

# **UK WEIGHING FEDERATION**

## **User Guide**

Guidance for ensuring regulatory compliance of scales used in the practice of medicine

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## UK Weighing Federation Guidance for Compliance of Scales used in Medicine

Any scales used in the practice of medicine for weighing patients for the purpose of monitoring, diagnosis and medical treatment must meet the requirements of the Non-automatic Weighing Instruments Regulations 2016. This will include weighing instruments used to calculate medication dosages, diagnose illness, monitor treatment and assess nutritional status. Any weighing instruments that do not meet the requirements of these regulations would mean that patients could be put at risk and hospitals and primary care practices could be liable for any resulting adverse events.

#### **Background**

A 2014 investigation into the accuracy of scales used in medical weighing conducted by Trading Standards Departments found that weighing equipment used in healthcare premises may be inaccurate, inappropriate or not used correctly, leading to potential errors in prescribing, diagnosis or treatment of patients.

The NHS recognises the inherent risk of not having correctly calibrated scales and has previously published notifications stressing the importance of having scales meet these requirements and that are calibrated appropriately, and the role this plays in reducing patient risk.

## **UKWF** Guidance for users of medical weighing equipment

#### 1. Labelling:

All scales used for medical purposes should bear all of the appropriate approval markings such as the CE mark and the M and should be at least of class III accuracy and should be appropriate for their intended use. It is also acceptable if the instrument bears a UKCA mark.

#### 2. Testing

To ensure that the risks are kept to a minimum, all the aspects that cover the accuracy of the weighing instrument should be tested properly.

The tests should include the following to ensure that potential risks associated with inaccurately weighing patients are minimised:

- A test of accuracy at a minimum of five load points up to 10% above the normal working range. This should include testing in both increasing and decreasing loads as it often possible to get different results in each circumstance.
- The instrument should have loads placed around each corner. If this is not
  possible, other off centre loading should take place. This is to ensure that it
  will be accurate if used in this condition.



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 A repeatability test, in which loads are placed on and off the instrument a number of times, should be carried out at around 50% of the maximum capacity.

These should be seen as the minimum tests necessary to ensure that the users can be confident in the results used in any clinical procedures or decisions.

If fewer tests than this are carried out the confidence in the results will open to greater doubt and potential challenge.

#### 3. Servicing Standards

It is important to ensure that after you have chosen the correct scales you continue to maintain their accuracy and compliance. The scales should be regularly calibrated to ensure that they stay within their limits of error. It is recommended that these checks should be done at least annually and the tests carried out should be the same as those outlined above.

If a weighing scale has been subject to adjustment, alteration, addition repair or replacement it will need to be re-verified. This is a legal procedure that is in addition to any regular calibrations and can only be carried out by persons that have a government approval. After the re-verification has been completed a crown mark will be applied to show that it can continue to be used. If these marks are not present it will not be possible to continue to use the instrument for any medical purpose

#### 4. MHRA Guidance

Weighing instruments used in a medical setting will almost certainly be a medical device for the purposes of the Medical Devices Regulations and must also comply with the Regulations that apply.

## About the UKWF

The UK Weighing Federation is the national trade body representing manufacturers and suppliers of weighing equipment. To become a member of the UKWF, businesses must demonstrate strong compliance with the highest levels of regulatory and quality standards. This guidance is intended to support all health practitioners in ensuring the medical weighing equipment they use minimises risk to patients and ensures accuracy and quality of measurement.

For more information about the UKWF and to find UKWF member companies, please visit <a href="https://www.ukwf.org.uk">www.ukwf.org.uk</a>