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Testing of wheelchairs and mobility scooters

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1. INTRODUCTION

Wheelchair manufacturers have to take several aspects into account when designing their products. In the first place, a wheelchair must be safe enough for its users and their assistants, as well as meet numerous mechanical and electrical requirements. This will not only have impact for its design, but also with respect to the minimum performance requirements. The manufacturer shall also pay increasing attention to providing proper documentation and information.

The requirements for manually operated wheelchairs, electrically powered wheelchairs and scooters are described in the European standards, EN 12183 and EN 12184. The ISO 7176 standard, parts 1 to 28, provides more detailed specifications of what needs to be tested and how this tests must be executed.

However, although manufacturers are well aware of the standard requirements and of many aspects of in-house testing, experts at TÜV Rheinland point out that not all products receive approval after application of the relevant standards. In this white paper, which is based on their practical experience, test engineers at TÜV Rheinland explain some of the most common mistakes and shortcomings. Their know-how will help you negotiate these key obstacles to product commercialisation.

2. TRENDS IN WHEELCHAIR DEVELOPMENT

A quick look at today's marketplace for wheelchairs will tell you that functionality is no longer the be-all-and-end-all of product development. Nowadays, fashionable colours, new materials, compact design and modern operating interfaces, for example, are in. In this respect, the wheelchair is no longer immune from the prevailing trends in product development as a whole.

Nevertheless, these trends can have a considerable impact on a wheelchair's functionality. For example, progress in electronics has meant that the size and the mass of motors and batteries have diminished. For a large part, a wheelchair's electric propulsion will determine its functional suitability. A kerb will be easier to mount when the design incorporates two larger wheels at the front on which the motor is mounted. If the larger wheels are at the rear, the procedure will be more difficult, even dangerous. The larger wheels at the front transform the wheelchair into a type of outdoor wheelchair: if these wheels are at the rear, the wheelchair is more suited to indoor use because of its manoeuvrability. A new development in this respect is the mid-wheel drive. In this situation, the drive wheels are directly underneath the wheelchair's centre of gravity and, with castor wheels on the front and rear, it's possible to rotate on its axis. This wheelchair is therefore highly suitable for indoor use.

Use of new materials is primarily intended to cut down the mass of the wheelchair. A lower mass is more comfortable, especially in the case of manual wheelchairs, and with electrically powered wheelchairs, in combination with a larger battery capacity, this will increase its operating range.

3. DEVELOPMENTS IN WHEELCHAIR STANDARDS

Wheelchairs are covered by the European Regulation on Medical Devices, risk class 1. Since wheelchairs are categorised in the lowest risk class, manufacturers are permitted to practice self-certification on these products. If a manufacturer has compiled technical documentation which satisfies the regulations set down in the Regulation on Medical Devices, in theory, a short attestation ("Declaration of Conformity") in which the manufacturer specifies that the product meets the requirements of the Regulation, making reference to the technical documentation (including a risk analysis), will suffice.

However, large-scale purchasers of wheelchairs (such as statutory authorities and health-care organisations) are now demanding that test reports be drawn up by an independent and accredited testing agency, authenticating that the product meets the European standards. In practice almost every manufacturer has its products tested based on the relevant standard.

Which standards?

The requirements for manually operated wheelchairs are described in EN 12183; those for electrically powered wheelchairs and scooters are in EN 12184.

Both standards also refer to EN 12182 for a number of other general requirements, such as trapping. ISO 7176, parts 1 to 22 describe in more detail what must be tested and how. The guiding principle in these are the EN standards: for the majority of testing these refer to ISO standards, but they may differ from these.
The first European standards for wheelchairs were published in 1999. The standards have been updated over the years, the latest in 2014 being the fourth version. Due to the publication of the new regulation, Medical Device Regulation (EU) 2017/745, it is expected that the EN 12183 and EN 12184 will be updated again in near future.

New regulation for Medical Devices

An important change is that the set of requirements for medical devices is no longer named as directive but as regulation. Whereas for Directives, each EU member state is at liberty to incorporate these into its national legislation, in the case of Regulations these will be mandatory: the regulations will become law in all EU member states.

4. PRODUCT REQUIREMENTS: WHAT TO LOOK FOR

EN 12183 and EN 12184 provide a comprehensive and detailed guide to the requirements set for wheelchairs and mobility scooters. This white paper gives a general outline of these, but focuses primarily on those requirements which have in the past resulted in the rejection of, or adaptations to the prototype being required, after testing by TÜV Rheinland.

Performance

Whereas, in practice, electrically powered wheelchairs for outdoor use can attain a 50 to 60-kilometre operating range, for some of them, the theoretically calculated operating range of 35 kilometres for a class C wheelchair (primarily intended for outdoors) has proved a bridge too far.
In tests for the operating range, a wheelchair must cover a distance of 1000 metres on a test track. A kWh meter registers how many kWh are used when the wheelchair is being driven. Using a formula, a theoretical value is calculated on the basis of this which must meet a set standard value, depending on its class.
If a manufacturer claims that a wheelchair can climb a specific angle of slope, it must do so at a speed of at least 2 m/s. In order to attain this speed/angle-of-slope combination, its electrical power capacity must be sufficient. This doesn't always have to be the case, since the electronics are configured in such a way that power becomes limited in certain situations, thus enhancing safety. It is likewise important to specify the maximum mass of the wheelchair user, because the test is actually performed using that same mass.

Mechanical strength

As wheelchair users become ever more mobile, so too does the importance of mechanical reliability. Weak points

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shown up by testing on the roller dynamometer or the drop test appear to be the wheel axle and the wheel suspension. Under duress, these may fracture or even break in two.
Another test which sometimes reveals weaknesses in a wheelchair's construction is the armrest test. This measures the considerable force exerted by the user on the armrest when they push themselves out of the wheelchair. Use of relatively weaker materials such as aluminium, in combination with a less robust construction (e.g. multiple holes in the tube to facilitate adjustment of the armrest), heightens the risk of the armrests buckling.
Impact testing on the front of the wheelchair and pressure testing on the footrests has revealed mechanical shortcomings to a much lesser extent.

Drive and brake systems

Whereas performance tests have shown wheelchairs being unable to negotiate a specified angle of slope at the required speed due to an inadequately configured drive, it is the job of the braking system to prevent the wheelchair from rolling backwards. In most cases, the brakes work well, but sometimes a wheelchair might topple over. A wheelchair might also tip over when the wheelchair's castors come away from the surface when taking the slope test. This can be prevented by mounting two small wheels on the rear of the wheelchair. In such cases, the wheelchair will pass this test, as long as the additional anti-tip wheels come as a standard feature.
An important aspect of the brake tests is that users can easily reach the controls.

Safety

Electrical safety is rarely a problem. Manufacturers routinely buy electrical components from third parties, which have already undergone stringent safety and EMC testing and are approved. The only deficiency that may sometimes be detected is a faulty system due to a loose cable or incorrect insulation of electrical components.
Not uncommonly, finishings can be a source of possible hazards. It's important that any sharp edges are properly eliminated. Whether metal, plastic or wood, any protrusions are required to be smoothed over so that they cannot

injure the user or attendant. Another often-witnessed fault are the V-shaped holes in which fingers, hands or feet can get trapped. These openings must either be smaller than the minimum size, or larger than the maximum size that the standard prescribes. When the design of an adult wheelchair is transposed to that of a children's wheelchair, manufacturers sometimes fail to adapt the size of these holes accordingly.

Controls

Controls, of course, must be within easy reach of the user. It's essential too, that after being exposed to extreme temperatures (such as in storage or in transport), electronic components still function properly.
The human factor has a real part to play in the operation of electric wheelchairs. Human error cannot be eliminated when a wheelchair is being incorrectly manoeuvred or steered. This can be compensated for to some extent by making repeated warnings in the documentation about what can happen if the user is inattentive or makes a rash judgement.

Information/documentation

In the latest version of the standards (2014), the requirements with respect to product information have been expanded considerably. The manufacturer's folder, intended for prospective buyers, must clearly specify the performance data, for example, the extent to which gradients and kerbs can be safely negotiated.
In addition to detailed technical specifications, the manual must clearly indicate the medical devices that the wheelchair can and cannot be used in combination with. For example, the effectiveness of a pressure-relief cushion is dependent on an even seating surface. If a user pushes a purse or wallet underneath the cushion, it will no longer work properly. User manuals should include such warnings.
What makes putting together a good manual even more complex is that information on the standards gets hidden away as a result of all sorts of cross-referencing. Manufacturers are quick to satisfy the documentation requirements set down in EN 12183/4, but then neglect to mention the standards to which these standards refer: ISO 7176-15 and EN 12182, which in turn refers to EN 1041. Manufacturers fail to delve deeply enough into the standards, resulting in the product's rejection, even though the wheelchair is technically in order.
In the latest version, there are additional requirements covering visually impaired users, who must also be able to read the manual. For example, if a 12-point typeface is too small, he or she must be able to refer to the website on which a version with a larger typeface is available. To be sure that all documentation conforms to all applicable requirements, ask for our documentation checklist EN 12183 or EN 12184.

5. TESTING IN COMPLIANCE WITH THE STANDARD

ISO 7176 (parts 1 to 22) describes in detail *what* and *how* tests must be carried out for a wheelchair to satisfy the requirements of the EN standard in question. For the most important tests, a description is given of how these are carried out and what aspects are being tested. On the basis of this information, manufacturers can apply their know-how in product development, if necessary by testing these aspects in-house beforehand.
It's important to know that wheelchairs are almost always tested carrying a load. This is a wooden construction, loaded down by steel masses, which in turn is designed in compliance with a 'dummy' standard - this can vary in size of mass according to the test, the manufacturer's specifications and/or the objective of the test (adult, child). Almost every test standard refers to ISO 7176-22 for the configuration and settings of the wheelchair before testing actually commences.

Large and small test ramps

The large test ramp at TÜV Rheinland in Arnhem, the only one of its kind in Europe, has a length of 18 metres and a width of 5 and has an angle-adjustable slope of up to 15°, equivalent to a gradient of more than 25 %. The ramp is used for several tests, e.g. to test braking distances at 0°, 3°, 6° and 10° respectively. Due to its length, the wheelchair can attain a maximum testing speed of 15 kph before the brakes can be applied. In practice, this means that the most important testing parameters can be measured. Another test identifies whether a wheelchair is capable of climbing a manufacturer-specified slope at a speed of 2 m/s.
Dynamic tests, for example, to check on whether wheelchairs roll backwards at a standstill, and tip backwards when driving off or at a standstill, can be carried out on the large test ramp.

Dynamometer

The dynamometer is fitted with a number of adjustable rollers so that they fit precisely under the mid-point of the wheelchair's wheels. The rollers are fitted with a raised section, so that with every revolution the wheelchair is

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jolted back and forth. According to the ISO test standard, a sequence of 200,000 cycles (around two days of testing) is sufficient to determine whether mechanical fatigue will occur in the wheel suspension and/or wheel axle over the lifetime of the wheelchair. There are also manufacturers who voluntarily specify longer test cycles, e.g. 300,000.

Drop test

Whereas the dynamometer simulates an uneven surface, the drop test measures the effects of a wheelchair dismounting a kerb. The drop test is carried out at 1/30th of the number of cycles of the dynamometer test, that is – in relation to the standard – 6,666 times.

Impact test

The impact strength of a wheelchair is tested by dropping a weight onto specific parts of it at a certain angle. The construction is then checked for any fractures, deformation or loose parts.

Armrest test

The armrest test is carried out once only over a period of 5 to 10 seconds. At a 15° angle, a force is exerted on the armrest. The force exerted is dependent on the mass being tested in the wheelchair. For example, with a children's wheelchair a smaller mass will be used than with a wheelchair for adults. If the armrest is not robust enough, five to ten seconds of pressure is enough to show up any shortcomings, for example, in the form of a buckled armrest.

Other pressure tests

By converting the same test rig as for the armrest test, various durability tests can be performed using force applied by means of cylinders. For instance, by applying pressure on the push handles 20,000 times over.

Climate chamber

In a climate chamber a wheelchair can be exposed to temperatures ranging from -40°C to +65°C. This temperature range covers all possible extremes that might occur in storage conditions, whilst less extreme temperatures (between -25°C and +50°C) cover normal conditions of use. Once the wheelchair has been removed from the chamber, tests are carried out to find whether the wheelchair responds adequately to the commands given via the joystick. If this is not the case, condensation, for example, may have occurred in the electronics, causing short-circuiting. The dimensions of the climate chamber are 8 m x 5 m. This makes is possible to also drive in extreme conditions.

6. EVERYTHING UNDER ONE ROOF

Of all the test laboratories throughout Europe, TÜV Rheinland has the most comprehensive range of in-house testing apparatus for the testing of wheelchairs and mobility scooters in conformity with ISO 7176, parts 1 to 22. The test lab singles itself out on account of its test ramp, which is large enough to test wheelchairs at maximum speed. The 2014 standard states that manufacturers should not necessarily expect a test lab to have a test ramp of this magnitude - testing otherwise has to take place on an outdoor slope. TÜV Rheinland however, had such a test ramp constructed because it forms an essential tool for testing various aspects of wheelchair characteristics. The test ramp, together with all the other necessary test installations, have been assembled at a single site, which also houses other test facilities and expertise, for example, fire-safety testing of upholstery as used for wheelchairs.
The test and certification services for wheelchairs and mobility scooters distinguish TÜV Rheinland from other test labs.

- Specialised know-how of the relevant regulations and standards.
- More than 30 years' experience in testing wheelchairs and scooters.
- Quick turnaround times and competitive pricing.
- Full detailed test reports
- Helpful checklists
- Up-to-date information on the changes in the standards which every wheelchair manufacturer should be familiar with.
- A worldwide client base.
- The possibility for clients to attend testing.

7. CONCLUSION

Manufacturers of wheelchairs and mobility scooters would be well advised to familiarise themselves with the ins-and-outs of product and test standards and to apply this know-how in the design of their products. To increase the chances of success, it is recommended that, whenever possible, manufacturers carry out testing on specific product features themselves before submitting their products to independents test labs, such as TÜV Rheinland.

Wheelchair developers should focus not only on the performance, mechanical and electrical safety in their design, but also familiarise themselves with the increasing requirements in respect of documentation and information.

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