance is critical to the performance of brake systems. Manufacturer’s information should be followed for the frequency of brake checks and maintenance (see sections 4.12 and 7).
4.9 Effects of obstacles, soft ground or gravel

When travelling up, down or across a slope contact with relatively small obstacles can cause instability leading to tipping or sliding (See Figures 32 to 35). Hitting obstacles can also cause the seated occupant to slide forwards or fall forwards out of the wheelchair. Use on soft ground can lead to similar problems as the front wheels tend to sink into the ground and act as if the wheels have come into contact with an obstacle. Care should be taken whenever obstacles or soft ground are encountered. Alternative routes should be used wherever possible.

Figure 32 Stable before obstacle
Figure 33 Unstable after hitting obstacle
Figure 34 Stable before obstacle
Figure 35 Unstable after climbing obstacle
4.10 Ramps and slopes

4.10.1 Ramps

Ramps used for wheelchair access can present a high risk to the user. Appropriate gradients and surfaces should not cause problems if they are within the capability of the wheelchair, user and attendant (see sections 3 and 4).

The following are the minimum points required to provide appropriate ramps or slopes:

- ramps should have a high friction surface, which will remain effective in wet conditions so the risk of slip is reduced;

- maximum ramp gradient must be less than the maximum limit for the wheelchairs that use it;

- adjustable ramps should be labelled to show their maximum safe operating limits;

- all ramps should be labelled to show their maximum carrying capacity;

- maximum ramp carrying capacity must be greater than the maximum combined mass of the wheelchair, user and accessories for the wheelchairs that use it;

- ramps should be, as a minimum, fixed at one end before being used by a wheelchair (for both buildings and vehicles);

- information relating to the maintenance required to keep the ramp operating safely should be available;

- ramps that are made of separate parts e.g. channels or two-stage ramp construction, should have a positive location between each section;

- override edges to stop wheelchairs falling from the sides or landings should be fitted to all ramps. For fixed ramps, handrails should also be fitted;

- ramps to door entries that do not have automatic opening devices should have a level platform in front of the doorway, of sufficient size for the wheelchair and, where necessary, an attendant to allow safe operation of the door.

Note: BS 8300:2001 ‘Design of buildings and their approaches to meet the needs of disabled people. Code of practice’ gives specific guidance on ramps which should also be adhered to [1].
• doorway thresholds or weather strips at the top of ramps give added complications to a wheelchair. Thresholds over 10mm can cause problems for some wheelchairs. Fillet strips or similar should be used to give easier travel but the overall height of the strip may still be a problem where a wheelchair is near to its limit of stability;

• ramps that start from uneven or sloping ground can provide increased risks of forwards, rearwards, and/or sideways instability. If possible, ramps should be positioned to start from level ground.

4.10.2 Double or composite ramps and slopes

During movement of a wheelchair from one level to another a user or carer will come across ramps or slopes which in some cases can be made up from various elements. Some ramps or slopes are simple short runs directly from one level to another. However, other double or composite ramps or slopes do not continue at the same angle along their whole length.

The wheelchair may be well within its limits of stability on parts of such a slope or ramp, but subsequent steepening of the gradient further along the slope or ramp may invoke instability. Generally this will only be a problem when the transition from one gradient to a steeper gradient occurs abruptly, or where body movement or sudden movement of the control input device from one direction to another is made. However, if the gradient gradually increases over a long distance it may also become a problem if sudden body or control movements are made on the steeper part of the gradient.

Users should take care when approaching changes of gradient on slopes or ramps. Sudden control or body movement as the gradient change occurs may invoke instability (see section 4.5).
4.11 Travelling in vehicles

The safe transportation of wheelchairs in vehicles is provided in greater detail in DB2001(03) [2] and DB2003(03) [3]. However the following points highlight the potential effects on stability:

- entry ramps not securely fixed to the vehicle either when used for entry or exit or when not in use and being carried in the vehicle;

- entry or exit ramps too steep, with the angle being greater than the maximum safe usage gradient as specified by the wheelchair manufacturer or for the reduced safe usage gradient due to the addition of accessories etc.

- when in cars, taxis or minibuses wheelchair tie-down and occupant restraints (WTORS) must be used;

- failure to use an upper body restraint or using an inadequate/inappropriate restraint could allow sideways movement of the upper body under normal vehicle movement. This could result in injuries to the user through contact with other equipment or the vehicle structure or in extreme cases tipping or falling from the wheelchair;

- for forward facing occupants inadequate, inappropriate or unused upper body restraints could allow forwards movement of the upper body under breaking or impact;

- inadequate, inappropriate or unused wheelchair tie-downs could allow the wheelchair to tip forwards, sideways or rearwards during normal vehicle movement;
4.12 Maintenance

Poor maintenance could lead to the failure of components that may cause the user to change position unexpectedly and either fall from the wheelchair or tip over with the wheelchair. In extreme cases a carer may also be injured either by falling with the wheelchair or in trying to stop the wheelchair and user tipping. Manufacturer’s maintenance instructions should be adhered to.

See the Medical Devices Management Controls Assurance Standard [4] and DB9801 [5].

Poor maintenance can lead to reduced stability for example:

- castors coming loose and falling out leading to tipping (especially when kerb climbing or on raising the front of the wheelchair);
- low tyre pressures leading to side slip on slopes/ramps in addition to reduced effectiveness of brakes on some wheelchairs;
- inappropriate position of anti-tips or anti-tips not providing adequate restriction to tipping;
- armrest mounting loose, not locating, damaged, moving or giving way under body weight of user;
- backrest mountings loose, moving or giving way under body weight of user;
- backrest canvas stretching or tearing and giving way under body weight of user;
- inappropriate positioning or securement of batteries on powered wheelchairs;
- rear wheels coming loose and detaching;
- reclining backrests or tilting seat units not locking correctly in position;
- lap belts giving way in use due to weakness or faults in stitching, buckles or mountings;
- adjustable features or accessory mountings coming loose or being incorrectly repositioned after repair or maintenance actions.
5 Risk management

The decision to provide a wheelchair or seating system requires the residual risks to be balanced against the anticipated benefits for the user. Such judgements should take into account the intended use, purpose, performance, risks and benefits associated with the wheelchair, seating system or accessories and the particular circumstances of use. These judgements should only be made with knowledge of the state of health and needs of the individual user, the benefits that can be provided by the equipment and the need to reduce or eliminate risk.

The ability of the user to acquire skill in using the equipment should not be ignored. Some may learn but some may not. Also some user's condition deteriorates in time with subsequent reduction in physical capabilities e.g. balance, upper body strength and control etc.

Manufacturers generally use a risk management process when considering the safety of the intended user of a wheelchair or seating system. This process includes the acceptability of risks, taking into account the generally accepted state of the art. Any subsequent warnings of residual risk must be clearly displayed in the user instructions and product markings.

The manufacturer must also provide sufficient information on how to use the equipment safely including the necessary maintenance that will keep it operating safely throughout its intended life. Users, carers and prescribers need to carefully consider the content of all such warnings of residual risk and the equipment should only be used in line with the manufacturer's recommendations.

The addition of accessories, supportive seating, cushions or other assistive technology will have an effect on the stability of the original wheelchair. The manufacturers of these additional items, intended for use on a wheelchair, must provide information on these effects. Users, carers and prescribers must carefully consider the content and adapt their individual risk management process accordingly.

The principle of risk management within BS EN ISO 14971 [6] provides assistance for this process for manufacturers. Users, carers and prescribers may also benefit from considering the contents of this document and the Controls Assurance Standard on Risk Management [7].
5.1 Stability testing for individual users

Sufficient information should be obtained to allow an appropriate risk assessment to be carried out in all cases to establish any potential or real safety problems for a user or carer. This could initially be in the form of a simple check list covering elements such as, local environment and occupants body proportions, e.g. lower limb wasting or amputation, increased upper torso mass, upper torso height and obesity, etc. In many cases this initial check will show that the stability requirement for a user can be readily accommodated within the maximum safe gradient of a wheelchair as stated by the wheelchair manufacturer. This will also highlight situations where a more comprehensive individual assessment is required.

Where wheelchairs have been adapted to suit one individual by the addition of cushions, seating units or accessories or the intended use includes severe slopes or ramps, or uneven ground etc., it is essential to ensure that the end combination can function safely within the intended environment.

For the addition of simple accessories consideration of the effects of the change in stability as stated by the accessory manufacturer may be adequate. For more complex situations a stability test may be required. In the past this has generally taken the form of a static test carried out in a clinic situation or at a user’s home. Over the years, various manually operated test rigs have evolved to be used to carry out these tests. In some cases, these rigs may raise the possibility of increased risk to the user, carer and healthcare professional during the process of placing the wheelchair and user directly onto a fixed slope rig or by gradually increasing the ramp angle from the horizontal until an appropriate limit or instability is reached. Other equipment is also being used based on load cells under the wheels combined with appropriate software. This removes the need for the wheelchair to be tipped to extreme angles during the process hence reducing the risks to both the users and others involved.

Health services and suppliers of wheelchairs should review their practices for stability testing to ensure that risks to users, carers and healthcare staff are removed or reduced to a minimum by use of appropriate equipment and processes.

The processes should incorporate elements that consider all the points raised within this guidance with particular emphasis on how any results of static testing can be compared to the dynamic stability requirements for safe usage in all directions on slopes and ramps that the user will regularly come across.
5.2 Instability warning devices

It can be difficult to easily assess the gradient of a slope or ramp and then equate it to the safe gradient information provided by the manufacturer or established via an individual stability test. Some users and carers may benefit from a simple warning device attached to the wheelchair to give guidance on when the wheelchair is nearing the limits of its stability in any direction. Such warnings would then give the user or carer an opportunity to take appropriate action (e.g. use positive aspects of body movement, take care with powered control operation, find alternative route etc.) before the situation became unsafe due to instability.

Note: Audible warning alarms should not be of a similar output to other medical device alarms or warning devices for the visually impaired, such as pedestrian crossing or vehicle reverse alarms. See BS EN 60601-1-8:2004 [8].

Levelling or instability warning devices are available in various forms, but are not regularly offered as accessories or original fitment on wheelchairs at present. However, some research, design and production work has already been carried out on this subject in the UK. For users and carers who would benefit from such a device the wheelchair manufacturer or accessory manufacturer should be contacted to obtain the latest details.

6 Points to consider before purchase or prescription

6.1 Location/geography/environment of intended use

Consider the following:

- pavements and kerbs;
- slopes;
- soft ground;
- thresholds and small obstacles;
- ramps;
- transport.
6.2 User and carer physical size and capabilities

Consider the following:

- mass distribution/user size, e.g. obesity, skeletal deformity, lower limb amputee or wasting;
- user reach, user lean or change of position (voluntary/involuntary);
- understanding of stability by the user/carer (is training needed?);
- is the user using their feet to propel themselves or are they subject to significant body movement or spasm?
- lack of upper body control by the user during normal wheelchair movement;
- does the user require a posture belt (hip/pelvic belt) or posture support?
- the ability of the user or carer to control the wheelchair.

Users and carers should be given information, and where necessary training, about appropriate and inappropriate use of the wheelchair.

6.3 Other points to consider

- effect of accessories e.g. cushions, supportive seating, the use of elevating leg rests or other leg supports;
- adjustments to the wheelchair or accessories and their mountings;
- effects of carrying personal belongings such as bags, shopping etc.
- effect of reclining or tilting seating unit (tilt-in-space) wheelchairs;
- effects of the addition of other assistive technology such as: environmental controls, communication aids, breathing aids, computers and other personal items;
- manufacturer’s information and any limitations in use.
7 Manufacturers’ testing procedures

Most manufacturers test their products in line with the content of the latest European standards for wheelchairs BS EN 12183 [9] and BS EN 12184 [10]. However, the results of these laboratory tests require careful consideration before any declaration can be made concerning the maximum safe gradient shown within the information provided by manufacturers for users, carers and prescribers.

In addition to laboratory test results the manufacturer needs to consider other effects. These will include:

- the performance of the wheelchair brakes on slopes or ramps;
- the potential for reduced surface friction due to rain, dust, surface materials etc.
- the different mass and mass distribution of the range of users that the wheelchair is intended to accommodate;
- the effects of user body movement on the wheelchair;
- the effects of the control settings and control operation;
- the effects of any variants e.g. seat sizes, backrest angles, adjustable elements, accessories.

When all this has been considered the manufacturer needs to build in an appropriate factor of safety before declaring the maximum safe gradient up, down and across slopes within the user instructions for the basic wheelchair and all of its variants and accessories. Any residual risks that have not been removed within this process then require specific warnings to be placed in the user information and, if potentially a major safety risk, on the wheelchair itself. Manufacturers may also choose to offer instability warning devices to assist users and carers to keep within the limit of maximum safe gradient for a particular wheelchair.

Wheelchair accessory manufacturers should declare in their literature the extent to which the addition of their accessory to a wheelchair alters the stability of a wheelchair.

Users, carers, attendants and prescribers must read the information provided by the manufacturers of the product and adhere to the content.

A risk assessment (see section 5) should be undertaken when using a combination of products to identify any hazards that may be associated with their use or any adverse affect on the stability of the combination i.e. fitting cushions or postural supports that affect the centre of gravity.
8 Adverse incidents

The MHRA (Devices) aims to prevent adverse incidents happening and, where they have already happened, to prevent them happening again. No device should ever be considered 100% safe and constant effort is therefore required to reduce both the rate at which adverse incidents occur and the severity of the outcome. Reporting incidents to the Agency provides information that may be directly responsible for preventing similar incidents from happening again.

The first Medical Device Alert of each year gives details of adverse incident reporting (in 2004 this is MDA/2004/001) [11].

8.1 What is an adverse incident?

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of users or other persons.

Adverse incidents concerning wheelchairs, seating, cushions or accessories may arise due to:

- shortcomings in the design or manufacturer of the device itself;
- inadequate instructions for use;
- inadequate servicing and maintenance;
- locally initiated modifications or adjustments;
- inappropriate user practices (which may in turn result from inadequate instructions or training);
- inappropriate management procedures;
- the environment in which a device is used or stored;
- selection of the incorrect device for the purpose.

Conditions of use may also give rise to adverse incidents:

- environmental conditions (e.g. outdoor ramps, slopes or uneven surfaces).
8.2 What should be reported?

Any adverse incident involving a device should be reported to the MHRA (Devices), especially if the incident has led to or, were it to occur again, could lead to:

- death, life-threatening illness or injury or the potential for death or injury in the future;
- deterioration in health or permanent impairment of body structure or function;
- the necessity for medical or surgical intervention;
- inpatient hospitalisation or prolongation of existing hospitalisation.

You should also inform us of:

- any other device-related adverse incidents;
- any minor faults and discrepancies.

These may take on a greater significance when aggregated with other similar events as they may help demonstrate trends or may indicate inadequate design, manufacture or quality assurance on the part of the manufacturer or supplier.

Reports of adverse incidents that appear to be caused by human error are also helpful as:

- the error may be partly (or wholly) due to deficiencies in the design of the device or instructions for use;
- they will help prevent repetition of mistakes possibly by promulgation of advice or through improvements to the design of future devices.

Please remember that the MHRA (Devices) is concerned with preventing the occurrence of adverse incidents; not with assigning blame or liability.

8.3 When should an incident report be made?

All incidents should be reported as soon as possible. Serious cases should be reported to the MHRA (Devices) by the fastest means available, preferably on-line via www.mhra.gov.uk, fax or e-mail followed up by a confirmatory telephone call. Telephone reports should be followed up as soon as possible by a written report.

The initial report of an incident should contain as much relevant detail as is immediately available, but should not be delayed for the sake of gathering additional information.
8.4 How do I report an incident?

**Online reporting** is now available throughout the MHRA website (www.mhra.gov.uk) or via our site on the NHSnet. We strongly recommend that, where possible, you report to us online. Successful use of this route will provide the reporter with immediate confirmation of receipt and a unique incident reference number.

**Paper forms** for reporting incidents can be downloaded from our website (www.mhra.gov.uk) and then either completed electronically and e-mailed or printed and sent by mail or fax.

Copies of forms are also available from:

MHRA
Adverse Incident Centre
Hannibal House
Elephant & Castle
London
SE1 6TQ
Tel: 020 7972 8080
Fax: 020 7972 8109
E-mail: aic@mhra.gsi.gov.uk

**Important:** Full contact details (name, post held, address and telephone numbers etc.) should always be included on your forms and in any telephone messages. This will allow us to contact you to acknowledge receipt of your report or message and to request any further information that may be needed.
9 References


Obtaining publications:

BSI
389 Chiswick High Road, London W4 4AL.
www.bsi-global.com (last accessed March 2004).

Controls Assurance

MHRA (and Medical Devices Agency publications)
Business Services, MHRA, Hannibal House, Elephant & Castle London SE1 6TQ. Tel: 020 7972 8360
www.mhra.gov.uk
DISTRIBUTION

This Device Bulletin should be brought to the attention of service providers, healthcare professionals and others involved in the provision and use of wheelchairs, seating and accessories. Wheelchair users and carers would also benefit from reading this bulletin.

TECHNICAL ENQUIRIES

Enquiries concerning the content of this Device Bulletin should be addressed to:

Jonathan Smith or Alan Lynch
MHRA
241 Bristol Avenue
Bispham
Blackpool
FY2 0BR

Tel: 01253 596 000 E-mail: jonathan.smith@mhra.gsi.gov.uk
Fax: 01253 596177 alan.lynch@mhra.gsi.gov.uk

HOW TO OBTAIN COPIES

Copies of this Device Bulletin are free to the NHS and public sector social care providers and may be obtained on written request from:

Department of Health
PO Box 777
London
SE1 6XH Fax: 01623 724 524 Email: doh@prologistics.co.uk

Quoting reference DB2004(01)

Other establishments will be charged £25 per copy on written request from:

MHRA
Business Services
Hannibal House
Elephant & Castle
London
SE1 6TQ Fax: 020 7972 8124 Tel: 020 7972 8360

Our website lists all current Device Bulletins and safety warnings: http://www.mhra.gov.uk