1.14 MEDICAL WEIGHING

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 2000. Under these Regulations, the design of medical weighing instruments must be approved by a Notified Body (in the UK this is the National Measurement Office) 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 1 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).

Selection of Accuracy Class for Required Applications
The UKWF believe that Class IIII 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 is 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 IIII instruments being used for more critical applications.

Recommended Minimum Classes for specific applications

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

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.

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			

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.