Buyers’ guide

Low cost non-invasive blood pressure monitors

CEP 08035

September 2008
General

This report is intended to assist in the selection of low cost automated non-invasive blood pressure (NIBP) monitors. A similar buyers’ guide for hospital grade NIBP monitors was published in May 2008 (CEP 08018). Information is presented in a standardised format to help purchasers prepare a short-list of devices. The 44 models in this issue represent the majority of low cost devices designed for use on the upper arm that were on the UK market during 2007 and 2008.

Several manufacturers offer a wide range of models. Where this is the case, we have chosen a representative sample of models from those available.

Models are presented alphabetically by manufacturer. Abbreviations used in this report are defined in the Glossary (page 129).

Scope

The report reviews low cost monitors selected (see Method, page 12) from the large number of automated blood pressure monitors available in the UK. Their prices ranged from £8.50 to £98.99.

All 44 of the devices were capable of making automated measurement of blood pressure using the oscillometric measurement technique. This works on the principle that when an inflated cuff partially occludes blood flow in the brachial artery, pulsatile changes in blood volume during each heart beat induce small (typically < 3 mmHg) pulses in the cuff. Devices measure the size of these pressure pulses while inflating or deflating the cuff (see box, page 7).

Devices were available for use on the upper arm or wrist. We excluded wrist devices from this study (see European Society of Hypertension guidelines, page 5).

Eight devices required the cuff to be inflated manually using a supplied bulb inflator. As well as making straightforward measurements of blood pressure and pulse rate, some monitors had additional features, such as memory for storing multiple previous readings, and connectivity to external printers and/or PCs, with software available to download readings for archiving.

National guidance

British Hypertension Society guidelines

In 2004 the British Hypertension Society (BHS) issued guidelines [1] for management of hypertension. Those relating to blood pressure measurements are reproduced below:

- Use a properly maintained, calibrated and validated device.
- Measure sitting blood pressure routinely; standing blood pressure should be recorded at the initial estimate in elderly and diabetic patients.
- Remove tight clothing, support arm at heart level, ensure hand relaxed and avoid talking during the measurement procedure.
• Use a cuff of appropriate size: the bladder should surround at least 80% of the upper arm; using too large a cuff will result in an underestimation of blood pressure, while too small a cuff will lead to overestimation.

• When using the auscultatory method (see box, page 6) lower mercury column slowly (2 mmHg/s); read blood pressure to the nearest 2 mmHg; measure diastolic as disappearance of sounds (phase V).

• Take the mean of at least two readings; more recordings are needed if marked differences between initial measurements are found.

• Do not treat on the basis of an isolated reading.

MHRA guidelines
In 2005 the Medicines and Healthcare Products Regulatory Agency (MHRA) issued a report containing recommendations of the Independent Advisory Group on Blood Pressure Monitoring in Clinical Practice [2] and followed it up with a medical device alert [3]. Those recommendations which are relevant to the selection of NIBP monitors are reproduced below:

• **Recommendation 3**
  Where oscillometric blood pressure measurement is used, it should **not** be assumed that a CE marked blood pressure monitor is automatically suitable for use in the diagnosis of hypertension.

• **Recommendation 4**
  In those clinical conditions where oscillometry is inappropriate (e.g. arrhythmias, pre-eclampsia and certain vascular diseases) an alternative method of pressure measurement (auscultation, arterial cannulation) should be used.

• **Recommendation 5**
  The MHRA, in collaboration with the Committee on Blood Pressure Monitoring in Clinical Practice, should define acceptable performance criteria against which automated non-invasive blood pressure monitors should be evaluated. Evidence for compliance with these criteria should be obtained from properly conducted clinical trials [4, 5, 6, 7, 8]. The population characteristics for which the device has been evaluated should be specifically included.

• **Recommendation 6**
  The NHS and other healthcare sectors should only purchase devices that meet the performance criteria in the recommendation above.

• **Recommendation 7**
  Auscultation as a method of determining blood pressure should continue to be taught to healthcare workers as appropriate. Calibrated non-mercury devices, which do not rely on oscillometry, should be made available in all clinical areas. These should be used to check oscillometric results and other non auscultatory alternative blood pressure measurement determination on individual patients. These devices should also be used in clinical conditions where alternative methods may be inappropriate e.g. arrhythmia, pre-eclampsia or specific vascular disease.
The "acceptable performance criteria" were not defined explicitly in the MHRA report, which left some users uncertain as to how to take action on the associated device alert [3]. In practice, acceptable performance criteria for validation have been published in international standards and in test protocols and acceptance criteria published by clinical groups. These are summarised below.

**Devices placed on the market before June 2005**

Prior to June 2005, manufacturers were required [9] to collect sufficient evidence to satisfy a notified body that the new device agreed with trained human observers to within a mean error of 5 mmHg, with a standard deviation not exceeding 8 mmHg. However the size or composition of the study population was not specified and the results of the trial were not required to be put in the public domain. Scrutiny of the validation trial results is at the discretion of the notified body.

Some manufacturers opted to validate their devices according to one of several recognised protocols requiring 85 subjects [5,6,8] or 33 subjects [4]. In many cases the trial results are available from the manufacturer, or were published in peer reviewed journals.

**Devices placed on the market after June 2005**

The minimum criteria for a validation protocol (including the number of subjects and composition of the group) were published in an EU standard [7]. In June 2005, an amendment to EN1060-3 [10] was published which requires manufacturers to follow a validation protocol which meets the EU standard [7]. Of the common protocols, three [5,6,8] comply with this standard. The "International Protocol" [4] does not. Scrutiny of the results of the validation trial remains at the discretion of the notified body.

Manufacturers are not required to place their validation results in the public domain. In many cases the results were available from the manufacturer, or were published in peer reviewed journals.

**European Society of Hypertension guidelines**

- **Wrist devices**

The European Society of Hypertension (ESH) guidelines for blood pressure monitoring at home [11] discuss inaccuracies that are inherent to devices that measure at the wrist. These include remoteness of the measurement site, limb position, effects caused by wrist flexion and algorithm inaccuracies caused by the presence of two arteries contributing to the oscillometric signal. "As a result, there continue to be strong reservations about the use of wrist devices for routine clinical practice".
Blood pressure measurement

The standard method for blood pressure measurement, according to the World Health Organisation (WHO) guidelines, is the auscultatory technique using a mercury column pressure gauge.

The auscultatory technique [12]

- Place the stethoscope over the brachial artery at the point of maximal pulsation. The stethoscope should be held firmly and evenly but without excessive pressure, as this may distort the artery, producing sounds below diastolic pressure.
- The cuff should be inflated rapidly to approximately 30 mmHg above the palpated systolic pressure and deflated at a rate of 2–3 mmHg per pulse beat (or per second), during which the Korotkoff sounds will be heard:
  - Phase I The first appearance of faint, repetitive, clear tapping sounds that gradually increase in intensity for at least two consecutive beats is the systolic blood pressure.
  - Phase II A brief period may follow during which the sounds soften and acquire a swishing quality. In some patients, sounds may disappear altogether for a short time (auscultatory gap).
  - Phase III The return of sharper sounds, which become crisper, to regain or even exceed the intensity of phase I sounds.
  - Phase IV The distinct, abrupt muffling of sounds, which become soft and blowing in quality.
  - Phase V† The point at which all sounds finally disappear completely is the diastolic pressure.
- When all sounds have disappeared, the cuff should be deflated.

†There is now a general consensus that the disappearance of sounds (phase V) should be taken as diastolic pressure. When the Korotkoff sounds persist down to zero, muffling of sounds (phase IV) should be recorded for diastolic pressure, and a note made to this effect. The clinical significance, if any, of phases II and III has not been established.

Alternatives to mercury

There are two main alternatives to the use of a mercury sphygmomanometer. One is to continue using the auscultatory technique, but to use a non-mercury gauge such as an aneroid (in which changes in pressure are mechanically converted to the deflection of a needle) or an electronic manual gauge (in which pressure is measured by an electronic transducer and displayed numerically and/or graphically).

The second alternative is to use the oscillometric technique. This was originally developed in the 1980s to monitor blood pressure trends of intensive care patients.
Technical considerations

**How oscillometric blood pressure monitors work** [13]

- When an inflated brachial cuff partially constricts blood flow, pulsatile changes in blood volume during each heart beat induce small (typically < 3 mmHg) pressure pulses in the cuff; an oscillometric blood pressure device measures the size of these pulses.
- The device automatically inflates the cuff pressure above systolic pressure. Some devices do this by detecting the absence of oscillometric pulses. Others simply inflate to a pre-determined level; often this starting pressure is configurable.
- The device deflates the cuff at a controlled rate and measures the size of the oscillometric pressure pulses as a function of cuff pressure.
- Some devices measure the oscillometric pulses during inflation, the measurement concluding after the systolic pressure is determined.

A proprietary algorithm is applied to the pressure pulse profile to calculate the systolic, diastolic and mean blood pressure.

**Problems of inaccuracy**

The intricate mechanical design of aneroid gauges makes them susceptible to damage caused by mechanical shock and to wear and tear of moving parts. Where such damage does not lead to failure of the device, there is a risk that the displayed pressure may be in error, leading to inaccurate blood pressure measurement. Electronic manual gauges have few moving parts and are less susceptible to damage from mechanical shock.

Manufacturers of oscillometric devices use proprietary algorithms to calculate blood pressure; systematic differences of the order of 10 mmHg between devices have been measured due to differences between algorithms [14]. The oscillometric technique may not be clinically appropriate for important patient groups including pregnant women [15], diabetics [16] and those with cardiac arrhythmias. Some clinical bodies specifically state [17] that the use of oscillometric devices is not advised if blood pressure measurement is being used to determine treatment.

**Strategies to improve accuracy**

Errors in the measurement of blood pressure can arise from observer (or protocol) or from the device used. In auscultatory measurement, errors of the former type can be minimised by good training and by adherence to a recognised protocol, such as that published by the British Hypertension Society [5]. Some recommendations such as choosing the correct deflation rate (2-3 mmHg/s) and correct cuff size are often ignored.

Errors due to devices can be minimised by good equipment management. Aneroid gauges should be calibrated at least once a year and should at least have their calibration checked if they are dropped or suffer a similar accident. Electronic manual gauges should also be calibrated once a year.

Oscillometric devices incorporate a pressure transducer and should, in principle, undergo a similar static pressure calibration as an electronic manual gauge. Many, if not all, hospital grade NIBP monitors, have dedicated service and calibration modes which allow this. Very few low-cost monitors have a similar facility.

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Device selection should be based on matching device features to user needs. Table 1 illustrates the range of NIBP monitor characteristics that should be considered. These should be used along with the product information tables (page 16) found in the Market review section.

### Table 1 Device considerations

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional features</td>
<td>As well as measuring blood pressure and pulse rate, some devices have memory facilities to allow the storage of previous readings; these might be categorised so that several patients can separately identify their readings. Some devices provide connectivity to external printers and computers and can supply software to facilitate the transfer of stored data from the monitor via a USB port. Many were provided with a storage case, usually of fabric construction.</td>
</tr>
<tr>
<td>Patient categories</td>
<td>Unlike hospital grade monitors, there is no categorisation of these devices into adult, paediatric or neonatal types. Six devices had been validated for use during pregnancy, two for use on children and one for use on the obese.</td>
</tr>
<tr>
<td>Cuff sizes</td>
<td>Most of the manufacturers supply a single re-usable cuff for a medium adult arm 22–32 cm and designed for easy self application. Some provide additional adult sizes, usually as accessories. A minority provide cuff sizes suitable for children.</td>
</tr>
<tr>
<td>Display</td>
<td>In all cases a monochrome LCD is provided. A few provide a backlight.</td>
</tr>
<tr>
<td>Power</td>
<td>All of the devices were battery powered - in most cases by four 1.5 Volt size AA alkaline cells. Many of them provide a connection for a mains adaptor (sometimes supplied).</td>
</tr>
<tr>
<td>Physical size and weight</td>
<td>The majority are small and light in weight: there is unlikely to be a storage problem. A few are designed as small desk-top units and one of these has an integrated cuff into which the patient's arm is inserted.</td>
</tr>
</tbody>
</table>
Table 1 Device considerations cont.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price paid</td>
<td>All of the devices in this evaluation were purchased: we have shown the price paid excluding VAT or the current price advised by the supplier if lower. The higher priced models were those with most additional features. The price range of £8.50 to £98.99 had little or no correlation with our recommendations on page 119. Prices for volume purchase may differ.</td>
</tr>
<tr>
<td>Servicing costs</td>
<td>Many suppliers provided a fixed price for servicing. Others do not offer servicing facilities.</td>
</tr>
<tr>
<td>Validation</td>
<td>We have shown which monitors are clinically validated, which protocol was used and whether the results have been published in a peer reviewed journal. Where possible, we have also shown the BHS grade for systolic and diastolic pressure. Users should carefully consider the validation information when choosing a monitor. We would not recommend a device which had not been clinically validated (see pages 14 and 119).</td>
</tr>
</tbody>
</table>
Additional costs to consider

To achieve best value when purchasing a low cost NIBP monitor users should consider the following costs:

**Accessories**

Are additional accessories (supplied at extra cost) required to use the monitor most effectively, e.g. mains adaptor, printer or PC?

Few devices had more than one cuff size, but manufacturers supply a range of sizes that can be purchased separately.

**Consumables**

All the monitors use commonly available batteries. Some manufacturers indicated the expected lifetime of a set of batteries (number of measurements). A mains adaptor (if not supplied) is worth considering.

**Training**

Training was not provided for any of these devices.

**Warranty**

Panasonic devices: three years.
A & D devices: two years.
All other devices: one year.
Purchasing procedures

PASA’s Trust Operational Purchasing Procedures Manual provides details of the procurement process [18].

European Union procurement rules apply to public bodies, including the NHS. The purpose of these rules is to open up the public procurement market and ensure the free movement of goods and services within the EU. In the majority of cases, a competition is required and decisions should be based on best value.

The EU procurement rules apply to contracts worth more than £90,319 (from January 1st 2008) [19]. Further details of the process are given in Appendix 2.

NHS Supply Chain (NHS SC) offers national contracts or framework agreements for some products, goods and services. Use of these agreements is not compulsory and NHS organisations may opt to follow local procedures.

Sustainable procurement

The UK Government launched its current strategy for sustainable development, “Securing the Future” [20] in March 2005. The strategy describes four priorities to progress sustainable development, in the UK and in the world as a whole:

- sustainable production and consumption – working towards achieving more with less
- natural resource protection and environmental enhancement – protecting the natural resources and habitats upon which we depend
- sustainable communities – creating places where people want to live and work, now and in the future
- climate change and energy – confronting the greatest identified threat facing the global community.

The strategy also highlights the key role of public procurement in delivering sustainability.

Energy consumption

Suppliers/manufacturers should offer guidance on energy-efficient use of devices. Where devices are in constant use, mains and battery energy costs should be included in whole-life cost calculations.

End of life disposal

Consideration should be given to the likely financial and environmental costs of disposal at the end of the product’s life. Where appropriate, suppliers of equipment placed on the market after the 13th August 2005 should be able to demonstrate compliance with the UK Waste Electrical and Electronic Equipment (WEEE) regulations (2006) [21]. The WEEE regulations place responsibility for financing the cost of collection and disposal on the producer. Electrical and electronic equipment is exempt from the WEEE regulations where it is deemed to be contaminated at the point at which the equipment is scheduled for disposal by the final user. However, if it is subsequently decontaminated such that it no longer poses an infection risk, it is again covered by the WEEE regulations, and there may be potential to dispose of the unit through the normal WEEE recovery channels.
Method

Starting in mid 2005 and continuing to the conclusion of the evaluation, we carried out a market review of NIBP devices on the UK market. We looked for information in medical literature, in validation reports, in marketing literature from known suppliers and from internet searches.

Establish device selection criteria
A large number of devices were identified; their prices ranged from £8.50 to £1800. Some manufacturers produced several models within a product range. A judgement was required to establish a dividing line between those indicated for personal home-use and devices appropriate to a hospital setting. Looking at the prices of the simplest model in each device range, we noted that none lay in the price band £100 to £240. Thus there was a natural grouping into devices costing £100 or less and devices costing £240 or more. This buyers’ guide concerns those devices for which the price of the base model is no more than £100.

Hospital grade devices were the subject of a previously published guide (CEP 08018).

Acquire devices
All of the assessed devices were purchased from manufacturers’ suppliers or retail outlets. Some devices identified in the market survey could not be obtained due to local purchasing procedures.

Assessment protocol
In the evaluation laboratory we carried out an assessment protocol (see below) to acquire information and test each device. Data were recorded in the pro-forma reproduced in Appendix 3.

Recommendations
We made recommendations based on the criteria described on page 15.

Assessment protocol

Product information
Much of the information included in this document was sourced from the suppliers’ or manufacturers’ product data or specifications published in user manuals—this was used as the basis of the comparative product information (page 16). Since each had its own corporate style and format we have presented the information in its simplest common format and as consistently as possible to more readily allow comparison between manufacturers. We gave suppliers an opportunity to check and comment on the report prior to publication.

CE marking and clinical validation
We inspected the CE marking and noted compliance with relevant standards.

Where clinical validation was claimed we inspected any evidence the manufacturers provided including published peer reviewed evidence. A short description of the validation process is given below.

Laboratory tests
We attached an NIBP simulator to the monitor under test and applied a series of simulated blood pressures to measure repeatability under normal conditions, in the presence of tremor artefact and with weak pulse.
Market review

**Measurement repeatability—normal conditions**
Thirty measurements were taken with each monitor using the NIBP simulator set at 120/80 (93) mmHg. The repeatability of the simulator (a Bio-Tek BP pump) is within 0.1 mmHg [14]. The results were averaged and the standard deviation (SD) calculated. A rating was given according to the consistency achieved for systolic, diastolic and mean pressures:

- **Excellent** SD ≤1 mmHg
- **Good** SD >1, ≤2 mmHg
- **Satisfactory** SD >2, ≤3 mmHg
- **Poor** SD >3, ≤4 mmHg
- **Very poor** SD >4 mmHg

**Measurement repeatability—tremor artefact /weak pulse**
Five measurements were taken at each of five different levels of tremor artefact (25 total) and four different levels of weak pulse (20 total). Using the criteria described below, we counted how many of the measurements could be described as misleading.

**Criteria for a misleading reading**
There is no widely accepted criterion for determining when a reading is misleading so we have adopted the following strategy:

When comparing two methods of measurement [22], e.g. an oscillometric device with human observers measuring blood pressures by auscultation, the ANSI/AAMI standard [8] requires that the bias must not exceed 5 mmHg and that the standard deviation of differences must not exceed 8 mmHg for 85 subjects.

For any given device which meets the ANSI/AAMI criteria, the bias and standard deviation are known from a clinical trial, and the 95% limits of agreement can be calculated. For a device chosen at random from a group of devices which meet the criteria, we can be (approximately) 95% confident that a single measurement will lie within -21 to +21 mmHg (-5-8x2 to +5+8x2 mmHg) of that of a trained observer.

Therefore we have set a limit of -21 to +21 mmHg with respect to the simulator setting to define a misleading measurement for both systolic and diastolic pressures.

**Pressure and pulse measurement ranges**
Five measurements were taken for each of the simulator's range of blood pressure settings and pulse-rate settings. Using the criterion below, we checked to see if each device performed acceptably well for each setting.
Criteria for acceptable pressure and pulse measurement ranges

There are no widely accepted criteria for determining acceptable performance over a range of blood pressures and pulse rates. The strategy we have adopted is based on the reasonable expectations of clinical staff using the monitor on a patient, in the absence of movement artefact. Two attempts at producing an acceptable reading are permitted. Where the device fails to give an acceptable reading twice in succession, performance is deemed unacceptable.

To be 95% confident of achieving at least one successful reading in two attempts we established, using binomial statistics, that any individual measurement must have a 78% probability (or more) of success.

To achieve that level of performance we calculated from a binomial distribution analysis that two or more successful measurements from five attempts at each pressure range setting and pulse rate setting would be required.

Documentation

We assessed the user manuals for the presence of relevant information such as setting up, operation, calibration, battery replacement, cleaning and sterilization. Where devices were capable of in-house repair, we assessed the service manual for fault finding guides, dismantling procedures, functional testing and calibration accuracy check instructions. This is a check only of the device's pressure transducer against a calibrated pressure gauge. It is not a check of the device's clinical validation.

Some devices could be repaired only by the manufacturer. In such cases, service manuals (if available) were assessed on this basis.

Clinical validation process

The measurement accuracy of an NIBP monitor requires a clinical trial using human subjects. There are a number of such protocols with different compositions of patient groups needed for the trial and different ways of presenting the results either as a grade or pass/fail. Devices in this report have been validated against protocols by the British Hypertension Society (BHS) [5], the US Association for the Advancement of Medical Instrumentation (ANSI/AAMI SP10-2002) [8] and the European Society of Hypertension (ESH) [4]. The first two of these require 85 subjects and the ESH requires 33 subjects.

Accuracy: O’Brien et al [23] made recommendations based on the following:

“A device fulfilling the AAMI criteria and graded A or B for both systolic and diastolic pressure under the BHS protocol has been recommended on grounds of accuracy without equivocation; one that fails the AAMI protocol for either systolic or diastolic pressure and has a grade of C or D for either systolic or diastolic pressure under the BHS protocol cannot be recommended on the grounds of accuracy”.

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Table 2  BHS grading criteria—see O'Brien E, et al [5]

<table>
<thead>
<tr>
<th>Grade</th>
<th>Cumulative percentage of readings</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>≤ 5 mmHg</td>
</tr>
<tr>
<td>A</td>
<td>60%</td>
</tr>
<tr>
<td>B</td>
<td>50%</td>
</tr>
<tr>
<td>C</td>
<td>40%</td>
</tr>
<tr>
<td>D</td>
<td>Worse than C</td>
</tr>
</tbody>
</table>

Readings taken by the device under validation are compared with those independently taken by two trained observers using the auscultatory technique. The observer’s measurements are performed simultaneously; the device measurements are performed sequentially to the observer measurements. There are 85 subjects; 255 measurements are taken in total. Grades are derived from the percentage of device readings within 5, 10 and 15 mmHg of the observers’ readings. To achieve a particular grade, all three percentages must be equal to or greater than the tabulated values above.

For studies where a BHS grade was not quoted in either a peer reviewed paper or in an unpublished report we used ANSI/AAMI SP10 data to derive an equivalent BHS grade.

Criteria for recommendation

Our general recommendations are based on three criteria which are important to consider when purchasing a device:

- Accuracy: Passed ANSI/AAMI SP10 and achieved a BHS grade A or B (or equivalent) in a clinical validation study for both systolic and diastolic pressure.

- Level of evidence, in order of preference:
  - Independent clinical validation study published in a peer reviewed journal.
  - Independent clinical validation study with an unpublished report.
  - In-house clinical validation study and report.

- Measurement performance comprising:
  - Excellent measurement repeatability (within 1 mmHg) from 30 consecutive measurements of 120/80 mmHg when tested using a repeatable [14] laboratory NIBP simulator.
  - At least two successful measurements from five attempts at each pressure range setting and pulse rate setting (settings are shown in the pro-forma reproduced in Appendix 3).
## Product information

<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Model</strong></td>
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<tr>
<td></td>
<td>UA-702</td>
<td>UA-704</td>
<td>UA-705</td>
</tr>
<tr>
<td></td>
<td>(manual inflation)</td>
<td>(manual inflation)</td>
<td>(manual inflation)</td>
</tr>
<tr>
<td><strong>Pressure range</strong></td>
<td>20–280 mmHg</td>
<td>20–280 mmHg</td>
<td>20–280 mmHg</td>
</tr>
<tr>
<td><strong>Systolic pressure range</strong></td>
<td>not specified</td>
<td>not specified</td>
<td>not specified</td>
</tr>
<tr>
<td><strong>Diastolic pressure range</strong></td>
<td>not specified</td>
<td>not specified</td>
<td>not specified</td>
</tr>
<tr>
<td><strong>Pulse rate range</strong></td>
<td>40–200 bpm</td>
<td>40–200 bpm</td>
<td>40–200 bpm</td>
</tr>
<tr>
<td><strong>Additional features</strong></td>
<td>none</td>
<td>irregular heartbeat indicator</td>
<td>irregular heartbeat indicator; blood pressure classification &amp; pressure bar indicators</td>
</tr>
<tr>
<td><strong>Cuff sizes</strong></td>
<td>Adult: 22–32 cm</td>
<td>Adult: Medium (22–32 cm); Large (32–42 cm)</td>
<td>Adult: Medium (22–32 cm); Large (32–45 cm)</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td>monochrome LCD</td>
<td>monochrome LCD</td>
<td>monochrome LCD</td>
</tr>
<tr>
<td><strong>Memory</strong></td>
<td>no</td>
<td>no</td>
<td>30 measurements + average</td>
</tr>
<tr>
<td><strong>Data transfer</strong></td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Printing</strong></td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td>4 x 1.5 V AA batteries</td>
<td>1 x 1.5 V AA battery</td>
<td>1 x 1.5 V AA battery</td>
</tr>
<tr>
<td><strong>AC adaptor</strong></td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Physical size (H x W x D)</strong></td>
<td>45 x 135 x 105 mm</td>
<td>37 x 100 x 51 mm</td>
<td>54 x 80 x 101 mm</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>0.22 kg (inc. batteries)</td>
<td>0.10 kg (inc. battery)</td>
<td>0.14 kg (inc. battery)</td>
</tr>
<tr>
<td><strong>Servicing Costs</strong></td>
<td>£20.00 + VAT &amp; return carriage</td>
<td>£20.00 + VAT &amp; return carriage</td>
<td>£20.00 + VAT &amp; return carriage</td>
</tr>
<tr>
<td><strong>Validation</strong></td>
<td>claimed ANSI/AAMI SP10 no supporting evidence found</td>
<td>yes: BHS A/A independent study and peer reviewed publication</td>
<td>yes: BHS A/A independent study and peer reviewed publication</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>A&amp;D</th>
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<th>A&amp;D</th>
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</thead>
<tbody>
<tr>
<td>Model</td>
<td>UA-767</td>
<td>UA-774</td>
<td>UA-779</td>
</tr>
<tr>
<td>Pressure range</td>
<td>20–280 mmHg</td>
<td>20–280 mmHg</td>
<td>20–280 mmHg</td>
</tr>
<tr>
<td>Systolic pressure range</td>
<td>not specified</td>
<td>not specified</td>
<td>not specified</td>
</tr>
<tr>
<td>Diastolic pressure range</td>
<td>not specified</td>
<td>not specified</td>
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</tr>
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<td>Pulse rate range</td>
<td>40–200 bpm</td>
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<td>40–200 bpm</td>
</tr>
<tr>
<td>Additional features</td>
<td>none</td>
<td>irregular heartbeat indicator; dual patient</td>
<td>none</td>
</tr>
<tr>
<td>Cuff sizes</td>
<td>Adult: 22–32 cm</td>
<td>Adult: Large: 32–42 cm; Medium: 22–32 cm; Small: 18–22 cm</td>
<td>Adult: 22–32 cm</td>
</tr>
<tr>
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<td>monochrome LCD</td>
<td>monochrome LCD</td>
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<tr>
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<td>no</td>
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<td>no</td>
<td>no</td>
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<td>4 x 1.5 V AA batteries</td>
<td>4 x 1.5 V AA batteries</td>
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<td>external 6 V mains adaptor (not supplied)</td>
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<td>UA-851</td>
<td>UA-853</td>
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<td>20–280 mmHg</td>
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<td>not specified</td>
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<td>Pulse rate range</td>
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<td>40–180 bpm</td>
<td>40–180 bpm</td>
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<td>Additional features</td>
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<td>Irregular heartbeat indicator; blood pressure classification &amp; pressure bar indicators</td>
<td>Irregular heartbeat indicator; blood pressure classification &amp; pressure bar indicators; AM/PM memory; 3 reminder alarms</td>
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<td>Cuff sizes</td>
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<td>Adult: Large: 32–45 cm; Medium: 22–32 cm; Small: 18–22 cm</td>
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<td>monochrome LCD</td>
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<td>90 measurements + overall average, AM &amp; PM average</td>
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<td>Data transfer</td>
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<td>no</td>
<td>no</td>
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<tr>
<td>Printing</td>
<td>no</td>
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<td>4 x 1.5 V AA batteries</td>
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<td>Manual BP monitor (manual inflation)</td>
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<td>not specified</td>
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<td>40–199 bpm</td>
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<td>external 6 V 1 A mains adaptor (not supplied)</td>
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<td>Diastolic pressure range</td>
<td>not specified</td>
<td>not specified</td>
<td>30–280 mmHg</td>
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<td>Pulse rate range</td>
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<td>40–180 bpm</td>
<td>40–200 bpm</td>
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<td>Adult: Standard (22–32 cm); X–Large (32–42 cm)</td>
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<td>monochrome LCD</td>
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<td>no</td>
<td>no</td>
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<tr>
<td>Printing</td>
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<td>no</td>
<td>no</td>
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<td>Power</td>
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## Market review

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<td>Fuzzy</td>
<td>MTA</td>
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<td>Diastolic pressure range</td>
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<td>not specified</td>
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<td>Pulse rate range</td>
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<td>40–199 bpm</td>
<td>40–200 bpm</td>
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<tr>
<td>Additional features</td>
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<td>none</td>
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<td>Printing</td>
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<td>not specified</td>
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<td>Diastolic pressure range</td>
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<td>not specified</td>
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<td>Pulse rate range</td>
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<td>40–200 bpm</td>
<td>40–200 bpm</td>
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<td>monochrome LCD</td>
<td>monochrome LCD</td>
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<tr>
<td>Memory</td>
<td>2 x 99 measurements + averages</td>
<td>last measurement recall</td>
<td>last measurement recall</td>
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<th>Model</th>
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<th>Systolic pressure range</th>
<th>Diastolic pressure range</th>
<th>Pulse rate range</th>
<th>Additional features</th>
<th>Cuff sizes</th>
<th>Display</th>
<th>Memory</th>
<th>Data transfer</th>
<th>Power</th>
<th>AC adaptor</th>
<th>Physical size (H x W x D)</th>
<th>Weight</th>
<th>Price paid (exc. VAT)</th>
<th>Servicing Costs</th>
<th>Validation</th>
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<tbody>
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<td>BP 3AC1-1</td>
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<td>40–200 bpm</td>
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<td>2 x 30 measurements</td>
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<td>77 x 118 x 177 mm</td>
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<td>40–200 bpm</td>
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## Market review

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<td>50–250 mmHg</td>
<td>50–250 mmHg</td>
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<td>40–140 mmHg</td>
<td>40–180 mmHg</td>
<td>40–140 mmHg</td>
</tr>
<tr>
<td><strong>Pulse rate range</strong></td>
<td>40–160 bpm</td>
<td>40–160 bpm</td>
<td>40–160 bpm</td>
</tr>
<tr>
<td><strong>Additional features</strong></td>
<td>none</td>
<td>dual patient</td>
<td>dual patient; irregular heartbeat indicator</td>
</tr>
<tr>
<td><strong>Cuff sizes</strong></td>
<td>Adult: 22–32 cm</td>
<td>Adult: 22–32 cm</td>
<td>Adult: 23–43 cm</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td>monochrome LCD</td>
<td>monochrome LCD</td>
<td>monochrome LCD</td>
</tr>
<tr>
<td><strong>Memory</strong></td>
<td>30 measurements + average</td>
<td>2 x 30 measurements + averages</td>
<td>2 x 30 measurements + averages</td>
</tr>
<tr>
<td><strong>Data transfer</strong></td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Printing</strong></td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td>1 x 1.5 V AA battery</td>
<td>4 x 1.5 V AA batteries</td>
<td>4 x 1.5 V AA batteries</td>
</tr>
<tr>
<td><strong>AC adaptor</strong></td>
<td>no</td>
<td>external 6 V mains adaptor (not supplied)</td>
<td>external 6 V mains adaptor (not supplied)</td>
</tr>
<tr>
<td><strong>Physical size (H x W x D)</strong></td>
<td>58 x 99 x 30 mm</td>
<td>52 x 163 x 120 mm</td>
<td>53 x 150 x 115 mm</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>0.10 kg (inc. battery)</td>
<td>0.34 kg (inc. batteries)</td>
<td>0.38 kg (inc. batteries)</td>
</tr>
<tr>
<td><strong>Price paid (exc. VAT)</strong></td>
<td>£25.00</td>
<td>£36.00</td>
<td>£46.00</td>
</tr>
<tr>
<td><strong>Servicing Costs</strong></td>
<td>£20.00 + VAT</td>
<td>£20.00 + VAT</td>
<td>£20.00 + VAT</td>
</tr>
<tr>
<td><strong>Validation</strong></td>
<td>no evidence found</td>
<td>no evidence found</td>
<td>yes: DIN 58130 independent study and unpublished report unable to derived BHS grade from data in supplied report</td>
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<thead>
<tr>
<th>Manufacturer</th>
<th>Omron</th>
<th>Omron</th>
<th>Omron</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model</td>
<td>705IT</td>
<td>M1 Classic (manual inflation)</td>
<td>M3</td>
</tr>
<tr>
<td>Pressure range</td>
<td>0–299 mmHg</td>
<td>0–299 mmHg</td>
<td>0–299 mmHg</td>
</tr>
<tr>
<td>Systolic pressure range</td>
<td>not specified</td>
<td>not specified</td>
<td>not specified</td>
</tr>
<tr>
<td>Diastolic pressure range</td>
<td>not specified</td>
<td>not specified</td>
<td>not specified</td>
</tr>
<tr>
<td>Pulse rate range</td>
<td>40–180 bpm</td>
<td>40–180 bpm</td>
<td>40–180 bpm</td>
</tr>
<tr>
<td>Additional features</td>
<td>supplied with printer</td>
<td>none</td>
<td>irregular heartbeat indicator</td>
</tr>
<tr>
<td>Cuff sizes</td>
<td>Small: 17–22 cm; Medium: 22–32 cm; Large: 32–42 cm</td>
<td>Small: 17–22 cm; Medium: 22–32 cm; Large: 32–42 cm</td>
<td>Medium: 22–32 cm; Large: 32–42 cm</td>
</tr>
<tr>
<td>Display</td>
<td>monochrome LCD</td>
<td>monochrome LCD</td>
<td>monochrome LCD</td>
</tr>
<tr>
<td>Memory</td>
<td>28 measurements + average via printer</td>
<td>14 measurements</td>
<td>42 measurements + average</td>
</tr>
<tr>
<td>Data transfer</td>
<td>optional</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Printing</td>
<td>yes</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Power</td>
<td>4 x 1.5 V AA batteries</td>
<td>4 x 1.5 V AA batteries</td>
<td>4 x 1.5 V AA batteries</td>
</tr>
<tr>
<td>AC adaptor</td>
<td>external 6 V mains adaptor (not supplied)</td>
<td>no</td>
<td>external 6 V mains adaptor (not supplied)</td>
</tr>
<tr>
<td>Physical size (H x W x D)</td>
<td>71 x 177 x 115 mm</td>
<td>84 x 106 x 116 mm</td>
<td>86 x 121 x 141 mm</td>
</tr>
<tr>
<td>Weight</td>
<td>0.44 kg (inc. batteries)</td>
<td>0.26 kg (inc. batteries)</td>
<td>0.42 kg (inc. batteries)</td>
</tr>
<tr>
<td>Price paid (exc. VAT)</td>
<td>£90.00</td>
<td>£26.99</td>
<td>£36.00</td>
</tr>
<tr>
<td>Servicing Costs</td>
<td>£20.00 + VAT</td>
<td>£19.00 + VAT</td>
<td>£20.00 + VAT</td>
</tr>
<tr>
<td>Validation</td>
<td>yes: ESH (and use with children), BHS A/A and ANSI/AAMI SP10 independent studies and peer reviewed publications</td>
<td>no evidence found</td>
<td>no evidence found</td>
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## Market review

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Omron MX3 Plus</th>
<th>Omron M4-I</th>
<th>Omron M6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Model</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pressure range</strong></td>
<td>0–299 mmHg</td>
<td>0–280 mmHg</td>
<td>0–299 mmHg</td>
</tr>
<tr>
<td><strong>Systolic pressure range</strong></td>
<td>not specified</td>
<td>not specified</td>
<td>not specified</td>
</tr>
<tr>
<td><strong>Diastolic pressure range</strong></td>
<td>not specified</td>
<td>not specified</td>
<td>not specified</td>
</tr>
<tr>
<td><strong>Pulse rate range</strong></td>
<td>40–180 bpm</td>
<td>40–180 bpm</td>
<td>40–180 bpm</td>
</tr>
<tr>
<td><strong>Additional features</strong></td>
<td>none</td>
<td>none</td>
<td>irregular heartbeat indicator; movement artefact indicator</td>
</tr>
<tr>
<td><strong>Cuff sizes</strong></td>
<td>Medium: 22–32 cm; Large: 32–42 cm</td>
<td>Small: 17–22 cm; Medium: 22–32 cm; Large: 32–42 cm</td>
<td>Small: 17–22 cm; Medium: 22–32 cm; Large: 32–42 cm</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td>monochrome LCD</td>
<td>monochrome LCD</td>
<td>monochrome LCD</td>
</tr>
<tr>
<td><strong>Memory</strong></td>
<td>14 measurements</td>
<td>14 measurements</td>
<td>90 measurements + average</td>
</tr>
<tr>
<td><strong>Data transfer</strong></td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Printing</strong></td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td>4 x 1.5 V AA batteries</td>
<td>4 x 1.5 V AA batteries</td>
<td>4 x 1.5 V AA batteries</td>
</tr>
<tr>
<td><strong>AC adaptor</strong></td>
<td>external 6 V mains adaptor (not supplied)</td>
<td>external 6 V mains adaptor (not supplied)</td>
<td>external 6 V mains adaptor (not supplied)</td>
</tr>
<tr>
<td><strong>Physical size (H x W x D)</strong></td>
<td>93 x 118 x 120 mm</td>
<td>65 x 168 x 106 mm</td>
<td>84 x 131 x 155 mm</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>0.42 kg (inc. batteries)</td>
<td>0.40 kg (inc. batteries)</td>
<td>0.44 kg (inc. batteries)</td>
</tr>
<tr>
<td><strong>Price paid (exc. VAT)</strong></td>
<td>£28.89</td>
<td>£46.99</td>
<td>£41.89</td>
</tr>
<tr>
<td><strong>Servicing Costs</strong></td>
<td>£19.00 + VAT</td>
<td>£19.00 + VAT</td>
<td>£19.00 + VAT</td>
</tr>
<tr>
<td><strong>Validation</strong></td>
<td>yes: ESH independent study and peer reviewed publication</td>
<td>yes: ESH (and use with children), BHS A/A and ANSI/AAMI SP10 due to similarity with Omron 705IT independent studies and peer reviewed publications</td>
<td>yes: ESH (and use with obese patients) also ESH use with children, BHS A/A and ANSI/AAMI SP10 due to similarity with Omron 705IT independent studies and peer reviewed publications</td>
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<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Omron</th>
<th>Omron</th>
<th>Panasonic</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Model</strong></td>
<td>M7</td>
<td>SpotArm i-Q132 (integrated cuff)</td>
<td>EW3106</td>
</tr>
<tr>
<td><strong>Pressure range</strong></td>
<td>0–299 mmHg</td>
<td>0–299 mmHg</td>
<td>0–280 mmHg</td>
</tr>
<tr>
<td><strong>Systolic pressure range</strong></td>
<td>not specified</td>
<td>not specified</td>
<td>not specified</td>
</tr>
<tr>
<td><strong>Diastolic pressure range</strong></td>
<td>not specified</td>
<td>not specified</td>
<td>not specified</td>
</tr>
<tr>
<td><strong>Pulse rate range</strong></td>
<td>40–180 bpm</td>
<td>40–180 bpm</td>
<td>30–160 bpm</td>
</tr>
<tr>
<td><strong>Additional features</strong></td>
<td>none</td>
<td>dual patient &amp; guest; irregular heartbeat indicator; movement artefact indicator; posture indicator; am/pm weekly averages</td>
<td>none</td>
</tr>
<tr>
<td><strong>Cuff sizes</strong></td>
<td>Adult: 22–42 cm</td>
<td>Integrated Adult: 17–32 cm</td>
<td>Adult: 20–34 cm</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td>monochrome LCD</td>
<td>monochrome LCD with backlight</td>
<td>monochrome LCD</td>
</tr>
<tr>
<td><strong>Memory</strong></td>
<td>90 measurements</td>
<td>2 x 84 measurements + averages</td>
<td>42 measurements</td>
</tr>
<tr>
<td><strong>Data transfer</strong></td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Printing</strong></td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td>4 x 1.5 V AA batteries</td>
<td>4 x 1.5 V AA batteries</td>
<td>4 x 1.5 V AA batteries</td>
</tr>
<tr>
<td><strong>AC adaptor</strong></td>
<td>external 6 V mains adaptor (not supplied)</td>
<td>external 6 V mains adaptor (supplied)</td>
<td>no</td>
</tr>
<tr>
<td><strong>Physical size (H x W x D)</strong></td>
<td>71 x 165 x 113 mm</td>
<td>217 x 230 x 228 mm</td>
<td>68 x 150 x 110 mm</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>0.48 kg (inc. batteries)</td>
<td>1.55 kg (inc. batteries)</td>
<td>0.38 kg (inc. batteries)</td>
</tr>
<tr>
<td><strong>Price paid (exc. VAT)</strong></td>
<td>£41.89</td>
<td>£76.99</td>
<td>£51.06</td>
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<tr>
<td><strong>Servicing Costs</strong></td>
<td>£19 + VAT (Medisave)</td>
<td>£21.00 + VAT</td>
<td>£27.50 + VAT + return delivery charge but the cost includes a new cuff</td>
</tr>
<tr>
<td><strong>Validation</strong></td>
<td>yes: ESH (population requiring large cuff), BHS A/A and ANSI/AAMI SP10 independent studies and peer reviewed publications also unpublished independent ESH validation</td>
<td>no evidence found</td>
<td>yes: EN 1060-4 independent unpublished report (in German) unable to derive BHS grade</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Panasonic EW3109</th>
<th>Panasonic EW3122</th>
<th>Ri-Tester Ri-Champion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Model</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pressure range</strong></td>
<td>0–280 mmHg</td>
<td>0–280 mmHg</td>
<td>40–280 mmHg</td>
</tr>
<tr>
<td><strong>Systolic pressure range</strong></td>
<td>not specified</td>
<td>not specified</td>
<td>not specified</td>
</tr>
<tr>
<td><strong>Diastolic pressure range</strong></td>
<td>not specified</td>
<td>not specified</td>
<td>not specified</td>
</tr>
<tr>
<td><strong>Pulse rate range</strong></td>
<td>30–160 bpm</td>
<td>30–160 bpm</td>
<td>40–180 bpm</td>
</tr>
<tr>
<td><strong>Additional features</strong></td>
<td>none</td>
<td>dual patient; blood pressure classification indicator; movement indicator</td>
<td>none</td>
</tr>
<tr>
<td><strong>Cuff sizes</strong></td>
<td>Adult: 20–34 cm</td>
<td>Cuff: 20–34 cm; Large: 35–44 cm</td>
<td>Adult: 24–32 cm; Adult thick arms: 32–42 cm; Children: 13–20 cm</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td>monochrome LCD</td>
<td>monochrome LCD</td>
<td>monochrome LCD</td>
</tr>
<tr>
<td><strong>Memory</strong></td>
<td>90 measurements</td>
<td>2 x 42 measurements</td>
<td>8 measurements</td>
</tr>
<tr>
<td><strong>Data transfer</strong></td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Printing</strong></td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td>4 x 1.5 V AA batteries</td>
<td>4 x 1.5 V AA batteries</td>
<td>4 x 1.5 V AA batteries</td>
</tr>
<tr>
<td><strong>AC adaptor</strong></td>
<td>external mains adaptor (not supplied)</td>
<td>external mains adaptor (not supplied)</td>
<td>no</td>
</tr>
<tr>
<td><strong>Physical size (H x W x D)</strong></td>
<td>53 x 207 x 53 mm</td>
<td>97 x 181 x 179 x mm</td>
<td>79 x 117 x 100 mm</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>0.36 kg (inc. batteries)</td>
<td>0.66 kg (inc batteries)</td>
<td>0.34 kg (inc. batteries)</td>
</tr>
<tr>
<td><strong>Price paid (exc. VAT)</strong></td>
<td>£55.31</td>
<td>£59.57</td>
<td>£68.00</td>
</tr>
<tr>
<td><strong>Servicing Costs</strong></td>
<td>£27.50 + VAT + return delivery charge but the cost includes a new cuff</td>
<td>£27.50 + VAT + return delivery charge but the cost includes a new cuff</td>
<td>£20.00 + VAT</td>
</tr>
<tr>
<td><strong>Validation</strong></td>
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<td>yes: EN 1060-4 due to similarity with EW3106 independent unpublished report (in German) unable to derive BHS grade</td>
<td>claimed DIN 58130 no supporting evidence</td>
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## Market review

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<tr>
<th>Manufacturer</th>
<th>Rossmax</th>
<th>Rossmax</th>
<th>Samsung</th>
</tr>
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<tbody>
<tr>
<td>Model</td>
<td>MS60 (manual inflation)</td>
<td>MS400i</td>
<td>BD-3000S</td>
</tr>
<tr>
<td>Pressure range</td>
<td>20–280 mmHg</td>
<td>20–280 mmHg</td>
<td>0–260 mmHg</td>
</tr>
<tr>
<td>Systolic pressure range</td>
<td>not specified</td>
<td>not specified</td>
<td>not specified</td>
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<tr>
<td>Diastolic pressure range</td>
<td>not specified</td>
<td>not specified</td>
<td>not specified</td>
</tr>
<tr>
<td>Pulse rate range</td>
<td>40–180 bpm</td>
<td>40–180 bpm</td>
<td>40–199 bpm</td>
</tr>
<tr>
<td>Additional features</td>
<td>none</td>
<td>dual patient</td>
<td>three patient</td>
</tr>
<tr>
<td>Cuff sizes</td>
<td>Adult: 24–36 cm</td>
<td>Adult: 24–36 cm</td>
<td>Adult: 23–33 cm</td>
</tr>
<tr>
<td>Display</td>
<td>monochrome LCD</td>
<td>monochrome LCD</td>
<td>monochrome LCD</td>
</tr>
<tr>
<td>Memory</td>
<td>60 measurements</td>
<td>2 x 50 measurements</td>
<td>3 x 30 measurements</td>
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<tr>
<td>Data transfer</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Printing</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Power</td>
<td>4 x 1.5 V AA batteries</td>
<td>4 x 1.5 V AA batteries</td>
<td>4 x 1.5 V AA batteries</td>
</tr>
<tr>
<td>AC adaptor</td>
<td>no</td>
<td>external 12V 600 mA mains adaptor (not supplied)</td>
<td>external 6 V 1 A mains adaptor (supplied)</td>
</tr>
<tr>
<td>Physical size (H x W x D)</td>
<td>72 x 111 x 155 mm</td>
<td>72 x 111 x 155 mm</td>
<td>77 x 110 x 150 mm</td>
</tr>
<tr>
<td>Weight</td>
<td>0.26 kg (inc. batteries)</td>
<td>0.38 kg (inc. batteries)</td>
<td>0.38 kg (inc. batteries)</td>
</tr>
<tr>
<td>Price paid (exc. VAT)</td>
<td>£42.00</td>
<td>£50.00</td>
<td>£55.00</td>
</tr>
<tr>
<td>Servicing Costs</td>
<td>£21.00 + VAT</td>
<td>not provided</td>
<td>£20.00 + VAT</td>
</tr>
<tr>
<td>Validation</td>
<td>claimed ANSI/AAMI SP10 no supporting evidence</td>
<td>claimed ANSI/AAMI SP10 no supporting evidence</td>
<td>claimed ANSI/AAMI SP10 no supporting evidence</td>
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<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Samsung BF-180M</th>
<th>Samsung SBM-600F</th>
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<tbody>
<tr>
<td><strong>Pressure range</strong></td>
<td>0–260 mmHg</td>
<td>20–285 mmHg</td>
</tr>
<tr>
<td><strong>Systolic pressure range</strong></td>
<td>not specified</td>
<td>not specified</td>
</tr>
<tr>
<td><strong>Diastolic pressure range</strong></td>
<td>not specified</td>
<td>not specified</td>
</tr>
<tr>
<td><strong>Pulse rate range</strong></td>
<td>40–200 bpm</td>
<td>30–150 bpm</td>
</tr>
<tr>
<td><strong>Additional features</strong></td>
<td>three patient</td>
<td>none</td>
</tr>
<tr>
<td><strong>Cuff sizes</strong></td>
<td>Adult: 23–33 cm; Adult large: 33–43 cm</td>
<td>Adult: 23–33 cm</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td>monochrome LCD</td>
<td>monochrome LCD</td>
</tr>
<tr>
<td><strong>Memory</strong></td>
<td>3 x 30 measurements</td>
<td>8 measurements</td>
</tr>
<tr>
<td><strong>Data transfer</strong></td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Printing</strong></td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td>4 x 1.5 V AA batteries</td>
<td>4 x 1.5 V AA batteries</td>
</tr>
<tr>
<td><strong>AC adaptor</strong></td>
<td>external 6 V 1 A mains adaptor (supplied)</td>
<td>no</td>
</tr>
<tr>
<td><strong>Physical size (H x W x D)</strong></td>
<td>56 x 110 x 147 mm</td>
<td>67 x 131 x 117 mm</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>0.44 kg (inc. batteries)</td>
<td>0.38 kg (inc. batteries)</td>
</tr>
<tr>
<td><strong>Price paid (exc. VAT)</strong></td>
<td>£67.00</td>
<td>£28.00</td>
</tr>
<tr>
<td><strong>Servicing Costs</strong></td>
<td>£20.00 + VAT</td>
<td>£20.00 + VAT</td>
</tr>
<tr>
<td><strong>Validation</strong></td>
<td>claimed ANSI/AAMI SP10 no supporting evidence</td>
<td>claimed ANSI/AAMI SP10 no supporting evidence</td>
</tr>
</tbody>
</table>
A&D UA-702*

Brief description

The A&D UA-702 was a blood pressure monitor which required manual inflation. Its only control was an on/off switch.

After switching on the device, the cuff was inflated by an external bulb inflator to the target pressure (initially 150 mmHg). The cuff continuously deflated via a pin-hole in the inflator during which the device measured the subject's blood pressure.

The device had a buzzer that sounded at switch on, when cuff pressure reached 160, 200, 240 and 280 mmHg, during the measurement when each pulse was detected and at the end of the measurement. If initial inflation pressure was inadequate, no reading was displayed—instead, a ▲ prompt indicated to increase the inflation pressure. When the measurement was complete, a ▼ prompt indicated to press the exhaust valve air-release button that was attached to the inflator bulb.

The LCD panel showed pressure measurements, pulse rate and error messages. In addition to the pressure prompts (above) there were icons for pulse detection and low battery.

The device had to be turned off then on again before each new measurement; otherwise it powered down automatically after three minutes. No previous measurements were stored.

Summary

Validation

The manufacturer claimed (in the user manual) that the NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. However, no evidence was provided nor could any published evidence be found to verify this claim.

Good points

Good measurement consistency across a range of blood pressures (SD ± 1.5 mmHg). Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.8 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Gave fifteen misleading readings from 25 tests when subjected to varying degrees of tremor artefact.

*Note: This device has been discontinued.
Market review

Results

NIBP performance tests
- pressure and pulse rate ranges: acceptable
- measurement consistency
  - fixed 120/80 mmHg\(^{†}\): excellent, SD ± 0.8 mmHg
  - variable pressure\(^{‡}\): good, SD ± 1.5 mmHg
  - variable pulse rate\(^{‡}\): satisfactory, SD ± 2.1 mmHg
- susceptibility to artefact: 15 misleading readings from 25 tests
- variable pulse strength: gave no misleading readings

General
- usability: satisfactory

Manuals
- user manual: satisfactory

Construction
- mechanical: satisfactory
- electrical: satisfactory
- CE marking: CE\(_{0366}\)

\(^{†}\) 30 measurements \quad \(^{‡}\) 5 measurements

Technical discussion

Construction
The monitor was supplied with a 22–32 cm reusable adult cuff with a hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a single circuit board populated with discrete un-miniaturised components and a pressure transducer. The cuff pressure was released by a manually operated valve adjacent to the bulb inflator.

Power supply
The device was powered by four 1.5 V AA batteries.

Serviceability
The user manual stated that the device should only undergo authorised servicing and that ‘technical testing’ should be completed every 3 years.
A&D UA-704

Brief description

The A&D UA-704 was a blood pressure monitor which required manual inflation. Its only control was an on/off switch.

After switching on the device, the cuff was inflated by an external bulb inflator to the target pressure (initially 150 mmHg): this was known by watching the increasing pressure and a flashing ▲ prompt which disappeared when the target pressure was achieved.

The cuff continuously deflated via a pin-hole in the inflator during which the device measured and displayed the subject's blood pressure. When the measurement was complete a ◀ prompt indicated to press the exhaust valve air-release button that was attached to the inflator bulb. If initial inflation pressure was inadequate, no reading was displayed and the ▲ prompt returned indicating to increase the inflation pressure.

The LCD panel showed pressure measurements, pulse rate and error messages. As well as the pressure prompts (above), there were icons for pulse detection, irregular heart beat and low battery.

The device had to be turned off then on again before each new measurement; otherwise it powered down automatically after one minute. No previous measurements were stored. This was the smallest device evaluated and could be held in the palm of the hand as shown on its packaging. During measurement, the device should not be held as the hand must be relaxed during measurement (see BHS guidelines page 3).

Summary

Validation

The NIBP performance was clinically validated using the British Hypertension Society (BHS) protocol, under which it was graded A/A. This was supported by a peer reviewed publication [24].

Good points

Good measurement consistency across a range of blood pressures (SD ± 2.0 mmHg). Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.6 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Gave two misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests
- pressure and pulse rate ranges: acceptable
- measurement consistency
  - fixed 120/80 mmHg†: good, SD ± 1.6 mmHg
  - variable pressure‡: good, SD ± 2.0 mmHg
  - variable pulse rate‡: satisfactory, SD ± 3.0 mmHg
- susceptibility to artefact: 2 misleading readings from 25 tests
- variable pulse strength: gave no misleading readings

General
- usability: satisfactory

Manuals
- user manual: satisfactory

Construction
- mechanical: satisfactory
- electrical: satisfactory
- CE marking: CE0366

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 40 cm. The casing was all plastic.

Inside the case was a single circuit board populated with surface mounted components and a pressure transducer. The cuff pressure was released by a manually operated valve adjacent to the bulb inflator.

Power supply
The device was powered by a 1.5V AA battery.

Serviceability
The user manual stated that the device should only undergo authorised servicing and that ‘inspection’ should be completed every 2 years.
A&D UA-705

Brief description
The A&D UA-705 was a blood pressure monitor which required manual inflation. Its only control was an on/off switch.

After switching on the device, the cuff was inflated by an external bulb inflator to the target pressure (initially 150 mmHg): this was known by watching the increasing pressure and a flashing ▲ prompt until it disappeared and a buzzer sounded.

The cuff continuously deflated via a pin-hole in the inflator during which the device measured and displayed the subject’s blood pressure. When the measurement was complete a ▼ prompt indicated to press the exhaust valve air-release button that was attached to the inflator bulb. If initial inflation pressure was inadequate, no reading was displayed and the ▲ prompt returned indicating to increase the inflation pressure.

The LCD panel showed pressure measurements and pulse rate. As well as the pressure prompts (above), there were display icons for pulse detection, irregular heart beat detection, memory recall and low battery. It also gave an indication of the reading’s classification* as defined in the BHS Guidelines [1].

The device had to be turned off then on again before each new measurement; otherwise it powered down automatically after one minute. Thirty measurements could be stored and reviewed, together with their average.

Summary

Validation
The NIBP performance was clinically validated using the British Hypertension Society (BHS) protocol, under which it was graded A/A. This was supported by a peer reviewed publication [25].

Good points
Excellent measurement consistency across a range of blood pressures (SD ± 0.7 mmHg), at a fixed pressure of 120/80 mmHg (SD ± 0.7 mmHg) and across a range of pulse rates (SD ± 0.9 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages
Gave three misleading readings from 25 tests when subjected to varying degrees of tremor artefact.

* A six point scale of risk: optimal, normal, high normal, mild hypertension, moderate hypertension, severe hypertension.
Results

**NIBP performance tests**
- pressure and pulse rate ranges: acceptable
- measurement consistency
  - fixed 120/80 mmHg*: excellent, SD ± 0.7 mmHg
  - variable pressure*: excellent, SD ± 0.7 mmHg
  - variable pulse rate*: excellent, SD ± 0.9 mmHg
- susceptibility to artefact: 3 misleading readings from 25 tests
- variable pulse strength: gave no misleading readings

**General**
- usability: satisfactory

**Manuals**
- user manual: satisfactory

**Construction**
- mechanical: satisfactory
- electrical: satisfactory
- CE marking: CE0366

* 30 measurements ‡ 5 measurements

Technical discussion

**Construction**
The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a single circuit board populated with surface mounted components and a pressure transducer. The cuff pressure was released by a manually operated valve on the bulb inflator.

**Power supply**
The device was powered by a 1.5 V AA battery.

**Serviceability**
The user manual stated that the device should only undergo authorised servicing and that 'inspection' should be completed every 2 years.
A&D UA-767

Brief description

The A&D UA-767 was a blood pressure monitor which inflated the cuff by a motorised air pump. Before a measurement, the user could set the initial inflation pressure selector switch 30–40 mmHg above expected systolic pressure. Otherwise there was only a single control: an on/off button labelled 'Start'.

After pressing 'Start', the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. If the selected target pressure was too low, the device automatically pumped the cuff to a higher pressure and resumed measurement. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the 'Start' button.

The LCD panel showed pressure measurements and pulse rate. There were two display icons; they indicated measurement in progress and low battery. A tone chimed in time with the pulse and at the beginning/end of the measurement.

The device had to be turned off then on again before each new measurement; otherwise it powered down automatically after one minute. No previous measurements were stored.

Note: A UK A&D supplier advised us that the A&D UA-767 Plus 30 is also available. However, it is specified and validated as a 30 memory reading version of the A&D UA-774 (page 39).

Summary

Validation

The NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol and also the British Hypertension Society (BHS) protocol, under which it was graded A/A. Both validations were supported by a peer reviewed publication [26].

Good points

Excellent measurement consistency across a range of blood pressures (SD ± 0.8 mmHg), at a fixed pressure of 120/80 mmHg (SD ± 0.9 mmHg) and across a range of pulse rates (SD ± 0.9 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Gave 13 misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Market review

Results

**NIBP performance tests**
- pressure and pulse rate ranges: acceptable
- measurement consistency
  - fixed 120/80 mmHg: excellent, SD ± 0.8 mmHg
  - variable pressure: excellent, SD ± 0.9 mmHg
  - variable pulse rate: good, SD ± 0.9 mmHg
- susceptibility to artefact: 13 misleading readings from 25 tests
- variable pulse strength: gave no misleading readings

**General**
- usability: satisfactory

**Manuals**
- user manual: satisfactory

**Construction**
- mechanical: satisfactory
- electrical: satisfactory
- CE marking: CE0366

† 30 measurements ‡ 5 measurements

Technical discussion

**Construction**
The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatic circuit. The circuit board was populated with discrete, un-miniaturised components and a pressure transducer. The pneumatic circuit connected to the pressure transducer included a pump and mechanical valve to release the cuff pressure.

**Power supply**
The device was powered by four 1.5 V AA batteries.

**Serviceability**
The user manual stated that the device should undergo technical test every 3 years by the manufacturer or an authorised repair service.
A&D UA-774

Brief description

The A&D UA-774 was a blood pressure monitor which inflated the cuff by a motorised air pump. It had two controls to start inflation, so that two individuals could use the device and store their measurements separately.

After pressing one of the 'Start' buttons, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. If the initial pressure was too low, the device automatically pumped the cuff to a higher pressure and resumed measurement. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing 'Start'.

The LCD panel showed pressure measurements and pulse rate. There were three display icons; they indicated measurement in progress, irregular heartbeat and low battery. It also gave an indication of the reading's classification* as defined in the BHS Guidelines [1].

The device had to be turned off then on again before each new measurement; otherwise it powered down automatically after one minute. Thirty measurements could be stored and reviewed together with their average for each button (total of sixty measurements).

Summary

Validation

The NIBP performance was clinically validated using the British Hypertension Society (BHS) protocol, under which it was graded A/A. This was supported by a peer reviewed publication [27].

Good points

Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Poor measurement consistency across a range of pulse rates (SD ± 3.2 mmHg). Gave four misleading readings from 25 tests when subjected to varying degrees of tremor artefact.

* A six point scale of risk: optimal, normal, high normal, mild hypertension, moderate hypertension, severe hypertension.
Market review

Results

NIBP performance tests
- pressure and pulse rate ranges acceptable
- measurement consistency
  - fixed 120/80 mmHg † satisfactory, SD ± 2.4 mmHg
  - variable pressure ‡ satisfactory, SD ± 3.0 mmHg
  - variable pulse rate ‡ poor, SD ± 3.2 mmHg
- susceptibility to artefact 4 misleading readings from 25 tests
- variable pulse strength gave no misleading readings

General
- usability satisfactory

Manuals
- user manual satisfactory

Construction
- mechanical satisfactory
- electrical satisfactory
- CE marking CE0366

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatic circuit. The circuit board was populated with surface mounted components and a pressure transducer. The pneumatic circuit connected to the pressure transducer included a pump and an electro-mechanical valve to release the cuff pressure.

Power supply
The device was powered by four 1.5V AA batteries.

Serviceability
The user manual stated that the device should be inspected every 2 years by the manufacturer or an authorised repair service to ensure proper functionality and accuracy.
A&D UA-779

Brief description

The A&D UA-779 was a blood pressure monitor which inflated the cuff by a motorised air pump. It had an on/off button labelled 'Start' and a control to review stored measurements.

After pressing 'Start', the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. If the initial pressure was too low, the device automatically pumped the cuff to a higher pressure and resumed measurement. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing 'Start'.

The LCD panel showed pressure measurements and pulse rate. There were three display icons: they indicated measurement in progress, low battery and 'M' when viewing stored readings.

The device had to be turned off then on again before each new measurement; otherwise it powered down automatically after one minute. Seven measurements could be stored and reviewed.

Summary

Validation
The NIBP performance was clinically validated using the European Society of Hypertension (ESH) protocol. This was supported by a peer reviewed publication [28].

Good points
Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.6 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages
Failed to measure blood pressure of 255/195 mmHg in 4 out of 5 attempts. Gave five misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

**NIBP performance tests**
- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 255/195 mmHg setting for 4 out of 5 attempts
  - pulse range acceptable
- measurement consistency
  - fixed 120/80 mmHg†
    - excellent, SD ± 0.6 mmHg
  - variable pressure‡
    - good over the range which could be measured, SD ± 1.7 mmHg
  - variable pulse rate‡
    - satisfactory, SD ± 2.2 mmHg
- susceptibility to artefact
  - 5 misleading readings from 25 tests
- variable pulse strength
  - gave no misleading readings

**General**
- usability
  - satisfactory

**Manuals**
- user manual
  - satisfactory

**Construction**
- mechanical
  - satisfactory
- electrical
  - satisfactory
- CE marking
  - CE_0366

† 30 measurements ‡ 5 measurements

Technical discussion

**Construction**
The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatic circuit. The circuit board was populated with surface mounted components and a pressure transducer. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

**Power supply**
The device was powered by four 1.5 V AA batteries.

**Serviceability**
The user manual made no recommendations for maintenance or calibration of the device.
A&D UA-787

Brief description

The A&D UA-787 was a blood pressure monitor which inflated the cuff by a motorised air pump. It had an on/off button labelled ‘Start’ and a control to review stored measurements.

After pressing ‘Start’, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. If the initial pressure was too low, the device automatically pumped the cuff to a higher pressure and resumed measurement. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing 'Start'.

The monitor also incorporated a clock with an alarm, so that reminder alarms could be set for three different times in a 24-hour period.

The LCD panel showed pressure measurements and pulse rate. There were two display icons; they indicated measurement in progress and irregular heartbeat. A three segment battery gauge indicated the remaining battery capacity.

The device had to be turned off then on again before each new measurement; otherwise it powered down automatically after one minute. Thirty measurements could be stored and reviewed.

Note: A UK supplier of the A&D-787 has advised us that this model is now called the A&D-787 Plus with a 60-reading memory, a 22–42 cm cuff and other added features.

Summary

Validation

The NIBP performance was clinically validated using the European Society of Hypertension (ESH) protocol. This was supported by a peer reviewed publication [29].

Good points

Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.9 mmHg).

Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Poor measurement consistency across a range of blood pressures (SD ± 3.3 mmHg). Poor measurement consistency across a range of pulse rates (SD ± 4.0 mmHg). Gave six misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests
- pressure and pulse rate ranges: acceptable
- measurement consistency:
  - fixed 120/80 mmHg†: good, SD ± 1.9 mmHg
  - variable pressure‡: poor, SD ± 3.3 mmHg
  - variable pulse rate‡: poor, SD ± 4.0 mmHg
- susceptibility to artefact: 6 misleading readings from 25 tests
- variable pulse strength: gave no misleading readings

General
- usability: satisfactory

Manuals
- user manual: satisfactory

Construction
- mechanical: satisfactory
- electrical: satisfactory
- CE marking: CE0366

Technical discussion

Construction
The monitor was supplied with a 26–36 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case were two circuit boards and pneumatic circuit. There was a main circuit board including the pressure transducer and a power circuit board. There were both populated with surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5 V AA batteries. However, it had the option of being powered from the mains via an AC adaptor, which could be purchased separately.

Serviceability
The user manual stated that the device should undergo technical test every 2 years by the manufacturer or an authorised repair service.
A&D UA-851

Brief description

The A&D UA-851 was a blood pressure monitor which inflated the cuff by a motorised air pump. It had a single on/off button labelled 'Start'.

After pressing 'Start', the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. If the initial pressure was too low, the device automatically pumped the cuff to a higher pressure and resumed measurement. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing 'Start'.

The LCD panel showed pressure measurements and pulse rate. There were three display icons for pulse, irregular heartbeat and stored measurement status. A three segment battery gauge indicated the remaining battery capacity. It also gave an indication of the reading's classification* as defined in the BHS Guidelines [1].

The device had to be turned off then on again before each new measurement; otherwise it powered down automatically after one minute. Ninety measurements could be stored and reviewed together with their average.

Summary

Validation

The manufacturer claimed (in the user manual) that the NIBP performance was clinically validated using the ANSI/AAMI SP10 and BHS protocols. However, no evidence was provided nor could any published evidence be found to verify this claim.

Good points

Good measurement consistency across a range of blood pressure (SD ± 1.6 mmHg). Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.9 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Gave six misleading readings from 25 tests when subjected to varying degrees of tremor artefact.

* A six point scale of risk: optimal, normal, high normal, mild hypertension, moderate hypertension, severe hypertension.
Market review

Results

**NIBP performance tests**
- pressure and pulse rate ranges: acceptable
- measurement consistency:
  - fixed 120/80 mmHg\(^\dagger\): excellent, SD ± 0.9 mmHg
  - variable pressure\(^\ddagger\): good, SD ± 1.6 mmHg
  - variable pulse rate\(^\ddagger\): satisfactory, SD ± 2.9 mmHg
- susceptibility to artefact: 6 misleading readings from 25 tests
- variable pulse strength: gave no misleading readings

**General**
- usability: good

**Manuals**
- user manual: good

**Construction**
- mechanical: excellent
- electrical: excellent
- CE marking: CE\(_{0366}\)

\(^\dagger\) 30 measurements \(^\ddagger\) 5 measurements

Technical discussion

**Construction**

The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic and designed to sit on the desktop with the cuff stored behind the display.

Inside the case was a circuit board and pneumatic circuit. The circuit board included the pressure transducer and was populated with surface mounted components. The pneumatic circuit connected to the pressure transducer included a pump, an electronically controlled pressure release valve and orifice for a fixed rate of release of cuff pressure.

**Power supply**

The device was powered by four 1.5 V AA batteries. However, it had the option of being powered from the mains via an AC adaptor, which could be purchased separately.

**Serviceability**

The user manual stated that the device should be inspected every 2 years by the manufacturer or an authorised repair service to check its functionality and accuracy.
A&D UA-853

Brief description

The A&D UA-853 was a blood pressure monitor which inflated the cuff by a motorised air pump. It had an on/off button labelled ‘Start’, which was illuminated in red or blue depending on the time of day.

After pressing ‘Start’, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. If the initial pressure was too low, the device automatically pumped the cuff to a higher pressure and resumed measurement. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing ‘Start’.

The LCD panel showed pressure measurements, pulse rate, time and date. There were three display icons for pulse, irregular heartbeat and stored measurement status. A three segment battery gauge indicated the remaining battery capacity. It also gave an indication of the reading's classification* as defined in the BHS Guidelines [1].

The device had to be turned off then on again before each new measurement; otherwise it powered down automatically after one minute with the time and battery gauge remaining on the display. Ninety measurements could be stored. These were stored with the time of day assigned, so that the average for morning or evening measurements could be determined. Stored measurements were reviewed by pressing the memory control; the morning or evening average could be viewed by pressing the ‘AM’ or ‘PM’ button immediately after the memory button.

Summary

Validation

The manufacturer claimed (in the user manual) that the NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. However, no evidence was provided nor could any published evidence be found to verify this claim.

Good points

Good measurement consistency across a range of blood pressures (SD ± 1.5 mmHg). Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.6 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Gave eleven misleading readings from 25 tests when subjected to varying degrees of tremor artefact.

* A six point scale of risk: optimal, normal, high normal, mild hypertension, moderate hypertension, severe hypertension

CEP 08035: September 2008
Results

NIBP performance tests

- pressure and pulse rate ranges: acceptable
- measurement consistency
  - fixed 120/80 mmHg: excellent, SD ± 0.6 mmHg
  - variable pressure: good, SD ± 1.5 mmHg
  - variable pulse rate: satisfactory, SD ± 2.5 mmHg
- susceptibility to artefact: 11 misleading readings from 25 tests
- variable pulse strength: gave no misleading readings

General
- usability: good

Manuals
- user manual: good

Construction
- mechanical: excellent
- electrical: excellent
- CE marking: CE0366

Technical discussion

Construction

The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic and designed to sit on the desktop with the cuff stored behind the display.

Inside the case was a circuit board and pneumatic circuit. The circuit board included the pressure transducer and was populated with surface mounted components. The pneumatic circuit connected to the pressure transducer included a pump, an electronically controlled pressure release valve and orifice for a fixed rate of release of cuff pressure.

Power supply

The device was powered by four 1.5 V AA batteries. However, it had the option of being powered from the mains via an AC adaptor, which could be purchased separately.

Serviceability

The user manual stated that the device should be inspected every 2 years by the manufacturer or an authorised repair service to check its functionality and accuracy.
Lloyds Pharmacy KD-525

Brief description

The Lloyds Pharmacy KD-525 was a blood pressure monitor which inflated the cuff by a motorised air pump. It had two controls; power on/off and 'Start'.

After pressing 'Start', the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing 'Start'.

The device had four pre-programmed initial inflation pressures; 187, 225, 263 and 300 mmHg. It inflated to 187 mmHg first but if this was below systolic pressure would inflate to the next highest on re-test.

The LCD panel showed pressure measurements and pulse rate. There were four display icons that indicated: ▲ monitor ready to use, ▼ monitor not ready to use, measurement in progress and low battery.

The device automatically powered down three minutes after the last measurement. No previous measurements were stored.

Summary

Validation
The manufacturer made no claims of clinical validation.

Good points
Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.7 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages
Very poor measurement consistency across a range of blood pressure (SD ± 8.1 mmHg). Very poor measurement consistency across a range of pulse rates (SD ± 37.8 mmHg). Gave eight misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Market review

Results

NIBP performance tests

• pressure and pulse rate ranges acceptable
• measurement consistency
  o fixed 120/80 mmHg† excellent, SD ± 0.7 mmHg
  o variable pressure‡ very poor, SD ± 8.1 mmHg
  o variable pulse rate‡ very poor, SD ± 37.8 mmHg
• susceptibility to artefact 8 misleading readings from 25 test
• variable pulse strength gave no misleading readings

General

• usability satisfactory

Manuals

• user manual satisfactory

Construction

• mechanical satisfactory
• electrical satisfactory
• CE marking CE_0123

† 30 measurements ‡ 5 measurements

Technical discussion

Construction

The monitor was supplied with a 22–30 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic.

Inside the case were two circuit boards and pneumatic circuit. There was a main circuit board that included the pressure transducer and another circuit on which the control buttons were mounted. Both were populated with surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply

The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V 600 mA DC) could be purchased separately.

Serviceability

The user manual made no recommendation on maintenance or calibration of the device.
Maplin Deluxe Automatic

Brief description

The Maplin Deluxe Automatic was a blood pressure monitor which inflated the cuff by a motorised air pump. After pressing the ‘Start/Stop’ button the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. When complete, the cuff deflated rapidly.

The initial inflation pressure was approximately 170 mmHg, or higher when the subject's systolic pressure was within 30 mmHg of this. Any measurement in progress could be stopped and the cuff deflated by pressing the ‘Start/Stop’ button.

Other controls on the device included a memory button for reviewing stored measurements and mode and set buttons used for setting the time and date.

The LCD panel showed pressure measurements and pulse rate. There were five display icons; they indicated pulse detection, cuff inflating, cuff deflating, low battery and error during measurement.

The device automatically powered down one minute after the last measurement. Up to 30 readings in each of three memory banks (e.g. for three separate subjects) could be stored and reviewed.

Summary

Validation

The manufacturer claimed (in the user manual) that the NIBP performance was clinically validated using the ANSI/AAMI SP10 and DIN 58130 protocols. However, no evidence was provided nor could any published evidence be found to verify this claim.

Good points

Good measurement consistency across a range of pulse rates (SD ± 1.8 mmHg). Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.6 mmHg) and. Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Very poor measurement consistency across a range of blood pressures (SD ± 5.9 mmHg). Gave ten misleading readings from 25 tests when subjected to varying degrees of tremor artefact. Inscriptions on the Start/Stop and memory buttons wore off very easily.
Results

**NIBP performance tests**
- pressure and pulse rate ranges: acceptable
- measurement consistency
  - fixed 120/80 mmHg†: good, SD ± 1.6 mmHg
  - variable pressure‡: very poor, SD ± 5.9 mmHg
  - variable pulse rate‡: good, SD ± 1.8 mmHg
- susceptibility to artefact: 10 misleading readings from 25 test
- variable pulse strength: gave no misleading readings

**General**
- usability: good

**Manuals**
- user manual: satisfactory

**Construction**
- mechanical: poor
- electrical: good
- CE marking: CE0197

† 30 measurements ‡ 5 measurements

Technical discussion

**Construction**
The monitor was supplied with a 24–32 cm reusable adult cuff with hose length of 80 cm. The casing was all plastic with the display angled towards the user. The durability of the legends inscribed on the Start/Stop and memory buttons was very poor.

Inside the case were two circuit boards and pneumatic circuit. There was a main circuit board that included the pressure transducer and another on which the buttons were mounted. Both were populated with surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

**Power supply**
The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V 1 A DC) could be purchased separately.

**Serviceability**
The user manual made no recommendation on maintenance or calibration of the device.
Maplin Manual*

Brief description

The Maplin Manual was a blood pressure monitor which required manual inflation. After switching on the device, the cuff was inflated by an external bulb inflator to the target pressure (approximately 160 mmHg): this was known by watching the increasing pressure and an inflate prompt until a 'beep' tone sounded.

The cuff continuously deflated via a pin-hole in the inflator during which the device measured and displayed the subject's blood pressure. When the measurement was complete a deflate prompt indicated to press the exhaust valve air-release button that was attached to the inflator bulb. If initial inflation pressure was inadequate, the device beeped and the inflate prompt returned indicating to increase the inflation pressure.

There were three other controls: a memory button for reviewing stored measurements and mode and set buttons used for setting the time and date.

The LCD panel showed pressure measurements, pulse rate, time and date. As well as the inflation/deflation prompts there were three display icons; they indicated pulse detection, low battery and an error during measurement.

The device automatically powered down one minute after the measurement. Forty-eight readings could be stored and reviewed.

Summary

Validation

The manufacturer claimed (in the user manual) that the NIBP performance was clinically validated using the ANSI/AAMI SP10 and DIN 58130 protocols. However, no evidence was provided nor could any published evidence be found to verify this claim.

Good points

Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.5mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Poor measurement consistency across a range of pulse rates (SD ± 3.3 mmHg). Gave fourteen misleading readings from 25 tests when subjected to varying degrees of tremor artefact.

*Note: This device has been discontinued.
Market review

Results

**NIBP performance tests**
- pressure and pulse rate ranges: acceptable
- measurement consistency
  - fixed 120/80 mmHg†: good, SD ± 1.5 mmHg
  - variable pressure‡: satisfactory, SD ± 2.1 mmHg
  - variable pulse rate‡: poor, SD ± 3.3 mmHg
- susceptibility to artefact: 14 misleading readings from 25 test
- variable pulse strength: gave no misleading readings

**General**
- usability: satisfactory

**Manuals**
- user manual: satisfactory

**Construction**
- mechanical: poor
- electrical: good
- CE marking: CE0197

† 30 measurements ‡ 5 measurements

Technical discussion

**Construction**
The monitor was supplied with a 24–32 cm reusable with hose length of 80 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a single circuit board populated with surface mounted components and a pressure transducer. The cuff pressure was released by a manually operated valve on the bulb inflator.

**Power supply**
The device was powered by four 1.5 V AA batteries.

**Serviceability**
The user manual made no recommendation on maintenance or calibration of the device.
Market review

Mars MS-752

Brief description

The Mars Vital Vision MS-752 was a blood pressure monitor which inflated the cuff by a motorised air pump. After pressing the 'Start/Stop' button the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. When complete, the cuff deflated rapidly.

The initial inflation pressure was approximately 170 mmHg, or higher when the subject's systolic pressure was within 30 mmHg of this. Any measurement in progress could be stopped and the cuff deflated by pressing the 'Start/Stop' button.

Other controls on the device included a memory button for reviewing stored measurements and mode and adjust buttons used for setting the time and date.

The LCD panel showed pressure measurements, pulse rate, time and date. There were three display icons; they indicated pulse detection, cuff deflating and low battery.

The device automatically powered down three minutes after the last measurement. Sixty-four readings and their average could be stored and reviewed.

The top of the device opened up to allow the cuff to be stored inside the casing.

Summary

Validation
The manufacturer made no claims of clinical validation.

Good points
Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.3 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages
Failed to measure blood pressure of 255/195 mmHg. Gave two misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
## Results

### NIBP performance tests

- **pressure and pulse rate ranges**
  - pressure range unacceptable: failed to measure 255/190 mmHg setting
  - pulse rate acceptable

- **measurement consistency**
  - fixed 120/80 mmHg†
    - good, SD ± 1.3 mmHg
  - variable pressure‡
    - satisfactory over the range which could be measured, SD ± 2.5 mmHg
  - variable pulse rate‡
    - satisfactory, SD ± 2.9 mmHg

- **susceptibility to artefact**
  - 2 misleading readings from 25 test

- **variable pulse strength**
  - gave no misleading readings

### General

- **usability**
  - satisfactory

### Manuals

- **user manual**
  - satisfactory

### Construction

- **mechanical**
  - good

- **electrical**
  - good

- **CE marking**
  - CE0044

† 30 measurements  ‡ 5 measurements

### Technical discussion

#### Construction

The monitor was supplied with a 22–33 cm reusable adult cuff with hose length of 55 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatic circuit. The circuit board was populated with surface mounted components and pressure transducer. The pressure transducer was connected to the pneumatic circuit, this included a pump and an electro-mechanical valve for releasing cuff pressure.

#### Power supply

The device was powered by four 1.5 V AA batteries.

#### Serviceability

The user manual made no recommendation on maintenance or calibration of the device, however, the device had a calibration mode.
Mars MS-1200*

Brief description

The Mars Vital Vision MS-1200 was a blood pressure monitor which inflated the cuff by a motorised air pump. After pressing the 'Start/Stop' button the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the 'Start/Stop' button.

The initial inflation pressure was approximately 170 mmHg, or higher when the subject's systolic pressure was within 30 mmHg of this.

Any measurement in progress could be stopped and the cuff deflated by pressing the 'Start/Stop' button. Other controls on the device included a memory button for reviewing stored measurements and mode and adjust buttons used for setting the time and date.

The LCD panel showed pressure measurements, pulse rate, time and date. There were three display icons; they indicated pulse detection, cuff deflating and low battery. An eight-segment bar gave an indication of "arterial stiffness".

The device automatically powered down three minutes after the last measurement. Sixty-four readings and their average could be stored and reviewed.

The top of the device opened up to allow the cuff to be stored inside the casing.

Summary

Validation
The manufacturer made no claims of clinical validation.

Good points
Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.3mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages
Failed to measure blood pressure of 255/195 mmHg and very poor measurement consistency (SD ± 36 mmHg) across the range of blood pressures it measured successfully. Very poor consistency across a range of pulse rates (SD ± 27.8 mmHg). Gave three misleading readings from 25 tests when subjected to varying degrees of tremor artefact.

*Note: This device has been discontinued.
Results

NIBP performance tests
- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 255/190 mmHg setting
  - pulse rate acceptable
- measurement consistency
  - fixed 120/80 mmHg†
    - good, SD ± 1.3 mmHg
  - variable pressure‡
    - very poor over the range which could be measured, SD ± 36.0 mmHg
  - variable pulse rate‡
    - very poor, SD ± 27.8 mmHg
- susceptibility to artefact
  - 3 misleading readings from 25 test
- variable pulse strength
  - gave no misleading readings

General
- usability
  - satisfactory

Manuals
- user manual
  - poor

Construction
- mechanical
  - good
- electrical
  - good
- CE marking
  - CE0044

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 22–33 cm reusable adult cuff with hose length of 55 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatic circuit. The circuit board was populated with surface mounted components and pressure transducer. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V DC) could be purchased separately.

Serviceability
The user manual made no recommendation on maintenance or calibration of the device, however, the device had a calibration mode.
Medel Check

Brief description

The Medel Check was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on and pressing the large on/off button, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject's expected systolic pressure. When the measurement was complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements and pulse rate. There were four display icons; they indicated pulse detection, cuff inflating, memory and low battery.

The device automatically powered down three minutes after making a measurement. Only the last measurement was stored.

The device had two operation modes: single and average. Single mode took one measurement and average mode took three at 15 second intervals.

Summary

Validation

The NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol and also the British Hypertension Society (BHS), under which it was graded A/A. It included validation for use during pregnancy. Both validations were supported by peer reviewed publications [31,32].

Good points

Excellent measurement consistency across a range of blood pressures (SD ± 0.8 mmHg) and at a fixed pressure of 120/80 mmHg (SD ± 0.7 mmHg). Good measurement consistency across a range of pulse rates (SD ± 1.5 mmHg). Validated for use during pregnancy.

Disadvantages

Gave six misleading readings from 25 tests when subjected to varying degrees of tremor artefact. Gave one misleading reading from 20 tests when subjected to low pulse strengths.
Results

**NIBP performance tests**
- pressure and pulse rate ranges: acceptable
- measurement consistency:
  - fixed 120/80 mmHg: excellent, SD ± 0.7 mmHg
  - variable pressure: excellent, SD ± 0.8 mmHg
  - variable pulse rate: good, SD ± 1.5 mmHg
- susceptibility to artefact: 6 misleading readings from 25 tests
- variable pulse strength: 1 misleading reading from 20 tests

**General**
- usability: good

**Manuals**
- user manual: satisfactory

**Construction**
- mechanical: good
- electrical: good
- CE marking: CE0123

† 30 measurements ‡ 5 measurements

Technical discussion

**Construction**

The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 72 cm. The casing was all plastic with the display housed in a flip up lid.

Inside the case was a circuit board and pneumatic circuit. The circuit board was populated with surface mounted components and a pressure transducer. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

**Power supply**

The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V 600 mA DC) could be purchased separately.

**Serviceability**

The user manual stated that there were no user-serviceable parts and it required no lubrication or maintenance. It did recommend that the static pressure display should be checked every 2 years.
Medel Fuzzy

Brief description

The Medel Fuzzy was a blood pressure monitor which inflated the cuff by a motorised air pump. It had a single large on/off control button.

After switching on and pressing the button, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject's expected systolic pressure. When the measurement was complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements and pulse rate. There were four display icons; they indicated pulse detection, cuff inflating, memory and low battery.

The device automatically powered down three minutes after making a measurement. Only the last measurement was stored.

Summary

Validation

The NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol and also the British Hypertension Society (BHS), under which it was graded A/A. It included validation for use during pregnancy. Both validations were supported by peer reviewed publications [31,32].

Good points

Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.6 mmHg). Gave no misleading readings when subjected to low pulse strengths. Validated for use during pregnancy.

Disadvantages

Poor measurement consistency across a range of blood pressures (SD ± 3.2 mmHg). Gave six misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests
- pressure and pulse rate ranges acceptable
- measurement consistency
  - fixed 120/80 mmHg† excellent, SD ± 0.6 mmHg
  - variable pressure‡ poor, SD ± 3.2 mmHg
  - variable pulse rate‡ satisfactory, SD ± 2.7 mmHg
- susceptibility to artefact 6 misleading readings from 25 tests
- variable pulse strength gave no misleading readings

General
- usability good

Manuals
- user manual satisfactory

Construction
- mechanical good
- electrical good
- CE marking CE0123

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 70 cm. The casing was all plastic with the display housed in a flip up lid.

Inside the case was a circuit board and pneumatic circuit. The circuit board was populated with surface mounted components and a pressure transducer. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V 600 mA DC) could be purchased separately.

Serviceability
The user manual stated that there were no user-serviceable parts and it required no lubrication or maintenance. It did recommend that the static pressure display should be checked every 2 years.
Medisana MTA

Brief description

The Medisana MTA was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on and pressing the on/off button, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject's expected systolic pressure. When the measurement was complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements, pulse rate, time and date. There were four display icons; they indicated pulse detection, memory indicator, memory number and low battery.

The device automatically powered down three minutes after making a measurement. Sixty readings could be stored and reviewed using the memory recall control.

Summary

Validation

The manufacturer claimed (in the user manual) that the NIBP performance was clinically tested but no protocols were identified. No evidence was provided nor could any published evidence be found to verify this claim.

Good points

Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.3 mmHg).

Disadvantages

Failed to measure blood pressure of 60/30 mmHg and poor measurement consistency (SD ± 3.6 mmHg) across the range of blood pressures it measured successfully. Very poor measurement consistency across a range of pulse rates (SD ± 4.4 mmHg). Gave one misleading reading from 25 tests when subjected to varying degrees of tremor artefact. Gave one misleading reading from 20 tests when subjected to low pulse strengths.
Results

NIBP performance tests
- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 60/30 mmHg setting
  - pulse range acceptable
- measurement consistency
  - fixed 120/80 mmHg†
    - good, SD ± 1.3 mmHg
  - variable pressure‡
    - poor over the range which could be measured, SD ± 3.6 mmHg
  - variable pulse rate‡
    - very poor, SD ± 4.4 mmHg
- susceptibility to artefact
  - 1 misleading reading from 25 tests
- variable pulse strength
  - 1 misleading reading from 20 tests

General
- usability
  - satisfactory

Manuals
- user manual
  - satisfactory

Construction
- mechanical
  - satisfactory
- electrical
  - satisfactory
- CE marking
  - CE0297

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 24–36 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic and circular with the display angled towards the user.

Inside the case were boards and pneumatic circuit. The circuit boards included a main board with the pressure transducer and another on which the buttons were mounted. Both were populated with surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V DC) could be purchased separately.

Serviceability
The user manual stated that service should only be undertaken by authorised service personnel. It recommended that the device should be calibrated every 2 years via an authorised supplier.
Medisana MTM

Brief description

The Medisana MTM was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on and pressing the on/off button, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject's expected systolic pressure. When the measurement was complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The device could be set to give an average reading based on three successive measurements at 15 second intervals. There were two memory stores allowing use by two individuals.

The backlit LCD panel showed pressure measurements, pulse rate, time and date. There were also display icons that indicated pulse detection, memory number, user 1 or 2, stored measurement type (i.e. single or average), average mode measurement data and low battery.

The device had a USB interface and cable to allow measurement data to be transferred to a PC using included software (supplied on CD).

The device automatically powered down three minutes after making a measurement. Ninety-nine measurements for each of two users could be stored and reviewed using the memory recall control.

Summary

This device was very similar in functionality to the MTP device with the addition of USB connectivity and related software, three-measurement averaging and the LCD was backlit.

Validation

The manufacturer claimed (in the user manual) that the NIBP performance was clinically validated using the ANSI/AAMI SP10 and DIN 58130 protocols. However, no evidence was provided nor could any published evidence be found to verify this claim.

Good points

Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.8 mmHg) and across a range of blood pressures (SD ± 0.8 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Gave six misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NiBP performance tests

- pressure and pulse rate ranges  acceptable, though failed to measure at pulse rate of 40 bpm for 2 of 5 attempts
- measurement consistency
  - fixed 120/80 mmHg† excellent, SD ± 0.8 mmHg
  - variable pressure‡ excellent, SD ± 0.8 mmHg
  - variable pulse rate‡ satisfactory, SD ± 2.9 mmHg
- susceptibility to artefact  6 misleading readings from 25 tests
- variable pulse strength  gave no misleading readings

General

- usability  satisfactory

Manuals

- user manual  satisfactory

Construction

- mechanical  good
- electrical  good
- CE marking  CE0297

† 30 measurements ‡ 5 measurements

Technical discussion

Construction

The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 70 cm. The casing was all plastic with the display angled towards the user.

Inside the case were two circuit boards and pneumatic circuit. The circuit boards included a main board with the pressure transducer, a USB connector board. Both were populated with surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply

The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V DC) could be purchased separately.

Serviceability

The user manual stated that service should only be undertaken by authorised service personnel. It recommended that the device should be calibrated every 2 years via an authorised supplier.
Medisana MTP

Brief description

The Medisana MTP was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on and pressing the on/off button, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject's expected systolic pressure. When the measurement was complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The timer and memory controls were used to change user and adjust the time and date.

The LCD panel showed pressure measurements, pulse rate, time and date. There were also display icons that indicated pulse detection, memory number, user 1 or 2, and low battery.

The device automatically powered down three minutes after making a measurement. Ninety-nine measurements on each of two subjects could be stored and reviewed using the memory recall control.

Summary

This device was very similar in functionality to the MTM device but without: USB connectivity, software, three-measurement averaging and the LCD was not backlit.

Validation

The manufacturer claimed (in the user manual) that the NIBP performance was clinically validated using the ANSI/AAMI SP10 and DIN 58130 protocols. However, no evidence was provided nor could any published evidence be found to verify this claim.

Good points

Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.7 mmHg).

Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Very poor measurement consistency across a range of pulse rates (SD ± 6.9 mmHg). Gave seven misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests

- pressure and pulse rate ranges: acceptable, though failed to measure at pulse rate of 40 bpm for 1 of 5 attempts
- measurement consistency
  - fixed 120/80 mmHg\(^\dagger\): excellent, SD ± 0.7 mmHg
  - variable pressure\(^\ddagger\): satisfactory, SD ± 2.5 mmHg
  - variable pulse rate\(^\ddagger\): very poor, SD ± 6.9 mmHg
- susceptibility to artefact: 7 misleading readings from 25 tests
- variable pulse strength: gave no misleading readings

General

- usability: good

Manuals

- user manual: satisfactory

Construction

- mechanical: good
- electrical: good
- CE marking: CE\(_{0297}\)

\(^\dagger\) 30 measurements  \(^\ddagger\) 5 measurements

Technical discussion

Construction

The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 70 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatic circuit. The circuit board was populated with surface mounted components and the pressure transducer. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply

The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V DC) adaptor could be purchased separately.

Serviceability

The user manual stated that service should only be undertaken by authorised service personnel. It recommended that the device should be calibrated every 2 years via an authorised supplier.
Microlife as easy as 123

Brief description

The Microlife ‘as easy as 123’ was a blood pressure monitor which inflated the cuff by a motorised air pump. Its only control was an on/off button labelled O/I Memory.

After switching on and pressing O/I Memory, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject’s expected systolic pressure. When the measurement was complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing O/I Memory.

The LCD panel showed pressure measurements and pulse rate.

There were four display icons; they indicated pulse detection, memory indicator, cuff inflating and low battery.

The device powered down automatically five minutes after making a measurement. To make a fresh measurement, it was necessary to switch the monitor off and begin anew. The last measurement could be recalled by pressing and holding the button for three seconds.

Summary

Validation

The NIBP performance was clinically validated using the protocols of ANSI/AAMI SP10, the European Society of Hypertension (ESH) and the British Hypertension Society (BHS) under which it was graded A/A and included validation for use during pregnancy. This was supported by peer reviewed publications [31,32,33].

Good points

Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.7 mmHg)
Gave no misleading readings when subjected to low pulse strengths. Validated for use during pregnancy.

Disadvantages

Very poor measurement consistency across a range of pulse rates (SD ± 40.7 mmHg). Gave eight misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

**NIBP performance tests**
- pressure and pulse rate ranges: acceptable
- measurement consistency:
  - fixed 120/80 mmHg\(^\dagger\): excellent, SD ± 0.7 mmHg
  - variable pressure\(^\ddagger\): satisfactory, SD ± 2.5 mmHg
  - variable pulse rate\(^\ddagger\): very poor, SD ± 40.7 mmHg
- susceptibility to artefact: 8 misleading readings from 25 tests
- variable pulse strength: gave no misleading readings

**General**
- usability: satisfactory

**Manuals**
- user manual: satisfactory

**Construction**
- mechanical: good
- electrical: satisfactory
- CE marking: CE\(_{0044}\)

† 30 measurements ‡ 5 measurements

Technical discussion

**Construction**
The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 70 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatic circuit. The circuit board was populated with discrete un-miniaturised components, surface mounted IC and pressure transducer. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

**Power supply**
The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V 600 mA DC) could be purchased separately.

**Serviceability**
The user manual recommended that the device be inspected every 2 years by the supplier.
Microlife BPA100

Brief description

The Microlife BPA100 was a blood pressure monitor which inflated the cuff by a motorised air pump. Its only control was an on/off button.

After switching on and pressing the button, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject's expected systolic pressure. When the measurement was complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements and pulse rate. There were four display icons; they indicated pulse detection, memory indicator, cuff inflating and low battery.

Alongside the LCD was a slot for displaying patient guidance cards, e.g. the manufacturer provided blood pressure classification* information as defined in the BHS Guidelines [1].

The device powered down automatically one minute after making a measurement. To make a fresh measurement, it was necessary to switch the monitor off and begin anew. The last measurement could be recalled by pressing and holding the button for a few seconds.

Summary

Validation

The NIBP performance was clinically validated using the protocols of ANSI/AAMI SP10, the European Society of Hypertension (ESH) and the British Hypertension Society (BHS) under which it was graded A/A and included validation for use during pregnancy. This was supported by peer reviewed publications [30,31,32].

Good points

Excellent measurement consistency across a range of blood pressures (SD ± 0.9 mmHg) and at a fixed pressure of 120/80 mmHg (SD ± 0.8 mmHg). Gave no misleading readings when subjected to low pulse strengths. Validated for use during pregnancy.

Disadvantages

Gave ten misleading readings from 25 tests when subjected to varying degrees of tremor artefact.

* A six point scale of risk: optimal, normal, high normal, mild hypertension, moderate hypertension, severe hypertension.

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Results

NIBP performance tests
- pressure and pulse rate ranges acceptable
- measurement consistency
  - fixed 120/80 mmHg† excellent, SD ± 0.8 mmHg
  - variable pressure‡ excellent, SD ± 0.9 mmHg
  - variable pulse rate‡ satisfactory, SD ± 2.4 mmHg
- susceptibility to artefact 10 misleading readings from 25 tests
- variable pulse strength gave no misleading readings

General
- usability satisfactory

Manuals
- user manual good

Construction
- mechanical good
- electrical satisfactory
- CE marking CE0044
† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 70 cm. The casing was all plastic with the display angled towards the user and had a moulded cuff holder.

Inside the case were two circuit boards and a pneumatic circuit. There was a main circuit board and a transducer circuit board, both populated with surface mount components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V 600 mA DC) could be purchased separately.

Serviceability
The user manual recommended that the device be tested by Microlife Service and should be accuracy tested every 2 years.
Microlife BP 3AC1-1

Brief description

The Microlife BP 3AC1-1 was a blood pressure monitor which inflated the cuff by a motorised air pump. The device had the option of being used by two different users and had two modes of operation: single measurement and three measurement average.

After switching on and pressing the 'Start' button, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject's expected systolic pressure. When the measurement was complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements, pulse rate, time and date. There were six display icons; they indicated pulse detection, user 1 or 2, averaging mode, memory recall, memory number and low battery. The device automatically powered down five minutes after making a measurement. Thirty readings could be stored and recalled for each of two users.

Measurements could be printed by connecting a small diagnostic printer (PR 1KA1), which could be purchased separately.

There was an alternative version of the monitor that included a PC connection so that measurements could be downloaded (with appropriate software), analysed and printed.

Summary

Validation

The NIBP performance was clinically validated using the European Society of Hypertension (ESH) protocol. This was supported by a peer reviewed publication [33].

Good points

Good measurement consistency across a range of blood pressures (SD ± 1.1 mmHg).
Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.8 mmHg).
Gave no misleading readings when subjected to low pulse strengths. Validated for use during pregnancy.

Disadvantages

Gave eight misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

**NIBP performance tests**
- pressure and pulse rate ranges: acceptable
- measurement consistency
  - fixed 120/80 mmHg\(^\dagger\) excellent, SD ± 0.8 mmHg
  - variable pressure\(^\ddagger\) good, SD ± 1.1 mmHg
  - variable pulse rate\(^\ddagger\) satisfactory, SD ± 2.3 mmHg
- susceptibility to artefact: 8 misleading readings from 25 tests
- variable pulse strength: gave no misleading readings

**General**
- usability: satisfactory

**Manuals**
- user manual: satisfactory

**Construction**
- mechanical: good
- electrical: good
- CE marking: CE\(0044\)

\(\dagger\) 30 measurements \(\ddagger\) 5 measurements

Technical discussion

**Construction**

The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 70 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a pneumatic circuit and two circuit boards; the main board, including the pressure transducer and a printer connector board. Both were populated with surface mount components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

**Power supply**

The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V 600mA DC) was available which could be purchased separately.

**Serviceability**

The user manual recommended that the device be tested by an authorised Microlife dealer and should be re-calibrated every 2 years.
Microlife BP 3AS1-2

Brief description

The Microlife BP 3AS1-2 was a blood pressure monitor which required manual inflation. Its only control was an on/off switch.

After switching on the device, the cuff was inflated by an external bulb inflator to the target pressure, i.e. 30 to 40 mmHg above expected systolic (if known). If the pressure was insufficient, a prompt indicated to increase the inflation pressure. The cuff continuously deflated via a pin-hole in the inflator during which the device measured the subject's blood pressure. When complete, an air release valve automatically opened to deflate the cuff rapidly.

The LCD panel showed pressure measurements and pulse rate. As well as the prompt, there were three other display icons; they indicated pulse detection, memory recall and low battery warning.

The device had to be turned off then on again before each new measurement; otherwise it powered down automatically after one minute. The last measurement could be recalled by pressing and holding the button for a few seconds.

Summary

Validation
The manufacturer made no claims of clinical validation.

Good points
Good measurement consistency across a range of blood pressures (SD ± 1.1 mmHg). Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.8 mmHg). Gave no misleading readings when subjected to low pulse strengths. Good measurement consistency across a range of pulse rates (SD ± 1.1 mmHg).

Disadvantages
Gave seven misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests

- pressure and pulse rate ranges: acceptable
- measurement consistency
  - fixed 120/80 mmHg†: excellent, SD ± 0.8 mmHg
  - variable pressure‡: good, SD ± 1.1 mmHg
  - variable pulse rate‡: good, SD ± 1.1 mmHg
- susceptibility to artefact: 7 misleading readings from 25 tests
- variable pulse strength: gave no misleading readings

General

- usability: good

Manuals

- user manual: satisfactory

Construction

- mechanical: good
- electrical: good
- CE marking: CE0044

† 30 measurements ‡ 5 measurements

Technical discussion

Construction

The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 75 cm. The all plastic casing was shaped for one-handed operation.

Inside the case were two circuit boards, one for the LCD and one for the pressure transducer. Both were populated with surface mount components.

Power supply

The device was powered by two 1.5 V AAA batteries.

Serviceability

The user manual recommended that the device be tested by a specialist dealer and should be re-calibrated every 2 years.
Microlife 3BTO-A(2)

Brief description

The Microlife 3BTO-A(2) was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on and pressing the on/off button, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject’s expected systolic pressure. When the measurement was complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

This device was marketed for use by women during pregnancy and was clinically validated for this [32]. A baby thermometer was included.

The LCD panel showed pressure measurements, pulse rate, time and date. There were four display icons; they indicate pulse detection, memory recall memory and low battery.

The device automatically powered down three minutes after making a measurement. Thirty measurements could be stored and recalled.

Summary

Validation

The NIBP performance was clinically validated using the protocols of ANSI/AAMI SP10, the European Society of Hypertension (ESH) and the British Hypertension Society (BHS) under which it was graded A/A and included validation for use during pregnancy. This was supported by peer reviewed publications [30,31,32].

Good points

Good measurement consistency across a range of blood pressures (SD ± 1.3 mmHg).
Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.7 mmHg).
Gave no misleading readings when subjected to low pulse strengths. Validated for use during pregnancy. Two cuff sizes supplied.

Disadvantages

Poor measurement consistency across a range of pulse rates (SD ± 4.0 mmHg). Gave six misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests
- pressure and pulse rate ranges acceptable, though failed to measure at pulse rate of 40 bpm for 1 of 5 attempts
- measurement consistency
  - fixed 120/80 mmHg† excellent, SD ± 0.7 mmHg
  - variable pressure‡ good, SD ± 1.3 mmHg
  - variable pulse rate§ poor, SD ± 4.0 mmHg
- susceptibility to artefact 6 misleading readings from 25 tests
- variable pulse strength gave no misleading readings

General
- usability satisfactory

Manuals
- user manual satisfactory

Construction
- mechanical good
- electrical satisfactory
- CE marking CE0044

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 22–32 cm and 32–42 cm reusable adult cuff, both with hose lengths of 75 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatics circuit. The board was populated with the pressure transducer, discrete un-miniaturised components and a surface-mount IC. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V 600mA DC) was available which could be purchased separately.

Serviceability
The user manual recommended that the device be tested by a Microlife dealer and should be re-calibrated every 2 years.
Nissei DS-400

Brief description

The Nissei DS-400 was a blood pressure monitor which required manual inflation. It had an on/off control labelled 'Start' and a memory recall button.

After switching on the device, the cuff was inflated using an external bulb inflator. An inflate prompt $\uparrow$ was displayed until the device beeped to indicate that its initial target pressure of 180 mmHg was reached. If this cuff pressure was not high enough to make a measurement, the inflate prompt returned. The cuff continuously deflated via a pin-hole in the inflator during which the device measured and displayed the subject's blood pressure. When the measurement was complete a $\downarrow$ prompt indicated to press the exhaust valve air-release switch that was attached to the inflator bulb.

The LCD panel showed pressure measurements and pulse rate. As well as the inflate/deflate prompts there were two other icons that indicated pulse detection and low battery.

The device automatically powered down three minutes after making a measurement. Thirty measurements could be stored and recalled.

Summary

Validation

The manufacturer made no claims of clinical validation.

Good points

Excellent measurement consistency across a range of blood pressures (SD $\pm$ 0.9 mmHg), at a fixed pressure of 120/80 mmHg (SD $\pm$ 0.8 mmHg) and across a range of pulse rates (SD $\pm$ 0.7 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Gave twelve misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests
- pressure and pulse rate ranges acceptable
- measurement consistency
  - fixed 120/80 mmHg† excellent, SD ± 0.8 mmHg
  - variable pressure‡ excellent, SD ± 0.9 mmHg
  - variable pulse rate† excellent, SD ± 0.7 mmHg
- susceptibility to artefact 12 misleading readings from 25 tests
- variable pulse strength gave no misleading readings

General
- usability good

Manuals
- user manual satisfactory

Construction
- mechanical good
- electrical good
- CE marking CE0123

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic.

Inside the case was a single circuit board populated with a surface mount components and the pressure transducer.

Power supply
The device was powered by a single 1.5 V AA battery.

Serviceability
The user manual recommended that the device be checked every 2 years by the manufacturer or a firm authorised by the manufacturer.
Nissei DS-1873

Brief description

The Nissei DS-1873 was a blood pressure monitor which inflated the cuff by a motorised air pump.

After pressing the start/stop button (labelled O/I) the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The initial inflation pressure was approximately 170 mmHg, or higher when the subject's systolic pressure was within 30 mmHg of this.

Other controls on the device included a two memory buttons for reviewing stored measurements. The LCD panel showed pressure measurements, pulse rate and time. There were four display icons; they indicated pulse detection, cuff inflating/deflating and low battery.

The device automatically powered down three minutes after making a measurement. Up to thirty readings in each of two memory banks (e.g. for two separate subjects) could be stored and reviewed.

Summary

Validation

The manufacturer made no claims of clinical validation.

Good points

Good measurement consistency across a range of blood pressures (SD ± 1.1 mmHg). Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.9 mmHg). Good measurement consistency across a range of pulse rates (SD ± 1.1 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Gave fifteen misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests

- pressure and pulse rate ranges 
  acceptable
- measurement consistency
  - fixed 120/80 mmHg†
    excellent, SD ± 0.9 mmHg
  - variable pressure‡
    good, SD ± 1.1 mmHg
  - variable pulse rate‡
    good, SD ± 1.1 mmHg
- susceptibility to artefact
  15 misleading readings from 25 tests
- variable pulse strength
  gave no misleading readings

General

- usability 
  good

Manuals

- user manual 
  satisfactory

Construction

- mechanical 
  good
- electrical 
  good
- CE marking 
  CE_0123

† 30 measurements ‡ 5 measurements

Technical discussion

Construction

The monitor was supplied with a 22–32 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic with the display angled towards the user and a moulded cuff holder.

Inside the case was a circuit board and pneumatics circuit. The board was populated with the pressure transducer and surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply

The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V 600mA DC) was available which could be purchased separately.

Serviceability

The user manual recommended that the device be checked every 2 years by the manufacturer or a firm authorised by the manufacturer.
Nissei DS-1902

Brief description

The Nissei DS-1902 was a blood pressure monitor which inflated the cuff by a motorised air pump.

After pressing the start/stop button (labelled O/I) the device did a brief self-test, before inflating the cuff to approximately 60 mmHg. It then increased pressure gradually while measuring the subject's blood pressure. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements, pulse rate and time. There were five display icons; they indicated pulse detection, irregular heart beat/motion, memory in use, cuff inflating/deflating and battery replacement.

The device automatically powered down three minutes after making a measurement. Up to thirty readings in each of two memory banks (e.g. for two separate subjects) could be stored and reviewed.

Summary

Measurement during inflation is a technique used by a minority of devices. It has the advantage of subjecting the patient to lower cuff pressures during the measurement.

Validation

The NIBP performance was clinically validated using the DIN 58130 protocol. This was supported by an unpublished independent report supplied by the manufacturer.

Good points

Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Failed to measure a full range of pressures including 200/150 mmHg and 255/195 mmHg and poor measurement consistency (SD ± 3.2 mmHg) across the range of pressures it measured successfully. Gave three misleading readings from 25 tests when subjected to varying degrees of tremor artefact. Failed to measure for 4 out 5 attempts at a pulse rate of 40 bpm, though good measurement consistency over the remainder of the range.
Results

NIBP performance tests
- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 200/150 mmHg and 255/195 mmHg settings
  - pulse range unacceptable: failed to measure at pulse rate of 40 bpm for 4 of 5 attempts
- measurement consistency
  - fixed 120/80 mmHg† satisfactory, SD ± 2.5 mmHg
  - variable pressure‡ poor over the range which could be measured, SD ± 3.2 mmHg
  - variable pulse rate‡ good over the range which could be measured, SD ± 1.6 mmHg
- susceptibility to artefact
  - 3 misleading readings from 25 tests
- variable pulse strength
  - gave no misleading readings

General
- usability good

Manuals
- user manual satisfactory

Construction
- mechanical good
- electrical good
- CE marking CE0123

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 23–43 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic.

Inside the case was a circuit board and pneumatics circuit. The board was populated with the pressure transducer and surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V 600mA DC) was available which could be purchased separately.

Serviceability
The user manual recommended that the device be checked every 2 years by the manufacturer or a firm authorised by the manufacturer.
Omron M1 Classic

Brief description
The Omron M1 Classic was a blood pressure monitor which required manual inflation.

After switching on the device (O/I button), the cuff was inflated by an external bulb inflator to the target pressure (initially 180 mmHg). The cuff continuously deflated via a pin-hole in the inflator during which the device measured the subject's blood pressure.

If initial inflation pressure was inadequate, no reading was displayed—instead, a ▲ prompt indicated to increase the inflation pressure. When the measurement was complete, a ▼ prompt indicated to press the exhaust valve air-release button that was attached to the inflator bulb.

The LCD panel showed pressure measurements, pulse rate, time and date. There were five display icons; they indicated pulse detection, release cuff pressure, increase cuff pressure, memory recall status and low battery.

The device automatically powered down five minutes after making a measurement. Up to fourteen readings could be stored and reviewed by pressing button labelled 'M'.

Summary

Validation
The manufacturer made no claims of clinical validation.

Good points
Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.7 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages
Failed to measure a full range of pressures including 200/150 mmHg and 255/195 mmHg. Very poor measurement consistency across a range of pulse rates (SD ± 6.1 mmHg). Gave four misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests

- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 200/150 mmHg and 255/195 mmHg settings
  - pulse range acceptable

- measurement consistency
  - fixed 120/80 mmHg†
    - excellent, SD ± 0.7 mmHg
  - variable pressure‡
    - excellent over the range which could be measured, SD ± 0.7 mmHg
  - variable pulse rate‡
    - very poor, SD ± 6.1 mmHg

- susceptibility to artefact
  - 4 misleading readings from 25 tests

- variable pulse strength
  - gave no misleading readings

General

- usability
  - satisfactory

Manuals

- user manual
  - satisfactory

Construction

- mechanical
  - satisfactory
- electrical
  - satisfactory
- CE marking
  - CE0197

† 30 measurements ‡ 5 measurements

Technical discussion

Construction

The monitor was supplied with a 23–32 cm reusable adult cuff with hose length of 1 m. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board, which was populated with the pressure transducer and surface mounted components.

Power supply

The device was powered by four 1.5 V AA batteries, with the capacity from new of providing approximately 1000 measurements.

Serviceability

The user manual stated that the device was considered a non-serviceable part.
Omron M3

Brief description

The Omron M3 was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on and pressing the combined on/off and 'Start' button, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject's expected systolic pressure. Alternatively, by pressing and holding 'Start', higher pressures could be obtained. When the measurement was complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements, pulse rate, time and date. There were six display icons; they indicated pulse detection, irregular heart beat, cuff deflating, memory recall, average value, speaker and low battery.

The device automatically powered down five minutes after making a measurement. Forty-two measurements could be stored and recalled using the 'Memory' button.

Summary

Validation
The manufacturer made no claims of clinical validation.

Good points
Excellent measurement consistency across a range of blood pressures (SD ± 0.8 mmHg) and at a fixed pressure of 120/80 mmHg (SD ± 0.5 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages
Very poor measurement consistency across a range of pulse rates (SD ± 3.2 mmHg). Gave two misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Market review

Results

NIBP performance tests
- pressure and pulse rate ranges acceptable
- measurement consistency
  - fixed 120/80 mmHg† excellent, SD ± 0.5 mmHg
  - variable pressure‡ excellent, SD ± 0.8 mmHg
  - variable pulse rate‡ poor, SD ± 3.2 mmHg
- susceptibility to artefact 2 misleading readings from 25 tests
- variable pulse strength gave no misleading readings

General
- usability good

Manuals
- user manual satisfactory

Construction
- mechanical good
- electrical good
- CE marking CE0197

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 23–32 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case were three circuit boards and pneumatics circuit. The main board incorporated the pressure transducer and the other two boards were for controls on the device. All used surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5 V AA alkaline batteries; these were claimed to provide approximately 1500 measurements. An optional mains adaptor (6 V DC) was available which could be purchased separately.

Serviceability
The user manual recommended that the device be inspected every 2 years by an authorised Omron dealer.
Omron M4-I

Brief description

The Omron M4-I was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on the device (O/I button) and pressing the 'Start' button the device did a brief self-test, inflated the cuff then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. If the initial pressure was too low, the device automatically pumped the cuff to a higher pressure and resumed measurement. Alternatively by pressing and holding the 'Start' button, the cuff could be inflated to a higher than normal initial cuff pressure. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements and pulse rate. There were six display icons; they indicated pulse detection, cuff inflating/deflating, memory recall, memory number and low battery.

The device automatically powered down five minutes after making a measurement. Up to 14 readings could be stored and reviewed.

Summary

Validation

The NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol, the European Society of Hypertension (ESH) protocol and the British Hypertension Society (BHS) protocol under which it was graded A/A. It was also validated for use with children. All of these validations were supported by peer reviewed publications [34,35,36].

Good points

Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.6 mmHg). Good measurement consistency across a range of pulse rates (SD ± 1.1 mmHg). Gave no misleading readings when subjected to low pulse strengths or when subjected to varying degrees of tremor artefact.

Disadvantages

Failed to measure a full range of pressures including 200/150 mmHg and 255/195 mmHg.
Market review

Results

NIBP performance tests

- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 200/150 mmHg and 255/195 mmHg settings
  - pulse range acceptable

- measurement consistency
  - fixed 120/80 mmHg†
    - excellent, SD ± 0.6 mmHg
  - variable pressure‡
    - excellent over the range which could be measured, SD ± 0.7 mmHg
  - variable pulse rate‡
    - good, SD ± 1.1 mmHg

- susceptibility to artefact
  - gave no misleading readings

- variable pulse strength
  - gave no misleading readings

General

- usability
  - satisfactory

Manuals

- user manual
  - satisfactory

Construction

- mechanical
  - good

- electrical
  - good

- CE marking
  - CE0197

† 30 measurements ‡ 5 measurements

Technical discussion

Pressure range

In our pressure range tests, the device repeatedly failed to measure blood pressures of 200/150 mmHg and 255/195 mmHg.

Construction

The monitor was supplied with a 23–32 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatics circuit. The board was populated with the pressure transducer and surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply

The device was powered by four 1.5 V AA alkaline batteries; these were claimed to provide approximately 300 measurements. An optional mains adaptor (6 V DC) was available which could be purchased separately.

Serviceability

The user manual stated that the device was considered a non-serviceable part, but recommended calibration every 2 years by an Omron supplier.
Omron M6

Brief description

The Omron M6 was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on and pressing the combined on/off and 'Start' button, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject's expected systolic pressure. Alternatively, by pressing and holding 'Start', higher pressures could be obtained. When the measurement was complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements, pulse rate, time and date. There were six display icons; they indicated pulse detection, irregular heart beat, patient movement, cuff deflating, memory recall, average reading and low battery.

The device automatically powered down five minutes after making a measurement. Up to 90 readings could be stored and reviewed. An average of the last three readings could also be displayed.

Summary

Validation

The NIBP performance was clinically validated using the European Society of Hypertension protocol. This was supported by a peer reviewed publications [37,38].

Good points

Excellent measurement consistency across a range of pulse rates (SD ± 0.9 mmHg) and at a fixed pressure of 120/80 mmHg (SD ± 0.6 mmHg). Good measurement consistency across a range of blood pressures (SD ± 1.3 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Gave one misleading reading from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests

- pressure and pulse rate ranges: acceptable
- measurement consistency
  - fixed 120/80 mmHg\(^\dagger\): excellent, SD ± 0.6 mmHg
  - variable pressure\(^\ddagger\): good, SD ± 1.3 mmHg
  - variable pulse rate\(^\ddagger\): excellent, SD ± 0.9 mmHg
- susceptibility to artefact: 1 misleading reading from 25 tests
- variable pulse strength: gave no misleading readings

General
- usability: good

Manuals
- user manual: satisfactory

Construction
- mechanical: good
- electrical: good
- CE marking: CE\(_{0197}\)

\(\dagger\) 30 measurements \(\ddagger\) 5 measurements

Technical discussion

Construction

The monitor was supplied with a 23–32 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case were three circuit boards and pneumatics circuit. The main board incorporated the pressure transducer and the other two boards were for controls. All used surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply

The device was powered by four 1.5 V AA alkaline batteries; these were claimed to provide approximately 1500 measurements. An optional mains adaptor (6 V DC) was available which could be purchased separately.

Serviceability

The user manual recommended the device be inspected every 2 years by an Omron supplier.
Omron M7

Brief description

The Omron M7 was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on the device (O/I button) and pressing the 'Start' button the device did a brief self-test, inflated the cuff then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject's expected systolic pressure. Alternatively, by pressing and holding 'Start', higher pressures could be obtained. When the measurement was complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements, pulse rate, time and date. There were six display icons; they indicated pulse detection, cuff inflating/deflating, memory recall, average reading and low battery.

The device automatically powered down five minutes after making a measurement. Up to 90 readings could be stored and reviewed. An average of the last three readings could also be displayed.

Summary

Validation

The NIBP performance was clinically validated using the European Society of Hypertension (ESH) protocol. This was supported by unpublished report and a peer reviewed publication [39]. It was also clinically validated using the British Hypertension Society (BHS) protocol, where it achieved the grading A/A. This was supported by a peer reviewed publication [40].

Good points

Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.7 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Failed to measure a full range of pressures including 200/150 mmHg and 255/195 mmHg. Gave one misleading reading from 25 tests when subjected to varying degrees of tremor artefact.
Results

**NIBP performance tests**

- **pressure and pulse rate ranges**
  - pressure range unacceptable: failed to measure 200/150 mmHg and 255/195 mmHg settings
  - pulse range acceptable: though failed to measure at pulse rate of 40 bpm for 1 of 5 attempts and 200 bpm for 2 of 5 attempts

- **measurement consistency**
  - fixed 120/80 mmHg†
    - excellent, SD ± 0.7 mmHg
  - variable pressure‡
    - good over the range which could be measured, SD ± 1.1 mmHg
  - variable pulse rate‡
    - satisfactory, SD ± 2.2 mmHg

- **susceptibility to artefact**
  - 1 misleading reading from 25 tests

- **variable pulse strength**
  - gave no misleading readings

**General**

- **usability**
  - satisfactory

**Manuals**

- **user manual**
  - satisfactory

**Construction**

- **mechanical**
  - satisfactory
- **electrical**
  - satisfactory
- **CE marking**
  - CE0197

† 30 measurements ‡ 5 measurements

Technical discussion

**Construction**

The monitor was supplied with a 23–42 cm reusable adult cuff with hose length of 150 cm. The casing was all plastic with the display angled towards the user.

Inside the case were two circuit boards and pneumatics circuit. The main board incorporated the pressure transducer and the other board were for controls. All used surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

**Power supply**

The device was powered by four 1.5 V AA alkaline batteries; these were claimed to provide approximately 300 measurements. An optional mains adaptor (6 V DC) was available which could be purchased separately.

**Serviceability**

The user manual stated that Omron considered the device as a non-serviceable part. However, it was recommended the device be inspected every 2 years by an Omron supplier.
Omron MX3 Plus

Brief description

The Omron MX3 Plus was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on the device (O/I button) and pressing the 'Start' button the device did a brief self-test, inflated the cuff then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. If the initial pressure was too low, the device automatically pumped the cuff to a higher pressure and resumed measurement. Alternatively by pressing and holding the 'Start' button, the cuff could be inflated to a higher than normal initial cuff pressure. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements and pulse rate. There were six display icons; they indicated pulse detection, cuff inflating/deflating, memory recall, memory number and low battery.

The device automatically powered down five minutes after making a measurement. Up to 14 readings could be stored and reviewed.

Summary

Validation

The NIBP performance was clinically validated using the European Society of Hypertension (ESH) protocol. This was supported by a peer reviewed publication [41].

Good points

Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.5 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Failed to measure a full range of pressures including 200/150 mmHg and 255/195 mmHg. Very poor measurement consistency across a range of pulse rates (SD ± 7.4 mmHg). Gave six misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Market review

Results

**NIBP performance tests**
- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 200/150 mmHg and 255/195 mmHg settings
  - pulse range acceptable
- measurement consistency
  - fixed 120/80 mmHg†: excellent, SD ± 0.5 mmHg
  - variable pressure‡: good over the range which could be measured, SD ± 1.1 mmHg
  - variable pulse rate‡: poor, SD ± 7.4 mmHg
- susceptibility to artefact: 6 misleading readings from 25 tests
- variable pulse strength: gave no misleading readings

**General**
- usability: satisfactory

**Manuals**
- user manual: satisfactory

**Construction**
- mechanical: satisfactory
- electrical: good
- CE marking: CE0197

† 30 measurements ‡ 5 measurements

Technical discussion

**Construction**
The monitor was supplied with a 23–32 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatics circuit. The board was populated with the pressure transducer and surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

**Power supply**
The device was powered by four 1.5 V AA alkaline batteries; these were claimed to provide approximately 300 measurements. An optional mains adaptor (6 V DC) was available which could be purchased separately.

**Serviceability**
The user manual stated that the device was considered a non-serviceable part, but recommended calibration every 2 years by an Omron supplier.
Omron SpotArm i-Q132

Brief description

The Omron SpotArm i-Q123 was a blood pressure monitor into which the cuff was integrated and was inflated by a motorised air pump.

In use, the cuff tipped forward allowing the upper arm to pass through it; the subject would then rest the elbow in a shaped recess on the case.

After switching on the device (O/I button) and pressing the 'Start' button the device did a brief self-test, inflated the cuff then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject's expected systolic pressure. Alternatively, by pressing and holding 'Start', higher pressures could be obtained. When the measurement was complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button or an emergency button on the rear of the case.

The LCD panel showed pressure measurements, pulse rate, time and date. There were fourteen display icons; they indicated pulse detection, cuff deflating, user select prompt, selected user, memory recall, average value, morning average, evening average, week number, morning hypertension, irregular heart beat, movement, posture and low battery.

The device automatically powered down five minutes after making a measurement. Eighty-four measurements each of two users could be stored and recalled. Information available for review included morning and evening averaging. A third user setting 'Guest' enabled use of the device without affecting the data stored by users one and two.

Summary

Validation
The manufacturer made no claims of clinical validation.

Good points
Good measurement consistency across a range of blood pressures (SD ± 2.0 mmHg).
Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.8 mmHg).
Good measurement consistency across a range of pulse rates (SD ± 1.3 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages
Gave one misleading reading from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests
- pressure and pulse rate ranges acceptable
- measurement consistency
  - fixed 120/80 mmHg† excellent, SD ± 0.8 mmHg
  - variable pressure‡ good, SD ± 2.0 mmHg
  - variable pulse rate‡ good, SD ± 1.3 mmHg
- susceptibility to artefact 1 misleading reading from 25 tests
- variable pulse strength gave no misleading readings

General
- usability good

Manuals
- user manual good

Construction
- mechanical good
- electrical good
- CE marking CE0197

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor had an integrated cuff suitable for arm circumference range of 17–32 cm. The casing was all plastic with the display angled towards the user.

Inside the case were two circuit boards and pneumatics circuit. The main board incorporated the pressure transducer and the other board was for the controls. All used surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5 V AA alkaline batteries; these were claimed to provide approximately 250 measurements. In our tests, the low battery warning occurred after 75 measurements, however, a mains adaptor (6 V 1000 mA DC) was provided.

Serviceability
The user manual recommended the device be inspected every 2 years by an Omron supplier.
Omron 705IT

Brief description

The Omron 705IT was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on the device (O/I button) and pressing the 'Start' button the device did a brief self-test, inflated the cuff then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. If the initial pressure was too low, the device automatically pumped the cuff to a higher pressure and resumed measurement. Alternatively by pressing and holding the 'Start' button, the cuff could be inflated to a higher than normal initial cuff pressure. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements, pulse rate, time and date. There were five display icons; they indicated pulse detection, cuff inflating/deflating, memory recall and low battery.

The device automatically powered down five minutes after making a measurement. Up to 28 readings could be stored and reviewed.

The monitor was supplied with a USB cable for connection of a PC and software to download readings. A printer was optionally available. A separate product was available (705CP-II) combining a 705IT with printer but omitting the USB cable and software.

Summary

Validation

The NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol, the European Society of Hypertension (ESH) protocol and the British Hypertension Society (BHS) protocol under which it was graded A/A. It was also validated for use with children. All of these validations were supported by peer reviewed publications [34,35,36].

Good points

Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.5 mmHg) and across a range of pulse rates (SD ± 1.0 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Failed to measure a full range of pressures including 200/150 mmHg and 255/195 mmHg. Gave one misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

**NIBP performance tests**

- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 200/150 mmHg and 255/195 mmHg settings
  - pulse range acceptable

- measurement consistency
  - fixed 120/80 mmHg†
    - excellent, SD ± 0.5 mmHg
  - variable pressure‡
    - excellent over the range which could be measured, SD ± 0.5 mmHg
  - variable pulse rate‡
    - excellent, SD ± 1.0 mmHg

- susceptibility to artefact
  - 1 misleading reading from 25 tests

- variable pulse strength
  - gave no misleading readings

**General**

- usability
  - good

**Manuals**

- user manual
  - satisfactory

**Construction**

- mechanical
  - good

- electrical
  - good

- CE marking
  - CE0197

† 30 measurements ‡ 5 measurements

Technical discussion

**Construction**

The monitor was supplied with a 23-32 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatics circuit. The board was populated with the pressure transducer and surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

**Power supply**

The device was powered by four 1.5 V AA alkaline batteries; these were claimed to provide approximately 300 measurements. An optional mains adaptor (6 V DC) was available which could be purchased separately.

**Serviceability**

The user manual recommended that the device be inspected every 2 years by an authorised Omron dealer.
Panasonic EW3106

Brief description

The Panasonic EW3106 was a blood pressure monitor which inflated the cuff by a motorised air pump.

After pressing the start/stop button (labelled O/I) the device did a brief self-test, before inflating the cuff to approximately 35 mmHg. It then increased pressure gradually while measuring the subject's blood pressure. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements and pulse rate. There were three display icons; they indicated pulse detection, memory recall and battery replacement.

The device automatically powered down five minutes after making a measurement. Forty-two measurements could be stored and reviewed.

Summary

Measurement during inflation is a technique used by a minority of devices. It has the advantage of subjecting the patient to lower cuff pressures during the measurement.

Validation

The NIBP performance was clinically validated using the using the BS EN 1060-4 protocol. This was supported by an unpublished report (supplied).

Good points

Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.5 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Failed to measure a full range of pressures including 255/195 mmHg and measurement consistency was very poor (SD ± 4.6 mmHg) across the range of pressures it measured successfully. Gave five misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests
- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 255/195 mmHg setting
  - pulse range acceptable
- measurement consistency
  - fixed 120/80 mmHg†
    - good, SD ± 1.5 mmHg
  - variable pressure‡
    - very poor over the range which could be measured, SD ± 4.6 mmHg
  - variable pulse rate‡
    - satisfactory, SD ± 2.7 mmHg
- susceptibility to artefact
- variable pulse strength
  - gave no misleading readings

General
- usability
  - satisfactory

Manuals
- user manual
  - satisfactory

Construction
- mechanical
  - good
- electrical
  - satisfactory
- CE marking
  - CE0197

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 20–34 cm reusable adult cuff with hose length of 80 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatics circuit. The board was populated with the pressure transducer and surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5 V AA batteries.

Serviceability
The user manual recommended the device be calibrated every 3 years.
Panasonic EW3109

Brief description

The Panasonic EW3109 was a blood pressure monitor which inflated the cuff by a motorised air pump.

After pressing the start/stop button, the device did a brief self-test, before inflating the cuff to approximately 35 mmHg. It then increased pressure gradually while measuring the subject's blood pressure. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements and pulse rate. There were three display icons; they indicated pulse detection, memory recall and battery replacement.

The device automatically powered down five minutes after making a measurement. Ninety measurements could be stored and reviewed.

Summary

Measurement during inflation is a technique used by a minority of devices. It has the advantage of subjecting the patient to lower cuff pressures during the measurement.

Validation

The NIBP performance was clinically validated using the BS EN 1060-4 protocol. This was supported by an unpublished report (supplied).

Good points

Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.2 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Failed to measure a full range of pressures including 255/195 mmHg and measurement consistency was very poor (SD ± 4.5 mmHg) across the range of pressures it measured successfully. Gave seven misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests
- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 255/195 mmHg setting
  - pulse range acceptable
- measurement consistency
  - fixed 120/80 mmHg†
    - good, SD ± 1.2 mmHg
  - variable pressure‡
    - very poor over the range which could be measured, SD ± 4.5 mmHg
  - variable pulse rate‡
    - satisfactory, SD ± 2.3 mmHg
- susceptibility to artefact
- variable pulse strength
gave no misleading readings

General
- usability
good

Manuals
- user manual
good

Construction
- mechanical
good
- electrical
good
- CE marking
  - CE0197

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 20–34 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatics circuit. The board was populated with the pressure transducer and surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5 V AA batteries, with the capacity from new of providing approximately 500 measurements. An optional mains adaptor (6 V DC) was available which could be purchased separately.

Serviceability
The user manual recommended the device be calibrated every 3 years.
Panasonic EW3122

Brief description

The Panasonic EW3122 was a blood pressure monitor which inflated the cuff by a motorised air pump.

After pressing the start/stop button (labelled O/ I) the device did a brief self-test, before inflating the cuff to approximately 35 mmHg. It then increased pressure gradually while measuring the subject's blood pressure. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The LCD panel showed pressure measurements, pulse rate, time and date. There were four display icons; they indicated pulse detection, memory recall, average of all readings and battery replacement.

Alongside the LCD panel was a blood pressure classifications display to show whether readings were normal or high. This was based loosely on classifications defined in the BHS Guidelines [1]. There were three LEDs for systolic classification and three for diastolic.

The device automatically powered down five minutes after making a measurement. Forty-two measurements for each of two users could be stored and reviewed.

Summary

Measurement during inflation is a technique used by a minority of devices. It has the advantage of subjecting the patient to lower cuff pressures during the measurement.

Validation

The NIBP performance was clinically validated using the using the BS EN 1060-4 protocol. This was supported by an unpublished report (supplied).

Good points

Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.3 mmHg) and across a range of pulse rates (SD ± 1.5 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Failed to measure a full range of pressures including 255/195 mmHg and measurement consistency was very poor (SD ± 5.1 mmHg) across the range of blood pressures it measured successfully. Gave four misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests
- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 255/195 mmHg setting
  - pulse range acceptable
- measurement consistency
  - fixed 120/80 mmHg†
    - good, SD ± 1.3 mmHg
  - variable pressure‡
    - very poor over the range which could be measured, SD ± 5.1 mmHg
  - variable pulse rate‡
    - good, SD ± 1.5 mmHg
- susceptibility to artefact
  - 4 misleading readings from 25 tests
- variable pulse strength
  - gave no misleading readings

General
- usability
  - good

Manuals
- user manual
  - good

Construction
- mechanical
  - good
- electrical
  - good
- CE marking
  - CE0197

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 20–34 cm reusable adult cuff with hose length of 80 cm. The cuff was stored in the back of the casing when not in use. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatics circuit. The board was populated with the pressure transducer and surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5 V AA batteries. An optional mains adaptor (6 V DC) was available which could be purchased separately.

Serviceability
The user manual recommended the device be calibrated every 3 years.
Riester ri-champion

Brief description

The Riester ri-champion was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on and pressing the on/off and start/stop button, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject's expected systolic pressure. When the measurement was complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the start/stop button.

The LCD panel showed pressure measurements and pulse rate. There were four display icons; they indicated pulse detection, cuff inflating/deflating, memory recall, average of readings and battery replacement.

The device automatically powered down 90 seconds after making a measurement. Eight measurements could be stored and reviewed.

Summary

Validation
The manufacturer claimed (in the user manual) that the NIBP performance was clinically validated using the DIN 58130 protocol. However, no evidence was provided nor could any published evidence be found to verify this claim.

Good points
Excellent measurement consistency across a range of blood pressures (SD ± 0.7 mmHg), at a fixed pressure of 120/80 mmHg (SD ± 0.6 mmHg) and across a range of pulse rates (SD ± 0.8 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages
Gave eight misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests
- pressure and pulse rate ranges: acceptable
- measurement consistency:
  - fixed 120/80 mmHg: excellent, SD ± 0.6 mmHg
  - variable pressure: excellent, SD ± 0.7 mmHg
  - variable pulse rate: excellent, SD ± 0.8 mmHg
- susceptibility to artefact: 8 misleading readings from 25 tests
- variable pulse strength: gave no misleading readings

General
- usability: good

Manuals
- user manual: satisfactory

Construction
- mechanical: good
- electrical: good
- CE marking: CE

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 24–32 cm reusable adult cuff with hose length of 80 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatics circuit. The board was populated with the pressure transducer and surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5V AA alkaline batteries; these were claimed to provide approximately 300 measurements.

Serviceability
The user manual recommended the device undergo accuracy checks every 2 years.
Rossmax MS60

Brief description

The Rossmax MS60 was a blood pressure monitor which required manual inflation. Its only control was an on/off switch.

After switching on the device, the cuff was inflated by an external bulb inflator to the target pressure (initially 150 mmHg): this was known by watching the increasing pressure and a flashing ▲ prompt which disappeared when the target pressure was achieved.

The cuff continuously deflated via a pin-hole in the inflator during which the device measured and displayed the subject's blood pressure. When the measurement was complete a ▼ prompt indicated to press the exhaust valve air-release button that was attached to the inflator bulb.

The LCD panel showed pressure measurements and pulse rate. There were four display icons; they indicated pulse detection, cuff inflating/deflating and low battery.

The device automatically powered down one minute after making a measurement. Sixty measurements could be stored and reviewed.

Summary

Validation

The manufacturer claimed (in the user manual) that the NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. However, no evidence was provided nor could any published evidence be found to verify this claim.

Good points

Excellent measurement consistency across a range of blood pressures (SD ± 0.9 mmHg) and at a fixed pressure of 120/80 mmHg (SD ± 0.6 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Gave three misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Market review

Results

NIBP performance tests
- pressure and pulse rate ranges acceptable
- measurement consistency
  - fixed 120/80 mmHg† excellent, SD ± 0.6 mmHg
  - variable pressure‡ excellent, SD ± 0.9 mmHg
  - variable pulse rate‡ satisfactory, SD ± 0.7 mmHg
- susceptibility to artefact 3 misleading readings from 25 tests
- variable pulse strength gave no misleading readings

General
- usability satisfactory

Manuals
- user manual satisfactory

Construction
- mechanical satisfactory
- electrical satisfactory
- CE marking CE0366

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 24–36 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case were two circuit boards, the main board and keyboard. The board was populated with the pressure transducer and surface mounted components.

Power supply
The device was powered by four 1.5 V AA batteries.

Serviceability
The user manual recommended the device was calibrated every 2 years.
Rossmax MS400i

Brief description

The Rossmax MS400i was a blood pressure monitor which inflated the cuff by a motorised air pump.

After pressing the start/stop button (labelled O/ I) the device did a brief self-test, before inflating the cuff to approximately 35 mmHg. It then increased pressure gradually while measuring the subject’s blood pressure. When complete, the cuff deflated rapidly. Any measurement in progress could be stopped and the cuff deflated by pressing the on/off button.

The device could be used by two individuals with measurements being stored in separate memories.

The LCD panel showed pressure measurements, pulse rate, time, date and memory number. There were three display icons; they indicated pulse detection, user and low battery.

The device automatically powered down five minutes after making a measurement. Fifty measurements for each of two users could be stored and reviewed. The average of the last three readings could be displayed.

Summary

Measurement during inflation is a technique used by a minority of devices. It has the advantage of subjecting the patient to lower cuff pressures during the measurement.

Validation

The manufacturer claimed (in the user manual) that the NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. No evidence was provided nor could any published evidence be found to verify this claim.

Good points

Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.7 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Failed to measure over a full range of pressures including 60/30 mmHg and 2 of 5 attempts at 255/195 mmHg. Very poor measurement consistency across a range of pulse rates (SD ± 5.1 mmHg). Gave one misleading reading from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests
- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 60/30 mmHg setting and 2 of 5 attempts at 255/195 mmHg setting
  - pulse range acceptable
- measurement consistency
  - fixed 120/80 mmHg: good, SD ± 1.7 mmHg
  - variable pressure: satisfactory over the range which could be measured, SD ± 2.8 mmHg
  - variable pulse rate: very poor, SD ± 5.1 mmHg
- susceptibility to artefact
  - 1 misleading reading from 25 tests
- variable pulse strength
  - gave no misleading readings

General
- usability
  - satisfactory

Manuals
- user manual
  - satisfactory

Construction
- mechanical
  - satisfactory
- electrical
  - satisfactory
- CE marking
  - CE0366

Technical discussion

Construction
The monitor was supplied with a 24–36 cm reusable adult cuff with hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case were two circuit board and pneumatics circuit. The main board was populated with the pressure transducer and surface mounted components and the other board was the keyboard. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5V AA batteries. An optional mains adaptor (6 V 600 mA DC) was available which could be purchased separately.

Serviceability
The user manual recommended the device was calibrated every 2 years.
Samsung BD-3000S

Brief description

The Samsung BD-3000S was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on and pressing the combined on/off and 'Start' button, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject's expected systolic pressure.

The LCD panel showed pressure measurements, pulse rate, time and date. There were four display icons; they indicated pulse rate, cuff inflating/deflating and battery replacement.

The device automatically powered down one minute after making a measurement. Thirty measurements for each of three users could be stored and reviewed.

Summary

Validation

The manufacturer claimed (in the user manual) that the NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. However, no evidence was provided nor could any published evidence be found to verify this claim.

Good points

Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 2.0 mmHg).

Disadvantages

Failed to measure a full range of pressures including 60/30 mmHg and 255/195 mmHg. Very poor measurement consistency across a range of pulse rates (SD ± 4.9 mmHg). Gave thirteen misleading readings from 25 tests when subjected to varying degrees of tremor artefact. Gave five misleading readings from 20 tests when subjected to low pulse strengths.
Results

NIBP performance tests
- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 60/30 mmHg and 255/195 mmHg settings
  - pulse range acceptable

- measurement consistency
  - fixed 120/80 mmHg†
    - good, SD ± 2.0 mmHg
  - variable pressure‡
    - satisfactory over the range which could be measured, SD ± 2.6 mmHg
  - variable pulse rate‡
    - very poor, SD ± 4.9 mmHg

- susceptibility to artefact
  - 13 misleading readings from 25 tests

- variable pulse strength
  - 5 misleading readings from 20 tests

General
- usability
  - satisfactory

Manuals
- user manual
  - poor

Construction
- mechanical
  - good
- electrical
  - good
- CE marking
  - CE0123

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 23–33 cm reusable adult cuff with a hose length of 80 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatics circuit. The board was populated with the pressure transducer and surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5 V AA batteries or the supplied mains adaptor (6 V 1000 mA DC).

Serviceability
The user manual made no recommendations for maintenance, servicing or calibration.
Samsung BF-180M

Brief description

The Samsung BF-180M was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on and pressing the combined start/stop button, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject’s blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject’s expected systolic pressure.

The LCD panel showed pressure measurements, pulse rate, time and date. There were four display icons; they indicated pulse rate, cuff inflating/deflating and battery replacement.

The device automatically powered down one minute after making a measurement. Thirty measurements for each of three users could be stored and reviewed.

Summary

Validation

The manufacturer claimed (in the user manual) that the NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. However, no evidence was provided nor could any published evidence be found to verify this claim.

Good points

Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.7 mmHg). Gave no misleading readings when subjected to low pulse strengths. Two cuff sizes supplied.

Disadvantages

Failed to measure a full range of pressures including 60/30 mmHg and 255/195 mmHg. Very poor measurement consistency across a range of pulse rates (SD ± 10.3 mmHg). Gave nine misleading readings from 25 tests when subjected to varying degrees of tremor artefact.
Results

NIBP performance tests
- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 60/30 mmHg and 255/195 mmHg settings
  - pulse range acceptable
- measurement consistency
  - fixed 120/80 mmHg†
    - good, SD ± 1.7 mmHg
  - variable pressure‡
    - poor over the range which could be measured, SD ± 4.6 mmHg
  - variable pulse rate‡
    - very poor, SD ± 10.3 mmHg
- susceptibility to artefact
- variable pulse strength
  - gave no misleading readings

General
- usability
  - satisfactory

Manuals
- user manual
  - poor

Construction
- mechanical
  - good
- electrical
  - good
- CE marking
  - CE0123

† 30 measurements ‡ 5 measurements

Technical discussion

Construction
The monitor was supplied with a 23–33 cm and a 33–43 cm reusable adult cuff, both with a hose length of 80 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatics circuit. The board was populated with the pressure transducer and surface mounted components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply
The device was powered by four 1.5V AA batteries. or the supplied mains adaptor (6 V 1000 mA DC)

Serviceability
The user manual made no recommendations for maintenance, servicing or calibration.
Samsung SBM-600F

Brief description

The Samsung SBM-600F was a blood pressure monitor which inflated the cuff by a motorised air pump.

After switching on and pressing the 'Start' button, the device did a brief self-test, inflated the cuff, then deflated it gradually under the control of an internal air bleed valve while measuring the subject's blood pressure. By monitoring pulse activity during inflation, the device set the target cuff pressure approximately 30 to 40 mmHg above the subject's expected systolic pressure.

The LCD panel showed pressure measurements and pulse rate. There were five display icons; they indicated pulse rate, cuff inflating/deflating, memory and battery replacement.

The device automatically powered down three minutes after making a measurement. Eight measurements could be stored and reviewed.

Summary

Validation

The manufacturer claimed (in the user manual) that the NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. However, no evidence was provided nor could any published evidence be found to verify this claim.

Good points

Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.3 mmHg) Gave no misleading readings when subjected to low pulse strengths.

Disadvantages

Failed to measure a full range of pressures including 255/195 mmHg. Failed to measure at pulse rate of 200 bpm. Gave one misleading reading from 25 tests when subjected to varying degrees of tremor artefact.
Market review

Results

NIBP performance tests

- pressure and pulse rate ranges
  - pressure range unacceptable: failed to measure 255/195 mmHg setting
  - pulse range unacceptable: failed to measure at pulse rate of 200 bpm

- measurement consistency
  - fixed 120/80 mmHg†
    - good, SD ± 1.3 mmHg
  - variable pressure‡
    - good over the range which could be measured, SD ± 1.9 mmHg
  - variable pulse rate‡
    - very poor over the range which could be measured, SD ± 6.3 mmHg

- pressure range
- measurement consistency
- variable pulse rate
- susceptibility to artefact
  - 1 misleading reading from 25 tests
- variable pulse strength
  - gave no misleading readings

General

- usability
  - satisfactory

Manuals

- user manual
  - poor

Construction

- mechanical
  - satisfactory
- electrical
  - satisfactory
- CE marking
  - CE0123

† 30 measurements ‡ 5 measurements

Technical discussion

Construction

The monitor was supplied with a 23–33 cm reusable adult cuff, with a hose length of 60 cm. The casing was all plastic with the display angled towards the user.

Inside the case was a circuit board and pneumatics circuit. The board was populated with the pressure transducer and discrete un-miniaturised components. The pressure transducer was connected to the pneumatic circuit; this included a pump and an electro-mechanical valve for releasing cuff pressure.

Power supply

The device was powered by four 1.5 V AA batteries.

Serviceability

The user manual made no recommendations for maintenance, servicing or calibration.
Results

The results obtained for each device are summarised in Table 3 (page 120). Three criteria were measured as described in Method (page 12): accuracy, level of evidence and measurement performance.

To show which devices perform best against these criteria we have displayed the results diagrammatically in a Venn diagram, Figure 1 (page 127). It contains three overlapping circles labelled Accuracy, Level of evidence and Measurement performance.

Every device is located on the diagram according to which of the criteria it satisfied. Those which satisfied all criteria are listed at the centre of the diagram where all three circles overlap—we would recommend these NIBP monitors. Devices which satisfied two criteria, where two circles overlap, might be worth considering. Devices that satisfied only one criterion and devices which satisfied none of the criteria (those shown outside of the circles) are monitors we cannot recommend to the NHS.

None of the monitors evaluated was rated worse than satisfactory for measurement consistency at 120/80 (93) mmHg.

Devices are listed in alphabetical order.

<table>
<thead>
<tr>
<th>Recommended</th>
<th>Consider</th>
<th>Not recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>A&amp;D UA-767</td>
<td>A&amp;D UA-774</td>
<td>A&amp;D UA-851</td>
</tr>
<tr>
<td>Medel Check</td>
<td>A&amp;D UA-779</td>
<td>A&amp;D UA-853</td>
</tr>
<tr>
<td>Medel Fuzzy</td>
<td>A&amp;D UA-787</td>
<td>Lloyds Pharmacy KD-525</td>
</tr>
<tr>
<td>Microlife as easy as 123</td>
<td>Omron M4I*</td>
<td>Maplin Automatic HL888JF</td>
</tr>
<tr>
<td>Microlife BPA 100</td>
<td>Omron MX3 Plus*</td>
<td>Maplin Manual HL888BM</td>
</tr>
<tr>
<td>Microlife BP 3AC1-1</td>
<td>Omron M7</td>
<td>Mars MS-752</td>
</tr>
<tr>
<td>Microlife BP 3PTO-A(2)</td>
<td>Omron 705IT</td>
<td>Mars MS-1200</td>
</tr>
<tr>
<td>Omron M6*</td>
<td></td>
<td>Medisana MTA</td>
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<tr>
<td></td>
<td></td>
<td>Medisana MTM</td>
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<td></td>
<td></td>
<td>Medisana MTP</td>
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<td></td>
<td></td>
<td>Microlife BP 3AS1-2</td>
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<tr>
<td></td>
<td></td>
<td>Nissee DS-400</td>
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<td></td>
<td></td>
<td>Nissee DS-1873</td>
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<tr>
<td></td>
<td></td>
<td>Nissee DS-1902</td>
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<tr>
<td></td>
<td></td>
<td>Omron M1 Classic</td>
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<tr>
<td></td>
<td></td>
<td>Omron M3</td>
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<td></td>
<td></td>
<td>Omron SpotArm i-Q132</td>
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<tr>
<td></td>
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<td>Panasonic EW3106</td>
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<td></td>
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<td>Panasonic EW3109</td>
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<td>Panasonic EW3122</td>
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<td></td>
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<td>Riester Ri-Champion</td>
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<td></td>
<td></td>
<td>Rossmax MS60</td>
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<tr>
<td></td>
<td></td>
<td>Rossmax MS400i</td>
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<tr>
<td></td>
<td></td>
<td>Samsung BD-3000S</td>
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<tr>
<td></td>
<td></td>
<td>Samsung BF-180M</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Samsung SBM-600F</td>
</tr>
</tbody>
</table>

Notes:
1. All of the devices gave some misleading results when subjected to varying degrees of tremor artefact under test conditions using a blood pressure simulator—care should be taken when measuring patients' blood pressure in the presence of tremor.
2. Devices with an asterisk have a validation uncertainty such as a questionable equivalence with another validated device or validation study limitations see Table 3.
3. M indicates that the device requires manual cuff inflation.
### Table 3 Summary of results

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Accuracy</th>
<th>Level of evidence</th>
<th>Measurement performance: Repeatability (mmHg) (30 measurements) Acceptable* pressure and pulse (P &amp; P) ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>A&amp;D UA-702</td>
<td>n/a</td>
<td>Claimed ANSI/AAMI SP10. We could find no evidence to substantiate the claim.</td>
<td>Repeatability excellent 119.2 ± 0.8 / 82.5 ± 0.8 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td>A&amp;D UA-704</td>
<td>BHS: A/A</td>
<td>SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg From BHS paper:</td>
<td>Repeatability good 117.0 ± 1.6 / 77.3 ± 1.0 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-1.9 ± 4.3 / -1.4 ± 4.0 mmHg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>BHS validation—peer reviewed publication [24].</td>
<td></td>
</tr>
<tr>
<td>A&amp;D UA-705</td>
<td>BHS: A/A</td>
<td>SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg From BHS paper:</td>
<td>Repeatability excellent 114.1 ± 0.5 / 77.5 ± 0.7 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.4 ± 7.7 / 0.3 ± 8.2 mmHg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>BHS validation—peer reviewed publication [25].</td>
<td></td>
</tr>
<tr>
<td>A&amp;D UA-767</td>
<td>BHS: A/A</td>
<td>SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg From BHS paper:</td>
<td>Repeatability excellent 121.1 ± 0.7 / 83.3 ± 0.8 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-0.4 ± 5.4 / -0.4 ± 4.8 mmHg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>ANSI/AAMI SP10 and BHS—peer reviewed publication [26].</td>
<td></td>
</tr>
<tr>
<td>A&amp;D UA-774</td>
<td>BHS: A/A</td>
<td>SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg From BHS paper:</td>
<td>Repeatability satisfactory 113.4 ± 2.4 / 74.8 ± 0.8 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-1.0 ± 7.1 / -1.4 ± 7.6 mmHg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>BHS validation—peer reviewed publication [27].</td>
<td></td>
</tr>
<tr>
<td>A&amp;D UA-779</td>
<td>ESH: Pass</td>
<td>BHS grade A/A (derived from ESH data) SP10: Mean difference less than ± 5 mmHg SD</td>
<td>Repeatability excellent 120.5 ± 0.6 / 84.2 ± 0.4 Pressure range unacceptable: 4 in 5 unsuccessful attempts at 255/195 mmHg Pulse range acceptable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>less than ± 8 mmHg From ESH paper:</td>
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<tr>
<td></td>
<td></td>
<td>2.0 ± 5.0 / 1.0 ± 3.0 mmHg</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>ESH validation—peer reviewed publication [28].</td>
<td></td>
</tr>
<tr>
<td>A&amp;D UA-787</td>
<td>ESH: Pass</td>
<td>BHS grade A/A (derived from ESH data) SP10: Mean difference less than ± 5 mmHg SD</td>
<td>Repeatability good 116.0 ± 1.9 / 76.5 ± 1.5 P &amp; P ranges acceptable</td>
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<td></td>
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<td>less than ± 8 mmHg From ESH paper:</td>
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<tr>
<td></td>
<td></td>
<td>1.0 ± 5.3 / 0.7 ± 5.3 mmHg</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>ESH validation—peer reviewed publication [29].</td>
<td></td>
</tr>
<tr>
<td>A&amp;D UA-851</td>
<td>n/a</td>
<td>Claimed ANSI/AAMI SP10. We could find no evidence to substantiate the claim.</td>
<td>Repeatability excellent 111.3 ± 0.9 / 74.7 ± 0.7 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Supplier claims BHS validation is underway.</td>
<td></td>
</tr>
</tbody>
</table>

* Acceptable means the device has achieved at least two successful measurements from five attempts at each pressure range setting and pulse rate setting (see Appendix 3).
## Recommendations

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Accuracy</th>
<th>Level of evidence</th>
<th>Measurement performance:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A&amp;D UA-853</td>
<td>n/a</td>
<td>Claimed ANSI/AAMI SP10. We could find no evidence to substantiate the claim. Supplier claims BHS validation is underway.</td>
<td>Repeatability excellent 114.6 ± 0.6 / 78.6 ± 0.6 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td>Lloyds Pharmacy Kindcare KD-525</td>
<td>n/a</td>
<td>We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability excellent 118.3 ± 0.7 / 83.5 ± 0.5 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td>Maplin automatic Health &amp; Life HL888JF</td>
<td>n/a</td>
<td>Claimed ANSI/AAMI SP10 and DIN58130. We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability good 112.7 ± 1.6 / 80.7 ± 0.9 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td>Maplin manual Health &amp; Life HL888BM</td>
<td>n/a</td>
<td>Claimed ANSI/AAMI SP10 and DIN58130. We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability good 112.3 ± 1.1 / 79.1 ± 1.5 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td>Mars MS-752</td>
<td>n/a</td>
<td>We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability good 132.5 ± 1.0 / 87.0 ± 1.3 Pressure range unacceptable: no successful attempts at 255/195 mmHg Pulse range satisfactory</td>
</tr>
<tr>
<td>Mars MS-1200</td>
<td>n/a</td>
<td>We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability good 128.1 ± 1.3 / 84.5 ± 1.2 Pressure range unacceptable: no successful attempts at 255/195 mmHg Pulse range acceptable</td>
</tr>
<tr>
<td>Medel Check</td>
<td></td>
<td>BHS: A/A [Use in pregnancy: Normotensive A/B; Non-proteinuric hypertension B/B; pre-eclampsia A/B] SP10: Mean difference less than ± 5 mmHg SD less than ±8 mmHg From BHS paper: -1.6 ± 7.7 / -2.1 ± 6.3 mmHg ESH: Pass</td>
<td>Uses the same algorithm as the validated Microlife BP 3BTO-A, which meets the BHS protocol according to a peer reviewed publication [30] and has also been validated for use in pregnancy [31]. The 3BTO-A is also equivalent to the BPA 100 Plus which is validated to the International protocol [32]. Repeatability excellent 123.5 ± 0.7 / 86.8 ± 0.7 P &amp; P ranges acceptable</td>
</tr>
</tbody>
</table>

* Acceptable means the device has achieved at least two successful measurements from five attempts at each pressure range setting and pulse rate setting (see Appendix 3).
## Recommendations

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Accuracy</th>
<th>Level of evidence</th>
<th>Measurement performance:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Uses the same algorithm as the validated Microlife BP 3BTO-A, which meets the BHS protocol according to a peer reviewed publication [30] and has also been validated for use in pregnancy [31]. The 3BTO-A is also equivalent to the BPA 100 Plus which is validated to the International protocol [32].</td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td><strong>Medel Fuzzy</strong></td>
<td>BHS: A/A [Use in pregnancy: Normotensive A/B; Non-proteinuric hypertension B/B; pre-eclampsia A/B]</td>
<td><strong>SP10</strong>: Mean difference less than ± 5 mmHg, SD less than ± 8 mmHg. From BHS paper: -1.6 ± 7.7 to -2.1 ± 6.3 mmHg. ESH: Pass</td>
<td>123.9 ± 0.6 / 87.2 ± 0.6 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repeatability good</td>
</tr>
<tr>
<td></td>
<td></td>
<td>We could find no evidence of a validation being performed on the device.</td>
<td>129.4 ± 1.3 / 85.5 ± 0.5 Pulse range satisfactory</td>
</tr>
<tr>
<td><strong>Medisana MTA</strong></td>
<td>n/a</td>
<td>Claimed ANSI/AAMI SP10 and DIN 58130. We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>123.6 ± 0.8 / 86.6 ± 0.7 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td><strong>Medisana MTM</strong></td>
<td>n/a</td>
<td>Claimed ANSI/AAMI SP10 and DIN 58130. We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>126.1 ± 0.7 / 88.8 ± 0.7 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td><strong>Medisana MTP</strong></td>
<td>n/a</td>
<td>Claimed ANSI/AAMI SP10 and DIN 58130. We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>123.3 ± 0.7 / 86.7 ± 0.6 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td><strong>Microlife</strong></td>
<td>BHS: A/A [Use in pregnancy: Normotensive A/B; Non-proteinuric hypertension B/B; pre-eclampsia A/B]</td>
<td><strong>SP10</strong>: Mean difference less than ± 5 mmHg, SD less than ± 8 mmHg. From BHS paper: -1.6 ± 7.7 to -2.1 ± 6.3 mmHg. ESH: Pass</td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td><strong>as easy as 123</strong></td>
<td></td>
<td></td>
<td>123.2 ± 0.8 / 86.7 ± 0.6 P &amp; P ranges acceptable</td>
</tr>
<tr>
<td><strong>Microlife</strong></td>
<td>BHS: A/A [Use in pregnancy: Normotensive A/B; Non-proteinuric hypertension B/B; pre-eclampsia A/B]</td>
<td><strong>SP10</strong>: Mean difference less than ± 5 mmHg, SD less than ± 8 mmHg. From BHS paper: -1.6 ± 7.7 to -2.1 ± 6.3 mmHg. ESH: Pass</td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td><strong>BP A 100</strong></td>
<td></td>
<td></td>
<td>123.2 ± 0.8 / 86.7 ± 0.6 P &amp; P ranges acceptable</td>
</tr>
</tbody>
</table>

* Acceptable means the device has achieved at least two successful measurements from five attempts at each pressure range setting and pulse rate setting (see Appendix 3).
## Recommendations

### Table

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Accuracy</th>
<th>Level of evidence</th>
<th>Measurement performance:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microlife BP 3AC1-1</td>
<td>ESH: Pass</td>
<td></td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td></td>
<td>BHS: A/A (derived from ESH paper)</td>
<td></td>
<td>123.9 ± 0.7 / 87.6 ± 0.8</td>
</tr>
<tr>
<td></td>
<td>SP10: Mean difference less than ± 5 mmHg</td>
<td></td>
<td>P &amp; P ranges acceptable</td>
</tr>
<tr>
<td></td>
<td>SD less than ± 8 mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>From ESH paper:             -0.2 ± 4.5 / -2.0 ± 4.8 mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microlife BP 3AS1-2</td>
<td>n/a</td>
<td>We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>124.9 ± 0.7 / 87.7 ± 0.8</td>
</tr>
<tr>
<td>Microlife BP 3BTO-A(2)</td>
<td>BHS: A/A [Use in pregnancy: Normotensive A/B; Non-proteinuric hypertension B/B; pre-eclampsia A/B]</td>
<td>Uses the same algorithm as the validated Microlife BP 3BTO-A, which meets the BHS protocol according to a peer reviewed publication [30] and has also been validated for use in pregnancy [31]. Also equivalent to the BPA 100 Plus which is validated to the International protocol [32].</td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td></td>
<td>SP10: Mean difference less than ± 5 mmHg</td>
<td></td>
<td>125.3 ± 0.7 / 88.6 ± 0.6</td>
</tr>
<tr>
<td></td>
<td>SD less than ± 8 mmHg</td>
<td></td>
<td>P &amp; P ranges acceptable</td>
</tr>
<tr>
<td></td>
<td>From BHS paper:             -1.6 ± 7.7 / -2.1 ± 6.3 mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ESH: Pass</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nissei DS-400</td>
<td>n/a</td>
<td>We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>122.0 ± 0.8 / 82.2 ± 0.4</td>
</tr>
<tr>
<td>Nissei DS-1873</td>
<td>n/a</td>
<td>We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>124.3 ± 0.9 / 84.5 ± 0.6</td>
</tr>
<tr>
<td>Nissei DS-1902</td>
<td>DIN: Mean difference less than ± 5 mmHg</td>
<td>DIN 58130 validation. German Hypertonia Society quality seal (Prüfsiegel). Unpublished independent report supplied by the manufacturer.</td>
<td>Repeatability satisfactory</td>
</tr>
<tr>
<td></td>
<td>SD less than ± 8 mmHg</td>
<td></td>
<td>128.9 ± 2.5 / 86.3 ± 1.2</td>
</tr>
<tr>
<td></td>
<td>4.2 ± 6.8 / -2.6 ± 5.4 mmHg</td>
<td></td>
<td>Pressure range unacceptable: no successful attempts at 200/150 mmHg and 255/195 mmHg</td>
</tr>
<tr>
<td>Omron M1 Classic</td>
<td>n/a</td>
<td>We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>121.9 ± 0.7 / 81.6 ± 0.5</td>
</tr>
<tr>
<td>Omron M3</td>
<td>n/a</td>
<td>We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>124.8 ± 0.5 / 81.9 ± 0.3</td>
</tr>
</tbody>
</table>

* Acceptable means the device has achieved at least two successful measurements from five attempts at each pressure range setting and pulse rate setting (see Appendix 3).

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## Recommendations

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Accuracy</th>
<th>Level of evidence</th>
<th>Measurement performance:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omron M4I</td>
<td>ESH: Pass (Children: Pass)</td>
<td></td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td></td>
<td>BHS: A/A</td>
<td></td>
<td>123.7 ± 0.6 / 81.3 ± 0.5</td>
</tr>
<tr>
<td></td>
<td>SP10: Mean difference less than ± 5 mmHg</td>
<td></td>
<td>Pressure range unacceptable: no successful attempts at 200/150 mmHg and 255/195 mmHg</td>
</tr>
<tr>
<td></td>
<td>SD less than ± 8 mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>From BHS paper:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.6 ± 6.0 / -3.2 ± 6.6 mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>According to the BHS website the M4I is a derivative of the validated 705IT, which meets the International protocol [35] and is validated for use with children [36]. It has also been validated against the BHS protocol and ANSI/AAMI SP10 [34]. Questionable evidence: equivalence not confirmed by the manufacturer.</td>
<td></td>
</tr>
<tr>
<td>Omron M6</td>
<td>ESH: Pass [37] (Obese patients: Pass [38])</td>
<td></td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td></td>
<td>BHS: A/A (derived from ESH paper [37])</td>
<td></td>
<td>123.1 ± 0.6 / 81.3 ± 0.4</td>
</tr>
<tr>
<td></td>
<td>SP10: Mean difference less than ± 5 mmHg</td>
<td></td>
<td>P &amp; P ranges acceptable</td>
</tr>
<tr>
<td></td>
<td>SD less than ± 8 mmHg</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>From ESH paper [37]:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.8 ± 2.7 / -1.9 ± 3.3 mmHg</td>
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<td></td>
<td></td>
<td>ESH validation—peer reviewed publications [37,38]; validated for use with obese patients [38]. According to the BHS website the M6 is a derivative of the validated 705IT, which meets the International protocol [35] and is validated for use with children [37]. It has also been validated against the BHS protocol and ANSI/AAMI SP10 [34]. Questionable evidence: equivalence not confirmed by the manufacturer.</td>
<td></td>
</tr>
<tr>
<td>Omron M7</td>
<td>BHS: A/A</td>
<td>BHS and ANSI/AAMI SP10 validation—peer reviewed publication [40]. ESH validation, population requiring large cuff use—peer reviewed publication [39]. ESH validation: unpublished independent report supplied by the manufacturer.</td>
<td>Repeatability excellent</td>
</tr>
<tr>
<td></td>
<td>SP10: Mean difference less than ± 5 mmHg</td>
<td></td>
<td>121.9 ± 0.7 / 81.6 ± 0.7</td>
</tr>
<tr>
<td></td>
<td>SD less than ± 8 mmHg</td>
<td></td>
<td>Pressure range unacceptable: no successful attempts at 200/150 mmHg and 255/195 mmHg</td>
</tr>
<tr>
<td></td>
<td>0.8 ± 6.5 / 1.3 ± 5.0 mmHg</td>
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<tr>
<td></td>
<td>ESH: Pass</td>
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<tr>
<td>Omron MX3 Plus</td>
<td>ESH: Pass (derived from ESH paper)</td>
<td>ESH validation—peer reviewed publication [41]. Questionable evidence: recruitment ranges omitted from plot, DBP high range appears undescribed.</td>
<td>Repeatability excellent</td>
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<tr>
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<td>BHS: A/A</td>
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<td>122.5 ± 0.5 / 81.2 ± 0.4</td>
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<td>SP10: Mean difference less than ± 5 mmHg</td>
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<td>Pressure range unacceptable: no successful attempts at 200/150 mmHg and 255/195 mmHg</td>
</tr>
<tr>
<td></td>
<td>SD less than ± 8 mmHg</td>
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<td>From ESH paper:</td>
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<td></td>
<td>-1.2 ± 5.7 / -1.6 ± 4.7 mmHg</td>
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<tr>
<td>Omron SpotArm i-Q132</td>
<td>n/a</td>
<td>We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability excellent</td>
</tr>
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<td></td>
<td>128.0 ± 0.8 / 83.2 ± 0.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P &amp; P ranges acceptable</td>
</tr>
</tbody>
</table>

* Acceptable means the device has achieved at least two successful measurements from five attempts at each pressure range setting and pulse rate setting (see Appendix 3).
<table>
<thead>
<tr>
<th>Monitor</th>
<th>Accuracy</th>
<th>Level of evidence</th>
<th>Measurement performance:</th>
<th>Repeatability (mmHg) (30 measurements)</th>
<th>Acceptable* pressure and pulse (P &amp; P) ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omron 705IT</td>
<td>ESH: Pass (Use with children: Pass)</td>
<td></td>
<td></td>
<td>Repeatability excellent</td>
<td>124.3 ± 0.5 / 82.0 ± 0.2</td>
</tr>
<tr>
<td></td>
<td>BHS: A/A</td>
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<td>Pressure range unacceptable: no successful attempts at 200/150 mmHg and 255/195 mmHg</td>
<td>Pulse range acceptable</td>
</tr>
<tr>
<td></td>
<td>SP10: Mean difference less than ± 5 mmHg</td>
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<tr>
<td></td>
<td>SD less than ± 8 mmHg</td>
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</tr>
<tr>
<td></td>
<td>From BHS paper: 0.6 ± 6.0 / -3.2 ± 6.6 mmHg</td>
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<tr>
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<td>The 705CP-II is a 705IT monitor with a printer. ESH validation—peer reviewed publication [35]; validated for use with children [36]. BHS validation and ANSI/AAMI SP10—peer reviewed publication [34].</td>
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<td>Panasonic EW3106</td>
<td>EN 1060-4: Mean difference less than ± 5 mmHg</td>
<td>EN 1060-4 validation. Unpublished independent report supplied by the manufacturer.</td>
<td>Repeatability good</td>
<td>122.6 ± 1.5 / 84.9 ± 1.1</td>
<td>Pressure range unacceptable: no successful attempts at 255/195 mmHg</td>
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<tr>
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<td>SD less than ± 8 mmHg</td>
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<tr>
<td></td>
<td>-2.2 ± 7.1 / 1.8 ± 5.2 mmHg</td>
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<tr>
<td>Panasonic EW3109</td>
<td>EN 1060-4: Mean difference less than ± 5 mmHg</td>
<td>EN 1060-4 validation. Unpublished independent report supplied by the manufacturer.</td>
<td>Repeatability good</td>
<td>121.3 ± 1.2 / 83.9 ± 1.0</td>
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<tr>
<td>Panasonic EW3122</td>
<td>EN 1060-4: Mean difference less than ± 5 mmHg</td>
<td>The EW3122 is identical in all respects with regards to clinical performance to the EW3106 as it uses the same algorithm according to a declaration statement supplied by the manufacturer. The EW3106 meets EN 1060-4 validation according to an unpublished independent report supplied by the manufacturer.</td>
<td>Repeatability good</td>
<td>121.5 ± 1.3 / 84.7 ± 1.0</td>
<td>Pressure range unacceptable: no successful attempts at 255/195 mmHg</td>
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<td>SD less than ± 8 mmHg</td>
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<tr>
<td></td>
<td>-2.2 ± 7.1 / 1.8 ± 5.2 mmHg</td>
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<td>Riester Ri-Champion</td>
<td>n/a</td>
<td>Claimed validated to DIN 58130. We could find no evidence of a validation being performed on the device.</td>
<td>Repeatability excellent</td>
<td>125.9 ± 0.6 / 85.2 ± 0.4</td>
<td>P &amp; P ranges acceptable</td>
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<tr>
<td>Rossmax MS60</td>
<td>n/a</td>
<td>Claimed ANSI/AAMI SP10. We could find no evidence to substantiate the claim.</td>
<td>Repeatability excellent</td>
<td>123.6 ± 0.6 / 84.2 ± 0.5</td>
<td>P &amp; P ranges acceptable</td>
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<td>Rossmax MS400i</td>
<td>n/a</td>
<td>Claimed ANSI/AAMI SP10. We could find no evidence to substantiate the claim.</td>
<td>Repeatability good</td>
<td>129.7 ± 1.7 / 85.6 ± 1.2</td>
<td>Pressure range unacceptable: no successful attempts at 60/30 mmHg</td>
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</table>

* Acceptable means the device has achieved at least two successful measurements from five attempts at each pressure range setting and pulse rate setting (see Appendix 3).
## Monitor Accuracies

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<th>Accuracy</th>
<th>Level of evidence</th>
<th>Measurement performance:</th>
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<tr>
<td>Samsung BD-3000S</td>
<td>n/a</td>
<td>Claimed ANSI/AAMI SP10. We could find no evidence to substantiate the claim.</td>
<td>Repeatability good</td>
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<td>121.4 ± 2.0 / 72.6 ± 2.0</td>
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<td>Pressure range acceptable: no successful attempts at 60/30 mmHg and 255/195 mmHg</td>
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<td></td>
<td>Pulse range acceptable</td>
</tr>
<tr>
<td>Samsung BF-180M</td>
<td>n/a</td>
<td>Claimed ANSI/AAMI SP10. We could find no evidence to substantiate the claim.</td>
<td>Repeatability good</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>120.2 ± 1.7 / 74.5 ± 1.5</td>
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<tr>
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<td></td>
<td></td>
<td>Pressure range unacceptable: no successful attempts at 60/30 mmHg and 255/195 mmHg</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Pulse range acceptable</td>
</tr>
<tr>
<td>Samsung SBM-600F</td>
<td>n/a</td>
<td>Claimed ANSI/AAMI SP10. We could find no evidence to substantiate the claim.</td>
<td>Repeatability good</td>
</tr>
<tr>
<td></td>
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<td>125.0 ± 1.3 / 75.7 ± 1.1</td>
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<td></td>
<td>Pressure range unacceptable: no successful attempts at 255/195 mmHg</td>
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<td></td>
<td>Pulse range unacceptable: no successful attempts at 200 bpm</td>
</tr>
</tbody>
</table>

* Acceptable means the device has achieved at least two successful measurements from five attempts at each pressure range setting and pulse rate setting (see Appendix 3).
**Recommendations**

**Figure 1 Venn diagram of results**

**Level of evidence**
- Peer reviewed study

**Accuracy**
- BHS grade A or B for systolic and diastolic pressure (or equivalent)

**Measurement performance**
- Excellent repeatability (SD ≤ 1 mmHg)
- Acceptable* pressure and pulse range

*Acceptable means the device has achieved at least two successful measurements from five attempts at each pressure range setting and pulse rate setting (see Appendix 3).

---

**Nissei DS-1902**
- Panasonic EW3106
- Panasonic EW3109
- Panasonic EW3122

**A&D UA-704**
- A&D UA-779
- A&D UA-787
- Omron M4i
- Omron M7
- Omron MX3 Plus
- Omron 7006T

**A&D UA-705**
- A&D UA-767
- Medel Check
- Medel Fuzzy
- Microlife as easy as 123
- Microlife BPA 100
- Microlife BP 3AC1-1
- Microlife BP 3PTO-A(2)
- Omron M6

**A&D UA-702**
- A&D UA-851
- A&D UA-853
- Lloyds Pharmacy KD-525
- Medisana MTM
- Medisana MTP
- Microlife BP 3AC1-2
- Nissei DS-400
- Nissei DS-1873
- Omron M3
- Omron SpotArm i-Q132
- Reister Ri-Champion
- Rossmax MS60

**Others**
- Maplin Automatic
- Maplin Manual
- Mars MS-752
- Mars MS-1200
- Medisana MTA
- Omron M1 Classic
- Rossmax MS400i
- Samsung BD-3000S
- Samsung BF-180M
- Samsung SBM-600F

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CEP 08035: September 2008
We should like to thank the manufacturers and suppliers for the provision of appropriate information on their respective products.
# Glossary

Terms and abbreviations used in this report

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>AC</td>
<td>alternating current</td>
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<tr>
<td>BPM</td>
<td>beats per minute</td>
</tr>
<tr>
<td>DC</td>
<td>direct current</td>
</tr>
<tr>
<td>LCD</td>
<td>liquid crystal display</td>
</tr>
<tr>
<td></td>
<td>This type of display can be monochrome or colour.</td>
</tr>
<tr>
<td>LED</td>
<td>light emitting diode</td>
</tr>
<tr>
<td>NIBP</td>
<td>non-invasive blood pressure</td>
</tr>
<tr>
<td>MAP</td>
<td>mean arterial pressure</td>
</tr>
<tr>
<td>PPM</td>
<td>planned preventative maintenance</td>
</tr>
<tr>
<td>SD</td>
<td>standard deviation</td>
</tr>
<tr>
<td>SMT</td>
<td>surface mount technology</td>
</tr>
</tbody>
</table>

A method for constructing electronic circuits in which the electronic components are mounted directly onto the surface of printed circuit boards, thus reducing the overall size.


3. MHRA. Medical Devices Alert, ref. MDA/2005/069. 2005


7. BS EN 1060-4:2004 Non-invasive sphygmanometer - Test procedure to determine the overall system accuracy of automated non-invasive sphygmanometers. 2004


42. Leasing. [http://www.pasa.nhs.uk/PASAWeb/productsandservices/leasing](http://www.pasa.nhs.uk/PASAWeb/productsandservices/leasing)


### Appendix 1: Supplier contact details

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Tel:</th>
<th>Fax:</th>
<th>Website:</th>
<th>Email:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A&amp;D and Mars</strong></td>
<td>+44 (0)1622 669767</td>
<td>+44 (0)1622 669766</td>
<td><a href="http://www.medscope.co.uk">www.medscope.co.uk</a></td>
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</tr>
<tr>
<td>Medscope Ltd.</td>
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<tr>
<td>PO Box 1142</td>
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<tr>
<td>Maidstone Kent ME14 9EL</td>
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<tr>
<td><strong>A&amp;D</strong></td>
<td>+44 (0)1628 773233</td>
<td>+44 (0)1628 770562</td>
<td><a href="http://www.pmsinstruments.co.uk">http://www.pmsinstruments.co.uk</a></td>
<td><a href="mailto:sales@pmsinstruments.co.uk">sales@pmsinstruments.co.uk</a></td>
</tr>
<tr>
<td>PMS (Instruments) Ltd.</td>
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<td></td>
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</tr>
<tr>
<td>Waldeck House Waldeck Road Maidenhead Berkshire SL6 8BR</td>
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<tr>
<td><strong>A&amp;D, Medel, Nissei, Omron, Riester and Samsung</strong></td>
<td>+44 (0)1788 553904</td>
<td>+44 (0)1788 560820</td>
<td><a href="http://www.whitemedical.co.uk">http://www.whitemedical.co.uk</a></td>
<td><a href="mailto:enquiries@white-medical.co.uk">enquiries@white-medical.co.uk</a></td>
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<tr>
<td>Sir Frank Whittle Business Centre Great Central Way Butlers Leap Rugby Warwickshire CV21 3XH</td>
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</tr>
<tr>
<td><strong>Lloyds Pharmacy</strong></td>
<td>+44 (0)845 600 3565</td>
<td>unknown</td>
<td><a href="http://www.lloydspharmacy.com">http://www.lloydspharmacy.com</a></td>
<td>via website</td>
</tr>
<tr>
<td>Lloydspharmacy Limited Sapphire Court Walsgrave Triangle Coventry CV2 2TX</td>
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</tr>
<tr>
<td><strong>Maplin</strong></td>
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<td>+44 (0)870 4296001</td>
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<td><a href="mailto:sales@maplin.co.uk">sales@maplin.co.uk</a></td>
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<tr>
<td>National Distribution Centre Valley Road Wombwell Barnsley South Yorkshire S73 0BS</td>
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</tbody>
</table>
## Appendix 1: Supplier contact details

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<th>Supplier</th>
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<td>Medisana Healthcare UK Ltd.</td>
<td>Tel: unknown</td>
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<td><a href="http://www.medisana.co.uk">http://www.medisana.co.uk</a></td>
<td><a href="mailto:info@medisana.co.uk">info@medisana.co.uk</a></td>
</tr>
<tr>
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<td>South East London</td>
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<td>NHS Supply Chain</td>
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<td><a href="http://www.supplychain.nhs.uk">http://www.supplychain.nhs.uk</a></td>
<td><a href="mailto:info@supplychain.nhs.uk">info@supplychain.nhs.uk</a></td>
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<tr>
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<td>Fax: +44 (0)1392 360126</td>
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<td><a href="mailto:orders@superliving.co.uk">orders@superliving.co.uk</a></td>
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CEP 08035: September 2008
## Appendix 1: Supplier contact details

<table>
<thead>
<tr>
<th><strong>Panasonic</strong></th>
<th><strong>Tel:</strong> +44 (0)1708 370000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiacare Ltd.</td>
<td>Fax: +44 (0)1708 349349</td>
</tr>
<tr>
<td>Unit 1A Conqueror Court</td>
<td>website: <a href="http://www.cardiacare.co.uk">http://www.cardiacare.co.uk</a></td>
</tr>
<tr>
<td>Spilsby Road</td>
<td>email: <a href="mailto:info@cardiacare.co.uk">info@cardiacare.co.uk</a></td>
</tr>
<tr>
<td>Harold Hill</td>
<td></td>
</tr>
<tr>
<td>Romford</td>
<td></td>
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<tr>
<td>Essex</td>
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</tr>
<tr>
<td>RM3 8SB</td>
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</table>

<table>
<thead>
<tr>
<th><strong>Rossmax</strong></th>
<th><strong>Tel:</strong> +44 (0)1685 844739</th>
</tr>
</thead>
<tbody>
<tr>
<td>Williams Medical Supplies PLC</td>
<td>Fax: +44 (0)1685 844725</td>
</tr>
<tr>
<td>The Maerdy Industrial Estate</td>
<td>website: <a href="http://www.wms.co.uk">http://www.wms.co.uk</a></td>
</tr>
<tr>
<td>Rhymney</td>
<td>email: <a href="mailto:sales@wms.co.uk">sales@wms.co.uk</a></td>
</tr>
<tr>
<td>Gwent</td>
<td></td>
</tr>
<tr>
<td>NP22 5PY</td>
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</tr>
</tbody>
</table>

CEP 08035: September 2008
EU procurement procedure

Lease options
National frameworks are in place for operating leases to help the NHS procure leases more cost efficiently and effectively. The framework came into place on 1st April 2007 and runs for two years. Further details are available from the PASA website [42].

EU procedures
The Public Sector Directive (2004/18/EC) has been transposed into UK law. This has been achieved by means of the following statutory instruments:

- the Public Contracts Regulations SI 2006 No.5 (the regulations)
- the Utilities Contracts Regulations SI 2006 No. 6 (not relevant to this guide).

The regulations apply to contracts worth more than £90,319 (from January 1st 2008) [18] over their whole life, and specify the procedures to be followed for public sector contracting, including adherence to strict timetables, requirements for advertising, invitation to tender and the award of contract. Organisations undertaking a procurement exercise covered by the regulations must give all suppliers an equal opportunity to express an interest in tendering for the contract by placing a contract notice in the Official Journal of the European Union (OJEU).

At all stages of the procurement process, the purchaser must be demonstrably fair, as any decision made can be challenged by the unsuccessful suppliers.

Establishing a procurement strategy
To achieve a successful outcome, decisions need to be made on:

- whether an existing contract/agreement can be used
- the need to consider sustainable development issues
- whether EU directives apply
- the type and form of contract
- sourcing potential suppliers
- duration of contract and opportunity to review/extend
- payment schedules
- how to minimise any risks with the chosen strategy, including supplier appraisal and evaluation/clarification of suppliers’ bids.

Preparing a business case
A business case should be drafted and approved before conducting any procurement exercise. Further guidance on preparing business cases is available from the Office of Government Commerce [43] and an illustrative example is provided in the NHS PASA Operational Purchasing Procedures Manual, Procedure 1-01 [44].
The EU tendering exercise
EU procurements usually take between 4 and 6 months to complete. This needs to be taken into account in the planning stages. The length of the exercise depends on the chosen procedure (open or restricted). Further information is available from the Department of Health [45].

The procurement panel
A multidisciplinary team should be selected to guide the purchase. Representatives from clinical, user, technical, estates and financial areas should be considered.

Identifying potential suppliers
Criteria for supplier selection must be established. A supplier pre-qualification questionnaire may be employed as an initial screen to exclude unsuitable suppliers, which asks for details such as skills and experience of the service engineers.

Evaluation criteria
Performance specifications should be derived from local operational requirements, and agreed by the procurement panel. They will form the basis for assessing the adequacy of suppliers’ technical specifications, provided in response to the technical specification questionnaire.

It is important to have agreed on the performance specifications of the product as they will be used in the adjudication against company specifications.

Requests for features which are supplier-specific are not permitted under the regulations. Very specific features which are not supported by operational requirements are also not allowed.

Award of contract
Following award of the contract to the successful supplier; unsuccessful suppliers may need to be debriefed. This is at the supplier’s request.

Buyers must be aware of the ‘Alcatel’ procedure (see the Trust Operational Purchasing Procedures Manual [17], Procedure No.T-08, section 6 - ‘Mandatory Standstill Period’).

For more information on procurement please refer to the Department of Health Website [46].
Appendix 3: Data collection pro-forma

Regional Medical Physics Department, Freeman Hospital Unit, Evaluation & Calibration section

Low cost NIBP devices – assessment protocol

<table>
<thead>
<tr>
<th>Device details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer:</td>
<td></td>
</tr>
<tr>
<td>Model &amp; serial number:</td>
<td></td>
</tr>
<tr>
<td>UK Supplier:</td>
<td></td>
</tr>
<tr>
<td>Launch date (approx.):</td>
<td></td>
</tr>
</tbody>
</table>

Acceptance tests – to include a log of supplied equipment & accessories

<table>
<thead>
<tr>
<th>Completed acceptance testing</th>
<th>Comments:</th>
</tr>
</thead>
</table>

Production information – complete product information specification spreadsheet (S:\Eval\NHB\Low cost NIBP info.xlsx) to include available cuff sizes (including disposables), cuff prices and supplier servicing/calibration costs

<table>
<thead>
<tr>
<th>Completed product information spreadsheet</th>
<th>Comments:</th>
</tr>
</thead>
</table>

CE marking – based on supplied documentation including the CE marking certificate of conformance

<table>
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<tr>
<th>CE marking information</th>
<th>Comments</th>
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<td>Listed standards:</td>
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Verification of claimed clinical validation – based on supplied information, scientific literature and reference to the www.dableducational.org website

<table>
<thead>
<tr>
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<th>Comments</th>
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<td>DIN 58130</td>
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<tr>
<td>Other</td>
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</table>

- Is the validation published?
- Number of subjects
- Where clinical validation carried out
- Number of normal subjects
- Number of patients in each clinical group (e.g. AF, pre-eclampsia, etc.)
## Simulator testing
- To include pressure range tests, measurement consistency test, variable pulse rate tests, artefact tests and pulse strength tests.

### Pressure Range Tests

<table>
<thead>
<tr>
<th>Reading No.</th>
<th>60/30 (40) HR=80</th>
<th>80/50 (60) HR=80</th>
<th>100/65 (70) HR=80</th>
<th>120/80 (93) HR=80</th>
<th>150/100 (116) HR=80</th>
<th>200/150 (166) HR=80</th>
<th>255/195 (215) HR=80</th>
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### Measurement Consistency Test

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**Average ± SD**

### Variable Pulse Rate Tests

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### Simulator Heart Rate Setting (bpm)

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### Comments & Rating

1. 
2. 

---

_Saved/Derek/NIHP/Low cost NIHP review/Low cost NIHP test protocol.doc_ Issued 16.5.07 Page 2 of 4
### Simulator Artefact Setting – Tremor

<table>
<thead>
<tr>
<th>Artefact Tests</th>
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<th>Level 8</th>
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### Simulator Pulse Strength Setting

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### Comments & rating:

- **Pneumatic layout**: to assess/sketch pneumatic layout and perform overpressure test (i.e. pinching off tubing to pressure transducer)

- **User & Service manuals** (if available) – complete checklist

**Comments & ratings**: 

Comments:

Completed user & service manual checklist:  
Including cleaning, disinfection and sterilization information: 

CEP 08035: September 2008
<table>
<thead>
<tr>
<th>Features and usability including data storage and transfer</th>
<th>Rating²</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Mechanical construction including cuff &amp; tubing</td>
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<tr>
<td>Electrical construction including data transfer of results (e.g. RS232)</td>
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</tr>
<tr>
<td>Serviceability including access to static calibration mode</td>
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**Photographs** – take photographs for publication and to highlight features of interest

**Overall comments**

---

**Notes**

1. Standard Deviation is a measure of repeatability.
2. Standard user assessment ratings: Excellent, Good, Satisfactory, Poor and Very Poor.

(DRB 16 May 2007)
Buyers’ guide:
Low cost non-invasive blood pressure monitors

C A Reay
D R Bousfield
E S Colechin
J A Menes
A J Sims

Regional Medical Physics Dept
Freeman Hospital
Freeman Hospital
Newcastle upon Tyne
NE7 7DN

Tel: 0191 2137787
Fax: 0191 2130290
Email: RMPDFHevaluation@nuth.nhs.uk
Web: www.rmpd.org.uk

About CEP

The Centre for Evidence-based Purchasing (CEP) is part of the Policy and Innovation Directorate of the NHS Purchasing and Supply Agency. We underpin purchasing decisions by providing objective evidence to support the uptake of useful, safe and innovative products and related procedures in health and social care.

We are here to help you make informed purchasing decisions by gathering evidence globally to support the use of innovative technologies, assess value and cost effectiveness of products, and develop nationally agreed protocols.

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Centre for Evidence-based Purchasing
Room 152C
Skipton House
80 London Road
SE1 6HL

Tel: 020 7972 6080
Fax: 020 7975 5795
Email: cep@pasa.nhs.uk
Web: www.pasa.nhs.uk/cep

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