



UK WEIGHING FEDERATION

GUIDANCE NOTES RELATING TO THE LEGAL PRESCRIPTION OF MEDICAL WEIGHING SCALES

Introduction

The Non-automatic Weighing Instruments (NAWI) Directive was made part of UK law on 1 January 1993. The Directive not only controls the technical and performance characteristics of NAWI, but also specifies which tasks require the use of “controlled” NAWI. One of those specified tasks is

“Weighing patients for the purposes of monitoring, diagnosis and medical treatment”.

This means that from 1 January 2003, when the full effects of the Directive come into force, all new weighing instruments used for medical weighing will have to comply with the requirements of the Directive. These notes are intended to make users and purchasers of medical weighing instruments aware of the requirements.

The Non-automatic Weighing Instruments Regulations 2000

The Directive is implemented in the UK by the Non-automatic Weighing Instruments Regulations 2002. Under these Regulations the design of medical weighing instruments must be approved by a Notified Body, (in the UK this is the National Weights and Measures Laboratory) and all product from the production line must be individually verified for conformity and accuracy by a Trading Standards Officer or other approved verifier. Each instrument must be covered by a Declaration of Conformity and bear the ‘green M’ label indicating conformity with the Directive and the Regulations.

Medical weighing instruments purchased and in use before 1st January 2003 can continue in use indefinitely even though they may not meet the requirements of the NAWI Regulations.

Medical weighing instruments not used for medical practice, for example in health clubs, fitness centres and slimming clubs do not have to conform to the NAWI Regulations.

From 1 January 2000, only metric units have been legal for controlled purposes. Weighing instruments that have both metric and imperial (lb. & oz.) indications can continue in use, but the Notified Bodies have told us that they will not be granting Type Approval for new models unless they have both indications available at the same time.

Accuracy Classes

The Regulations define 4 accuracy classes. Classes I and II are for very high accuracy instruments, Class III for weighing scales in general use for trade and Class IIII where a lower level of accuracy is acceptable such as weighing waste or ballast. The maximum permissible error (mpe) on the weighing instrument is related to its accuracy Class and its resolution (division size).

Table 1 to these Notes shows the various levels of accuracy that can be obtained using Class III and Class IIII instruments.

Selection of Accuracy Class for Required Applications

The UKWF believe that Class III scales only have sufficient accuracy for the checking of a patient's weight for record purposes as typically carried out in the GP's consulting room. Where a weighing result is required for diagnostic purposes or treatment we recommend that a Class III instrument should be used.

In hospitals there are a multiplicity of weighing scales used for both critical and non-critical weighing and for weighing babies through to obese adults. We recommend that whatever the intended application of the scales only Class III instruments are used in hospitals. Scales are often moved from department to department, and that could result in inappropriate Class III instruments being used for more critical applications.

Table 2 to these Notes summarises the recommendations.

Selection of Class III Weighing Scales for a required application

Within the Class III accuracy specifications there is a range of accuracies that may be chosen. In some instances even a Class III specification may not be accurate enough for a particular medical requirement. Accuracy is generally proportional to the size of weighing interval and purchasers should take this into account when making their choice.

Table 3 is a list of medical applications with a recommendation for the minimum weighing interval.

CE Marking

All instruments conforming to the Directive must carry the 'green M' label as well as the CE mark. (They will also have a 4 digit number indicating the organisation responsible for the verification of the instrument.) Weighing instruments that do not conform to the NAWI requirements may bear the CE mark to demonstrate conformity to other EC Directives such as the EMC, Low Voltage and Medical Devices Directives but such instruments cannot legally be used for medical purposes.

Enforcement

Enforcing the regulations will be the responsibility of Trading Standards Officers (TSOs) from the local Council. They will have the power to enter premises and inspect and test weighing instruments. If the instruments are outside the permitted error allowance the TSO may have them put out of use straight away. We recommend that medical establishments ensure that their weighing instruments are calibrated at yearly intervals to ensure they hold their accuracy to the required standards.

Use of Medical Weighing Scales

However accurate the weighing instrument may be, incorrect use will prejudice the weighing result. Note should be taken of the following:

1. Ensure that the scales are balanced, or display zero before weighing the patient.
2. When weighing a baby if a protective covering is placed in the weigh pan ensure that this is allowed for by pressing the appropriate 'tare' or 'zero' key.
3. Ensure that no part of the weigh platform or load receptor is touching a fixed object such as a wall.
4. Ensure the patient's clothing is not touching any fixed part of the scales or surroundings.
5. When using chair scales ensure the patient's feet are not touching the ground nor arms brushing against an adjacent fixture.
6. When monitoring periodical weight change ensure that the patient always wears clothing of similar weight.
7. Do not weigh young children on scales of high capacity designed for adults. The weighing interval may be too coarse resulting in a higher than acceptable percentage error.

These notes are only issued as a general guide to the requirements; for detailed advice and interpretation of the requirements contact your local Trading Standards Department. For advice on weighing instruments contact any member of the UK Weighing Federation – see details on back page – or visit our website at www.ukwf.org.uk.

TABLE 1

Comparative error allowances between Class III and Class III weighing instruments

Scale Interval	CLASS III - IN-SERVICE ALLOWANCE			CLASS III - IN-SERVICE ALLOWANCE		
2kg	0 - 100 kg <i>+/- 2kg</i>	100 -400 kg <i>+/- 4kg</i>	Above 400 kg <i>+/- 6kg</i>	0-1000kg <i>+/- 2kg</i>	1000- 4000 kg <i>+/- 4 kg</i>	
1 kg	0 - 50 kg <i>+/- 1 kg</i>	50 - 200 kg <i>+/- 2 kg</i>	Above 200 kg <i>+/- 3 kg</i>	0 - 500 kg <i>+/- 1 kg</i>	500 - 2000 kg <i>+/- 2kg</i>	
500g (0.5kg)	0 - 25 kg <i>+/- 500 g</i>	25 -100 kg <i>+/- 1 kg</i>	Above 100 kg <i>+/- 1.5 kg</i>	0- 250 kg <i>+/- 500 g</i>	250 - 1000 kg <i>+/- 1 kg</i>	
200g (0.2kg)	0 - 10 kg <i>+/- 200 g</i>	10 - 40 kg <i>+/- 400 g</i>	Above 40 kg <i>+/- 600 g</i>	0 - 100 kg <i>+/- 200 g</i>	100 - 500 kg <i>+/- 400 g</i>	
100g (0.1 kg)	0 - 5 kg <i>+/- 100 g</i>	5 - 20 kg <i>+/- 200 g</i>	Above 20 kg <i>+/- 300 g</i>	0 - 50 kg <i>+/- 100 g</i>	50 - 200 kg <i>+/- 200 g</i>	Above 200 kg <i>+/- 300g</i>
50g (0.05 kg)	0 - 2.5 kg <i>+/- 50 g</i>	2.5 - 10 kg <i>+/- 100 g</i>	Above 10 kg <i>+/- 150 g</i>	0 - 25 kg <i>+/- 50 g</i>	25 - 100 kg <i>+/- 100 g</i>	Above 100 kg <i>+/- 150 g</i>
20g (0.02 kg)	0 - 1 kg <i>+/- 20 g</i>	1 - 4 kg <i>+/- 40 g</i>	Above 4 kg <i>+/- 60 g</i>	0 - 10 kg <i>+/- 20 g</i>	10 - 40 kg <i>+/- 40 g</i>	Above 40 kg <i>+/- 60 g</i>
10g (0.01 kg)	0 - 500 g <i>+/- 10 g</i>	500g - 2 kg <i>+/- 20 g</i>	Above 2 kg <i>+/- 30 g</i>	0 - 5 kg <i>+/- 10 g</i>	5 - 20 kg <i>+/- 20 g</i>	Above 20 kg <i>+/- 30 g</i>
5g (0.005 kg)	0 - 250 g <i>+/- 5g</i>	250 g - 1 kg <i>+/- 10 g</i>	Above 1 kg <i>+/- 15 g</i>	0 - 2.5 kg <i>+/- 5 g</i>	2.5 - 10 kg <i>+/- 10 g</i>	Above 10 kg <i>+/- 15 g</i>
2g (0.002 kg)	NOT ALLOWED			0 - 1 kg <i>+/- 2g</i>	1 kg - 4 kg <i>+/- 4 g</i>	Above 4 kg <i>+/- 6 g</i>
1g (0.001 kg)	NOT ALLOWED			0 - 500 g <i>+/- 1 g</i>	500 g - 2 kg <i>+/- 2 g</i>	Above 2 kg <i>+/- 3 g</i>

KEY
Capacity shown In Plain text
Error Allowance Shown in <i>italic text</i>

Note: The apparent difference between two machines can be significant when one operates at the upper limit and one at the lower limit of permitted error.

TABLE 2**Recommended Minimum Classes for specific applications**

	Hospitals	Hospital associated medical centres	Ante / Post Natal Clinics	Medical Practice Treatment Rooms	GP Consulting Rooms	Mobile / Visiting Health care	Nursing Homes
Purpose: Monitoring	III	III	III	III	III	III	III
Diagnosis	III	III	III	III	III	III	III
Treatment	III	III	III	III	III	III	III

TABLE 3**Recommended maximum scale interval for specific applications**

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

The above figures were taken from a limited survey of medical practitioners and specialist scales distributors

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