

Weighing equipment used for medical purposes



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Background

As part of the Non-Automatic Weighing Instruments Directive, any weighing equipment used for medical purposes sold after January 1st 2003 must be of an approved type and be verified before being put in to service or following repair.

The recent project undertaken by LACORS (Local Authority Co-ordinating body on Regulatory Services) has highlighted widespread problems within the field of medical weighing. However the UKWF believes that further clarification is still needed in key areas (including calibration) to ensure the required improvements are made in a timely fashion.

The incorrect or inaccurate weighing of patients can have serious and life threatening consequences, especially where drug administration is calculated in relation to body weight. These notes are intended to provide some clarity and guidance to the subject.

Existing equipment (put into use before 1 January 2003)

Weighing equipment put in to service before 1st January 2003 can continue in use with no further legal control.

However, such equipment is:

- unlikely to be approved,
- may be weighing in **imperial units** or a mixture of **imperial** and **metric units** *and*
- may be of an inappropriate level of precision.

The UKWF recommends that any such equipment be taken out of service and replaced with suitable approved equipment as a matter of urgency.

Buying new medical weighing equipment

Any new equipment must be of an approved type and be verified.

Manufacturers of equipment for medical use must obtain approval for the design to demonstrate that the instrument type is suitable for that purpose. Then each instrument must be individually verified either by the manufacturer (if they are authorised to perform self-verification) or by a trading standards officer.

The following identification markings will show that the instrument is of an approved type and has been verified:



There are various levels of precision specified for weighing instruments, namely **class I, II, III and IIIB**. Medical scales are generally either **class III** or **class IIIB**. Although **class IIIB** instruments may be suitable for a limited number of applications (e.g. monitoring for general health and fitness in a GP consulting room), we recommend that only the higher precision **class III** machines are used in any medical establishment.

Although there may be rare instruments that still have an old approval allowing them to weigh in either **imperial** or **metric units**, we would mandate that only metric instruments are used. Failure to do so could result in an error **exceeding $\pm 100\%$** if the wrong units are inadvertently used. (e.g. This could result in double or half treatment doses being given to patients.)

Calibration, servicing & repair

Instruments must be tested with certified test weights at several points through the weighing range. For most medical weighing applications, it should be possible to apply full load to the scale during calibration. Where this is not practical then a significant proportion should be applied. A test certificate should be issued with readings before and after any adjustment is made and a sticker applied identifying the date of calibration. **This is consistent with the UKWF Calibration Code of Practice. Note calibration must be carried out by a suitably qualified weighing engineer.**

Acceptable errors are defined in the NAWI regulations 2000 and your service engineer should know how to apply these to assess the test results.

If an instrument shows errors which exceed these limits then some form of rectification may be required. In some cases this may be as simple as ensuring the instrument is level or removing any obstructions. In other cases the instrument may require repair or re-calibration and in these cases re-verification will almost certainly be required. The re-verification can be performed by the repairer if they are authorised to do so or by a trading standards officer and the owner or user of the equipment has a legal obligation to ensure that this is done.

Definition of medical use

Schedule 3 of the **Non-automatic Weighing Instrument Regulations 2000** includes the following applications that are subject to legal control:

- *Determination of mass in the practice of medicine for weighing patients for the purpose of monitoring, diagnosis and medical treatment.*
- *Determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories.*

Applications that are not in the practice of medicine, e.g. slimming clubs or sports centres, would not be included within these definitions.

Recommended maximum scale interval for specific applications

	Adults	Young Children	Babies
Checking weight for records	500 g	200 g	50 g
Regular monitoring to assess weight change	200 g	100 g	10/20 g
Measuring weight to assist medical diagnosis	200 g	50/100 g	10/20 g
Measuring weight for critical treatment e.g. dialysis	50/100 g	20/50 g	5 g
Recording birth weight			20 g
Measuring weight before and after breast feeding			10 g

The above figures were taken from a limited survey of medical practitioners and specialist scale suppliers. These tolerances may not be suitable/relevant for all applications.

Using Medical Weighing Equipment

It is vitally important that weighing scales are used under suitable conditions. Staff should be appropriately trained to use weighing equipment.

All scales must be level and on a suitably firm surface. Use on carpets or other flexible surfaces is not recommended. If scales are moved from one location to another, operators must ensure suitable adjustments are carried out to any adjustable feet to ensure the scale is stable and level.

Before commencing weighing, operators must ensure the scale reading is set to zero. After weighing has taken place, operators should then ensure the scale has returned to zero. If not, then they should consult an engineer.

The scales must be free to operate and unimpeded without the risk of weight (force) transfer to adjacent structures, which will affect accuracy. Patients must not be allowed to lean on or hold structures that are not part of the active (live) part of the weighing machine.

When carrying out repeat weighings on patients, operators must ensure readings are taken under identical circumstances (e.g. tare items such as clothes, shoes etc have a major impact on weight).

For critical weighing situations (especially those involving drug administration relating to body weight), it is recommended that at least two (ideally three) repeat weighings are made in order to ensure the correct weight reading is used for treatment calculations. If readings do not show repeatability within ± 1 scale division, then operators should consult an engineer. In such applications operators are advised to have the reading(s) checked by a second person to ensure errors (e.g. mis-reading decimal points) are not made when reading the display or similar.