NHS
Purchasing and Supply Agency

Centre for Evidence-based Purchasing

Buyers' guide

Hospital grade non-invasive blood pressure monitors

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Informing procurement - Encouraging innovation

Contents

Introduction

General

This buyers' guide is intended to assist in the selection of automated non-invasive blood pressure (NIBP) monitors for use in hospitals. Information is presented in a standardised format to help purchasers prepare a short-list of devices. The eighteen models in this issue represent the state of the UK market from late 2006 to late 2007.

Several manufacturers offer a range of related models. We have attempted to represent the full range of current models and major optional additions or upgrades that are available.

Models are presented alphabetically by manufacturer. Abbreviations used in this report are defined in the Glossary (page 64).

Scope

The guide reviews hospital grade monitors selected (see Method, page 13) from the large number of automated blood pressure monitors currently available in the UK.

All 18 of the devices assessed carried out automated measurements 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).

All 18 devices were capable of making single manually initiated measurements. Twelve of them were 'automatic cycling' types. These can work unattended because they have a built-in timer to allow repeated measurements to be made at intervals from 1 to 60 or more minutes. Such devices must have overpressure safety mechanisms (see page 14) and alarms.

Two devices provided the additional facility of allowing measurements to be made using manual auscultation (see box, page 6).

National guidance

British Hypertension Society (BHS) Guidelines [1]

In 2004 the BHS issued guidelines for management of hypertension. Those relating to blood pressure measurements are:

- 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 a 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 mm/s); read blood pressure to the nearest 2mmHg; 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.

Medicines and Healthcare Products Regulatory Agency (MHRA)

In 2005 the 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 hospital grade NIBP monitors are:

- **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. Whether to scrutinize 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 [4, 5, 6] or 33 subjects [7]. 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 and composition of subjects) are published in an EU standard [8]. In June 2005, an amendment to EN-1060-3 [10] was published which requires manufacturers to follow a validation protocol which meet these criteria. Of the common protocols, three [4, 5, 6] meet these criteria of [8], but one - the "International Protocol" [7] - does not. Whether to scrutinize the results of the validation study 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 are available from the manufacturer, or were published in peer-reviewed journals.

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 [11]

- 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.

How oscillometric blood pressure monitors work [12]

- 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 [13]. The oscillometric technique may not be clinically appropriateness of t for important patient groups including pregnant women [14], diabetics [15] and those with cardiac arrhythmias. Some clinical bodies specifically state [16] 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 [4]. 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, of hospital grade NIBP monitors have dedicated service and calibration modes which allow this.

Operational considerations

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 17) found in the Market review section.

Table 1 Device considerations

Feature	Description
Model ranges	Some manufacturers have multiple models to cover all possible variants; others have a model range and list of options. In the Product information tables (page 17) beside each model range is a figure in brackets which is our estimate of the distinct model variants on offer.
Parameters	As well as NIBP some devices include additional monitoring parameters such as SpO_2 and temperature. We have identified what is offered in the most basic model and additional features from other models in a range or options available. Additional parameters (usually at extra cost) may not be important if the device is to be used solely as an NIBP monitor.
Power	All of the devices in the buyers' guide are mains and battery powered. Some provide mains by a separate adaptor—worth noting if space is limited. All batteries are recharged in situ when mains power is provided. Various battery technologies are employed e.g. Li-ion, NiMH etc.
Display	This can either be an LED numerical display with accompanying indicators, an LCD flat panel or a combination of the two. Some displays are monochromatic whilst others are colour. Users should consider whether high visibility or brightly coloured displays are important.
Memory	Most of the monitors have a measurement memory. Some only recall the last measurement made whilst others can store several hundred readings for multiple patients. All of the automatic cycling monitors (i.e. those with timed measurements) store the readings in memory for subsequent review.

Table 1 Device considerations (cont.)

Feature	Description
Printer	These can be built-in, modular or external. Modular printers are usually attached to one of the main device's side panels. A typical printer produces a narrow format (50 mm) thermal paper output with numerical data and waveform(s) where applicable. Users should consider if a printer is necessary.
Connectivity	Most monitors have an RS-232 port that allows connection to a PC or printer for downloading measurement data. Use with a PC normally requires additional software provided by the manufacturer. Other interfaces can include infra-red, nurse call, USB and Ethernet.
Automatic cycling	These are monitors which can be configured to automatically perform an NIBP measurement at a fixed interval. Automatic cycling devices are required to have an overpressure detection system independent of the normal pressure measurement system (see page 14). We have listed the intervals for each monitor in minutes; some also have continuous and STAT modes. Users should consider whether they require a monitor capable of performing automatic NIBP measurements.
Paediatric/Neonatal	All of the monitors can carry out measurements on adults. Most also offer a range of paediatric cuffs; eleven of the models are indicated for use on neonates. Automatic cycling devices are required to have an overpressure detection system that takes account of the patient category; i.e. neonates should be safeguarded by a lower overpressure limit than adults. Some devices also provide separate overpressure protection for paediatrics. Users should consider whether they require a monitor capable of performing NIBP measurements on paediatric and neonatal patients.
Cuff sizes	Most of the manufacturers supply reusable and disposable cuffs in a range of sizes. We have listed those cuffs which are available. Users should check whether suitable cuffs are available for the monitor’s intended application.

Table 1 Device considerations (cont.)

Feature	Description
Physical size and weight	These factors may be important if the monitor is to be used for transfer/transport purposes. Sizes and weights are as measured in our laboratory of a basic unit without optional add-on modules, but including batteries.
Carrying handle	All of the monitors evaluated in the buyers' guide included a carrying handle but of differing designs e.g. top mounted handles, integrated grips or flip up. The type of handle may be important to consider depending on the monitors placement and main use.
Mounting options	We have listed the various mounting options which are available. Users should check whether suitable options are available for the monitor's intended application and placement.
Training	We have listed what training the manufacturer / supplier provides. Most have competency based training courses. Some also provide training for service personnel. Users should consider what training is required and whether the manufacturer / supplier training meets their needs.
List price	We have shown the price excluding VAT of a base model or a price range of several models. In most cases these can be taken as guide prices since actual prices paid will be dependent on commercial factors.
Validation	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 16 and 59).

Additional costs

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

Accessories

Are additional accessories (supplied at extra cost) required to use the monitor e.g. wall mounting brackets or roll stands?

Consumables

Cuffs: If disposable cuffs are to be used how many will be required and in what sizes? If re-usable cuffs are to be used, what is their life expectancy?

Batteries: What is the expected operating life of a battery? How much are replacements?

Other parameters: If the NIBP monitor has been specified with additional monitoring parameters, what additional consumables are required (e.g. SpO_2 probes, temperature probes, probe covers) and at what cost?

Training

In the product information tables (page 17) found in the Market review section we have listed what training the manufacturer /supplier provides and at what cost. Most manufacturers provide competency based training courses free of charge, but some charge hourly rates. Users should consider what training is required and take any costs into account.

Servicing

Some manufacturers / suppliers also provide training for service personnel to allow hospital EBME departments to carry out routine servicing and calibration. Alternatively, service contracts are available from the manufacturers / supplier. We have listed servicing costs in the product information tables (see page 17).

Warranty

Warranty periods vary from one to three years with the option to extend (for an additional cost) on some devices. We have listed warranty periods and associated costs in the product information tables (see page 17). Users should be aware of these costs especially if they do not have access to service personnel in their organisation.

Purchasing procedures

PASA's Trust Operational Purchasing Procedures Manual provides details of the procurement process [17].

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) [18]. Further details of the process are detailed 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" [19] 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) [20]. 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, from known suppliers, validation reports and from the internet.

Establish device selection criteria

A large number of devices were identified in the price range £30 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. The subjects of this report are those devices whose base model costs £240 or more.

Low cost devices will be the subject of a separate buyers' guide.

Acquire devices

All but one of the devices were borrowed from the manufacturers to carry out the assessment protocol. The remaining device had been evaluated previously. Sometimes suppliers provided devices with extra parameters and accessories compared with the simplest model.

Assessment protocol

In the evaluation laboratory we carried out an assessment protocol (see below) to acquire information and test each device. On multi-parameter models, vital signs other than blood pressure were not tested. We used the document reproduced in Appendix 3 to record results.

Recommendations

We made recommendations based on the criteria described on page 16.

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 17). 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.

Overpressure testing

Automatic cycling monitors are required to have overpressure limitation mechanisms due to the possibility of failure when running unattended. We would expect devices complying with this standard to have two independent pressure transducers.
We would not expect non-cycling devices to meet this requirement, but since some did we applied the same test to them all. We simulated single fault conditions on the NIBP monitors by pinching off the air supply to their pressure transducers prior to and during an NIBP determination and noted the resulting behaviour. BS EN 60601-2-30:2000 [21] states that the cuff pressure must not exceed 330 mmHg under single fault conditions.

Simulator testing

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 artifact and with weak pulse.

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 [13]. 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 [5] 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 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.

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

†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.

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) [4], the US Association for the Advancement of Medical Instrumentation (ANSI/AAMI SP10-2002) [5] and the European Society of Hypertension (ESH) [7]. The first two of these require 85 subjects and the ESH requires 33 subjects.

Accuracy

O'Brien *et a*l [22] 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".

Table 2 BHS grading criteria—see O'Brien E, *et al* [4]

	Absolute difference between standard and test device		
	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
Grade	Cumulative percentage of readings		
A	60%	85%	95%
B	50%	75%	90%
C	40%	65%	85%
D	Worse than C		

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.

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 review journal; independent clinical validation study with an unpublished report; in-house clinical validation study and report
- Excellent measurement repeatability (within 1mmHg) from 30 consecutive measurements of 120/80 mmHg when tested using a repeatable [13] laboratory NIBP simulator.

Product information

Manufacturer	BiOSYS Co. Ltd	CAS Medical Systems Inc	Criticare Systems Inc
Model range (*no.of models*)	Sentry *(4)*	CAS 740 *(4)*	506N3 *(8)*
Parameters & features			
Base model	NIBP; SpO_2	NIBP	NIBP; SpO_2 (Criticare or Nellcor)
Other models	printer; trend screen	SpO_2; temperature	temperature; printer
Options in all models	temperature	printer; RS-232 and nurse-call Interface	none
Power	mains; ext. 12 V DC supply; rechargeable 7.2 V 3 Ah Li ion battery	mains; ext. 12 V DC supply; rechargeable 7.2 V 3.7 Ah NiMH battery	mains; rechargeable 6 V 7.2 Ah SLA battery
Battery charger	built-in charger	built-in charger	built-in charger
Display	LED & LCD (trend screen)	LED	LED & LCD
Memory	up to 100 measurements	up to 480 measurements	last 24 hrs - all parameters, single or multi-patient data
Printer/recorder	yes: modular	yes: external printer via infrared interface	yes: built-in
Connection interface	no	infrared; RS-232 & nurse-call	RS-232
Pressure range	0 - 300 mmHg	not specified	adult: 30 - 300 mmHg paediatric: 30 - 150 mmHg neonate: 20 - 150 mmHg
Systolic pressure range	not specified	adult: 30 - 225 mmHg neonate: 30 - 135 mmHg	adult: 25 - 280 mmHg paediatric: 35 - 130 mmHg neonate: 25 - 130 mmHg
Diastolic pressure range	not specified	adult: 15 - 220 mmHg neonate: 15 - 110 mmHg	
Pulse rate range	adult & paediatric: 30 - 250 bpm neonate: 0 - 250 bpm	adult: 30 - 240 bpm neonate: 40 - 240 bpm	30 - 240 bpm (NIBP); 20 - 300 bpm (SpO_2)
Automatic measurement cycles	2, 5, 10, 15, 30, 60 or 120 mins	1, 2, 3, 4, 5, 10, 15, 30, 60 or 90 mins	1, 2, 3, 5, 10, 15, 30, 45, 60, 120 or 240 mins
Paediatric/neonate	yes	yes	yes
Cuff sizes	reusable: infant; child; small adult; adult; large adult; thigh neonatal disposable: sizes 1 - 5	reusable and disposable: infant; small child; child; small adult; adult; large adult; x-large adult neonatal disposable: 2.5 - 5.0 cm	reusable: infant; child/small adult; adult; large arm; thigh disposable: 3 - 6 cm; 4 - 8 cm; 6 -11 cm; 7 - 13 cm; 8 - 15 cm; infant; child; small adult; adult; large arm; thigh
Physical size (H x W x D)	248 x 180 x 175 mm	170 x 215 x 75 mm	220 x 180 x 165 mm
Weight	2.9 kg	1.4 kg	3.15 kg
Mounting options	rolling stand; IV pole mount	rolling stand; swivelled hard mount (ambulance application); universal mount	rolling stand; IV pole mount
Carrying handle	yes (recessed grip)	yes; carrying case (optional)	yes
Training	user training - free of charge	competency based training; service training	competency based training - free of charge
List price (exc. VAT)	£1000 - £1400	£995 - £1395	£1,850
Servicing costs	1 year warranty - free; maintenance contract not available	£110 plus parts	2 year warranty - free; annual contract - £96 or £165 inc. repairs & parts; 5 year cover - £260 or £445 inc. repairs & parts
Validation	no evidence found	yes: ANSI/AAMI SP10 independent study & unpublished report; derived BHS grade A/A	claimed due to similarity to Criticare Poet Plus 8100 according to independent study & unpublished report; derived BHS grade A/B

Market review

Manufacturer	Datascope Corp.	Datascope Corp.	GE Medical Systems
Model range (*no.of models*)	Accutorr Plus *(5)*	Duo *(3)*	Dinamap Pro *(4)*
Parameters & features ***Base model*** ***Other models*** ***Options in all models***	NIBP SpO_2 (Masimo or Nellcor); trend screen temperature; printer; choice of battery type	NIBP SpO_2 (Masimo or Nellcor); temperature	NIBP; printer; trend screen SpO_2; temperature none
Power	mains; rechargeable 11.1 V 4.4 Ah Li ion battery rechargeable SLA battery recently discontinued	mains; rechargeable 7.2 V 6.6 Ah Li ion battery	mains; ext. 12 - 30 V DC supply; int. rechargeable 12 V 2.3 Ah SLA battery
Battery charger	built-in charger	built-in charger	built-in charger
Display	LED; LCD (trend screen)	LED	LED & LCD
Memory	up to 100 measurements	no	up to 100 measurements
Printer/recorder	yes: modular	no	yes: built-in
Connection interface	RS-232	no	RS-232
Pressure range	adult: 0 - 300 mmHg paediatric: 0 - 220 mmHg neonate: 0 - 165 mmHg	0 - 325 mmHg	adult/paediatric: 0 - 290 mmHg neonate: 0 - 145 mmHg
Systolic pressure range	adult: 55 - 260 mmHg paediatric: 55 - 160 mmHg neonate: 45 - 120 mmHg	adult: 40 - 255 mmHg paediatric: 40 - 200 mmHg	adult/paediatric: 30 - 290 mmHg neonate: 30 - 140 mmHg
Diastolic pressure range	adult: 30 - 200 mmHg paediatric: 30 - 150 mmHg neonate: 20 - 100 mmHg	adult: 10 - 210 mmHg paediatric: 10 - 150 mmHg	ault/paediatric: 10 - 220 mmHg neonate: 10 - 110 mmHg
Pulse rate range	adult/paediatric: 35 - 245 bpm neonate: 70 - 245 bpm	40 - 240 bpm	adult/paediatric: 30 - 200 bpm neonate: 30 - 220 bpm
Automatic measurement cycles	off, cont, 1, 2.5, 5, 10, 15, 20, 30, 60, 120 or 240 mins	no	1, 2, 3, 4, 5, 10, 15, 20, 30, 45, 60, 90 or 120 mins
Paediatric/neonate	yes	paediatric only	yes
Cuff sizes	reusable & disposable: small child; child; small adult; adult long; adult; large adult long; large adult; adult thigh neonatal disposable: sizes 1 - 5	reusable: child; small adult; adult long; adult; large adult disposable: child; small adult; adult long; adult	reusable & disposable: infant; child; small adult; adult; large adult; thigh; a range of neonate sizes
Physical size (H x W x D)	270 x 190 x 210 mm	243 x 130 x 140 mm	250 x 248 x 175 mm
Weight	5 kg	2.1 kg	3.5 kg
Mounting options	integrated rear panel cam-lock for pole mounting; rolling stand; wall mount; universal mounting bracket; table mount	rolling stand	rolling stand
Carrying handle	yes (recessed grip)	yes	yes (recessed grip)
Training	EBME technician training course; user training courses	EBME technician training course; user training courses	competency based training
List price (exc. VAT)	£1495 - £2695	£775 - £1575	£2547 - £3252
Servicing costs	3 year warranty - free warranty / PPM contract (1 - 4+ years): £99 - £199 per annum; non-contract hourly rate: £120 - £180	2 year warranty - free warranty / PPM contract (1 - 4+ years): £99 - £199 per annum; non-contract hourly rate: £120 - £180	3 year warranty - free; extended warranty to 5 years - £100
Validation	yes: ANSI/AAMI SP10 & BHS independent studies and peer-reveiwed publications; BHS grade A/A	yes: ANSI/AAMI SP10 in-house study and unpublished report unable to derived BHS grade from data in supplied report	yes: ANSI/AAMI SP10 independent study and peer reviewed publication BHS grade B/C

Manufacturer	GE Medical Systems	Mindray Co., Ltd.	Nissei (Nihon Seimitsu Sokki Co., Ltd.)
Model range (*no.of models*)	Dinamap ProCare *(4)*	VS-800 (5)	DM-3000 *(1)*
Parameters & features			
Base model	NIBP	NIBP; trend screen	NIBP
Other models	SpO_2; temperature	SpO_2 (Mindray, OxiMax or Masimo)	-
Options in all models	printer;	temperature; printer; choice of battery type	none
Power	ext. 12 V DC mains adaptor; rechargeable 6 V 3.3 Ah SLA battery	mains; rechargeable 12 V 2.3 Ah sealed lead acid battery; rechargeable 11.1 V 4.4 Ah Li ion battery	ext. 7 V DC mains adaptor; rechargeable 4.8 V NiMH battery
Battery charger	ext. mains adaptor	built-in charger	ext. mains adaptor
Display	LED	LED & LCD	LCD (numeric & column)
Memory	up to 40 measurements	up to 1200 measurements on up to 100 patients	single (last) measurement
Printer/recorder	yes: modular	thermal array printer	no
Connection interface	RS-232	RS-232; nurse-call; ethernet	no
Pressure range	adult/paediatric: 0 - 290 mmHg neonate: 0 - 145 mmHg	adult: 10 - 270 mmHg child: 10 - 200 mmHg neonate: 10 - 135 mmHg	0 - 300 mmHg
Systolic pressure range	adult/paediatric: 30 - 290 mmHg neonate: 30 - 140 mmHg	information not provided	50 - 250 mmHg
Diastolic pressure range	ault/paediatric: 10 - 220 mmHg neonate: 10 - 110 mmHg	information not provided	40 - 180 mmHg
Pulse rate range	adult/paediatric: 30 - 200 bpm neonate: 30 - 220 bpm	40 - 240 bpm	40 - 160 bpm
Automatic measurement cycles	1, 2, 3, 4, 5, 10, 15, 20, 30, 45, 60, 90 or 120 mins	1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240 or 480 mins	no
Paediatric/neonate	yes	yes	no
Cuff sizes	reusable & disposable: infant; child; small adult; adult; large adult; thigh; a range of neonate sizes	reusable: infant; child; adult; large adult; thigh; full range of neonate sizes	reusable: standard; large
Physical size (H x W x D)	247 x 254 x 135 mm	240 x 170 x 170 mm	276 x 136 x 206 mm
Weight	2.9 kg	3.25 kg	1.3 kg
Mounting options	rolling stand; wall mounting plate	wall mount; rolling stand; IV pole; bed mount	rolling stand
Carrying handle	yes	yes (recessed grip)	yes (recessed grip)
Training	competency based training	competency based training training for technical staff free of charge	not deemed necessary (simple device with comprehensive user guide)
List price (exc. VAT)	£1240 - £2180	£975 - £1195	£249
Servicing costs	2 year warranty - free; extended warranty to 5 years - £150	information not provided	2 year warranty - free; service charges: £25 (returned to supplier) £400/day (on-site)
Validation	yes: ESH & ANSI/AAMI SP10 independent study and peer reviewed publication derived BHS grade A/A	yes: ANSI/AAMI SP10 independent study & unpublished report derived BHS grade A/B	yes: ANSI/AAMI SP10 & ESH studies completed but not yet published derived BHS grade A/A

Manufacturer	Nonin Medical Inc.	Omron Healthcare Co., Ltd.	Philips Medical Systems
Model range (*no.of models*)	Avant 2120 *(1)*	HEM-907 *(1)*	SureSigns VS1 *(8)*
Parameters & features ***Base model*** ***Other models*** ***Options in all models***	 NIBP; SpO_2 - printer	 NIBP - none	 NIBP SpO_2; temperature; printer -
Power	ext. 12 V DC mains adaptor; rechargeable 7.2 V 4.0 Ah NiMH battery	ext. 8V DC mains adaptor; rechargeable 4.8 V 1.6 Ah NiMH battery	mains; rechargeable 6 V 5 Ah SLA battery
Battery charger	ext. mains adaptor	ext.mains adaptor	built-in charger
Display	LED	LCD	LED & LCD
Memory	up to 300 measurements	up to 3 measurements in 'Average' mode	up to 400 measurements
Printer/recorder	yes: external	no	yes: internal
Connection interface	RS-232	no	RS-232
Pressure range	0 - 300 mmHg	0 - 299 mmHg	0 - 300 mmHg
Systolic pressure range	40 - 260 mmHg	not specified	adult/paediatric: 60 - 250 mmHg neonate: 40 - 120 mmHg
Diastolic pressure range	25 - 200 mmHg	not specified	adult/paediatric: 40 - 200 mmHg neonate: 20 - 90 mmHg
Pulse rate range	up to 200 bpm	30 - 199 bpm	adult/paediatric: 40 - 200 bpm neonate: 40 - 240 bpm
Automatic measurement cycles	1, 2, 3, 5, 10, 15, 45, 60 or 90 mins	no	1, 2, 2.5, 3, 5, 10, 15, 20, 30, 60, 90, 120 or 180 mins
Paediatric/neonate	paediatric only	no	yes
Cuff sizes	reusable: small; standard; large	reusable: small; medium; large	reusable & disposable: infant; paediatric; small adult; adult; large adult; thigh neonatal disposable: sizes 1 - 4
Physical size (H x W x D)	138 x 190 x 114 mm	203 x 139 x 131 mm	258 x 210 x 285 mm
Weight	1.35 kg	1.0 kg	3.75 kg
Mounting options	rolling stand; wall bracket; pole clamp	rolling stand; wall bracket; pole mount	rolling stand
Carrying handle	yes (recessed grip); carrying case (optional)	yes (recessed grip)	yes (recessed grip)
Training	training for clinical & technical staff - free of charge	competency based training - free of charge	training - free of charge
List price (exc. VAT)	£1595	£298.58	£1325 - £2525
Servicing costs	3 year warranty on main unit, sensor & NIBP module; 1 year warranty on charger/ cord & battery pack	recalibration: free of charge under 3 year warranty; £30 after 3 years	1 year warranty
Validation	yes: ANSI/AAMI SP10 in-house study and unpublished report derived BHS grade A/A	yes: ESH & ANSI/AAMI SP10 independent studies and peer reviewed publications derived BHS grade A/B	claimed ANSI/AAMI SP10 no supporting evidence

Manufacturer	Philips Medical Systems	Schiller AG	Smiths Medical PM Inc.
Model range (*no.of models*)	SureSigns VS3 *(6)*	Argus VCM (4)	Mini-Torr Plus *(1)*
Parameters & features ***Base model*** ***Other models*** ***Options in all models***	 NIBP SpO_2; temperature; printer	 NIBP SpO_2; temperature; printer none	 NIBP - SpO_2; temperature; printer
Power	mains, rechargeable battery 11.1 V 6 Ah Li ion battery	mains; rechargeable 6 V 4 Ah SLA battery	ext. 24 V DC mains adaptor; rechargeable 6 V NiCd battery
Battery charger	buit-in charger	built-in charger	ext. mains adaptor
Display	colour LCD	LED	LED
Memory	up to 400 measurements	up to 200 measurements	Information not provided
Printer/recorder	yes: internal	yes: internal	yes; internal or external
Connection interface	USB	RS-232 nurse call via RS232	RS-232
Pressure range	not specified	0 - 300 mmHg	adult: 20 - 250 mmHg neonate: 20 - 135 mmHg
Systolic pressure range	adult/paediatric: 30 - 255 mmHg neonate: 30 - 135 mmHg	adult: 30 - 260 mmHg paediatric: 30 - 160 mmHg neonate: 25 - 120 mmHg	Information not provided
Diastolic pressure range	adult/paediatric: 15 - 220 mmHg neonate: 15 - 110 mmHg	adult: 20 - 235 mmHg paediatric: 15 - 130 mmHg neonate: 10 - 105 mmHg	Information not provided
Pulse rate range	adult/paediatric: 30 - 240 bpm neonate: 40 - 240 bpm	30 - 220 bpm	adult: 30 - 180 bpm neonate: 40 - 180 bpm
Automatic measurement cycles	1, 3, 5, 10, 15, 30, 60, 90 mins; also 'Stat'	1, 2, 3, 4, 5, 10, 15, 30, 45, 60, 90, 120 or 240 mins; also 'Stat'	1, 2, 2.5, 5, 10, 15, 20, 30, 45, 60 or 90 mins
Paediatric/neonate	yes	yes	yes
Cuff sizes	reusable & disposable: infant; paediatric; small adult; adult; large adult; thigh neonatal disposable: sizes 1 - 4	reusable: neonate sizes 1 to 4; infant; small child; child; small adult; adult; large adult; thigh	reusable: newborn; infant; small child; child; small adult; adult; large adult disposable neonate: range of sizes
Physical size (H x W x D)	215 x 255 x 150	180 x 278 x 130 mm	82 x 216 x 140 mm
Weight	3.25 kg	2.7 kg	1.6 kg
Mounting options	rolling stand; wall mount	rolling stand	rolling stand; IV pole mount
Carrying handle	yes	yes	yes (flip up)
Training	training - free of charge	on-site training: cost depends on quantity provided	Information not provided
List price (exc. VAT)	not provided	£994 - £1576	£1550 - £2150
Servicing costs	1 year warranty	annual ppm £65 ex warranty parts & labour £126 repair £90 per hour	2 year warranty
Validation	yes: ANSI/AAMI SP10 independent study & unpublished report; derived BHS grade B/A	claimed ANSI/AAMI SP10 no supporting evidence	claimed ANSI/AAMI SP10 no supporting evidence

Manufacturer	Welch Allyn, Inc.	Welch Allyn, Inc.	Welch Allyn, Inc.
Model range (*no.of models*)	Spot Vital Signs (*6*)	Spot Vital Signs Lxi (*6*)	VSM 300 (*12*)
Parameters & features ***Base model*** ***Other models*** ***Options in all models***	 NIBP SpO_2 (Masimo or Nellcor); temperature none	 NIBP; temperature (Welch Allyn or Braun) SpO_2 (Masimo or Nellcor) printer	 NIBP SpO_2 (Masimo or Nellcor); temperature; printer none
Power	ext. 7.2 V 1 A DC mains adaptor; rechargeable 6 V 4.5 Ah SLA battery	ext. 9 V 1.5 A DC mains adaptor; 6 V 6 Ah rechargeable SLA battery	ext. 8 V DC mains adaptor; rechargeable 6 V 4 Ah SLA battery
Battery charger	ext. mains adaptor	ext. mains adaptor	ext. mains adaptor
Display	LCD	LCD	LED & LCD
Memory	last measurement only	up to 50 measurements	up to 99 measurements
Printer/recorder	no	yes: external	yes: internal
Connection interface	infra-red	RS-232; USB	RS-232; nurse-call
Pressure range	0 - 300 mmHg	0 - 300 mmHg	0 - 300 mmHg
Systolic pressure range	60 - 250 mmHg	60 - 250 mmHg	adult: 30 - 260 mmHg paediatric: 30 - 160 mmHg neonate: 25 - 120 mmHg
Diastolic pressure range	30 - 160 mmHg	30 - 160 mmHg	adult: 20 - 235 mmHg paediatric: 15 - 130 mmHg neonate: 10 - 105 mmHg
Pulse rate range	40 - 200 bpm	35 - 199 bpm	30 - 220 bpm
Automatic measurement cycles	no	no	1, 3, 4, 5, 10, 15, 30, 45, 60, 90, 120 or 240 mins; also 'Stat'
Paediatric/neonate	paediatric only	paediatric only	yes
Cuff sizes	durable and disposable ranges: small child; child; small adult; adult; large adult; thigh adult	reusable: child; adult; large adult; thigh. durable & disposable ranges: infant; small child; child; small adult; adult; large adult; thigh.	reusable: neonate sizes 1 to 6; infant; small child; child; small adult; adult; large adult; thigh
Physical size (H x W x D)	246 x 145 x 120 mm	270 x 203.2 (Braun) or 190 (Welch Allyn) x 133.4 mm	168 x 254 x 152 mm
Weight	2.2 kg	3.4 kg	2.4 kg
Mounting options	options: rolling stand; wall mount; IV pole mount	rolling stand; wall mount	rolling stand; wall mount; IV pole mount
Carrying handle	yes	yes	yes (recessed grip)
Training	competency based training; cost depends on quantity of units supplied and are dealt with individually	competency based training; cost dependent on quantity of units supplied, sometimes FOC where quantities are large	competency based training handbook supplied
List price (exc. VAT)	£625 - £1165	£1280 - £1820	Information not provided
Servicing costs	annual PPM £93; fully comprehensive £185; field service call out £121; unscheduled repair £218	annual PPM £127; fully comprehensive £273; field service call out £121; unscheduled repair £218	annual PPM £155; fully comprehensive £310; field service call out £121; unscheduled repair £218
Validation	yes: ANSI/AAMI SP10 in-house testing unpublished summary report BHS grade not derivable from summary	yes: ANSI/AAMI SP10 & BHS independent study and peer reviewed publication BHS grade A/A	yes: ANSI/AAMI SP10 in-house study and unpublished report derived BHS grade A/A

Biosys Sentry

Brief description

Four models were available in the range. The base model (Sentry NS) monitored NIBP including automatic timed measurements, SpO_2 and optionally temperature. NIBP was indicated for use on all patient categories (adult, paediatric and neonate).The other three models monitored the same parameters but included a printer module, a trend display screen or both.

The monitor was operated by 16 control buttons in conjunction with nine numerical indicator displays that showed patient parameter information. An LCD panel was provided on the two models with trend display capability. A large, clearly visible alarm indicator was mounted centrally above the display area. Other indicator icons showed NIBP patient category and mains/battery status.

NIBP measurements were performed during the cuff inflation phase, followed by immediate cuff deflation when the measurement was complete; this can be faster and more comfortable for patients than conventional measurement during deflation. Pressure readings were cleared after five minutes except when SpO_2 was also being measured. A pull-out reference card was slotted underneath the case.

Summary

Validation
We could find no evidence of a clinical validation of this monitor against an appropriate protocol or standard.

Good points
Well constructed. Good measurement consistency across a range of pulse rates (SD ± 2.0 mmHg) provided that no tremor artefact was present. 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	**Model tested:** NS (NIBP, SpO_2)
• pressure range	satisfactory, SD ± 2.3 mmHg
• measurement consistency	satisfactory, SD ± 2.1 mmHg
• variable pulse rate	good, SD ± 2.0 mmHg
• susceptibility to artefact	6 misleading readings from 25 tests
• variable pulse strength	no misleading readings
• overpressure	pass
General	
• usability	good
Manuals	
• user manual	satisfactory
• service manual	satisfactory
Construction	case material: plastic
• mechanical	good
• electrical	good
• serviceability in house	satisfactory (main assembly replacement)
o battery	replaceable
• CE marking	CE_{0470}

Technical discussion

Construction
The monitor was supplied with a 3 m hose and an adult reusable cuff. The rear panel housed the battery, a recessed carrying slot (not visible in photo) and an attachment point for a pole/roll stand. There was no RS-232 port for connection to a PC.

Internally, the monitor was well constructed with a metal chassis and assemblies securely mounted. Surface mount components were used on high quality circuit boards with good component labelling. The NIBP pneumatic components consisted of two pressure sensors and two pressure release valves.

Overpressure test
With a single fault applied to either of the two pressure transducers before or during a measurement, the monitor immediately aborted the measurement and immediately displayed an error message—an acceptable outcome.

Power supply
The monitor was powered from the mains or a 7.2 V rechargeable Li-ion battery specified to provide up to one hour of operating time. It was charged in-situ when AC mains was connected; the specified recharge time was two hours.

Serviceability
The user and service manuals stated that the device should be repaired by authorised personnel only but nevertheless provided some servicing information. NIBP calibration accuracy checks and leak tests could be accessed from a service menu and fault identification procedures were given. Replacement main assembly price lists were provided by the supplier.

CAS 740

Brief description

Four models were available in the range. The base model CAS 740-1 monitored NIBP including automatic timed measurements and was indicated for use on all patient categories (adult, paediatric neonate). Other parameters available, depending on model, were SpO_2 (Masimo, Nellcor or Nonin) and temperature. An optional external printer was available with data transferred via an infrared data port.

The monitor was operated by ten control buttons in conjunction with five numeric LED displays that showed patient parameter information; there was also an LED message area.

A set of indicator icons were used to show adult or neonatal mode, SpO_2 signal strength bar, battery status and alarm status. The battery indicator had three colours: green when charging; orange when running on battery power; red when the battery was low.

The monitor had a data storage capacity of up to 480 data entries.

Summary

Validation
The NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. It was supported by means of an independent study and an unpublished report (supplied). From the data we derived its equivalent BHS grade to be A/A.

Good points
Good construction. Excellent user manual. Good measurement consistency across a range of pressures (SD ± 1.5 mmHg) provided that no tremor artefact was present. Excellent measurement consistency across a range of pulse rates (SD ± 0.9 mmHg). Gave no misleading readings when subjected to tremor artefact or low pulse strength.

Disadvantages
None identified.

Results

NIBP performance tests	**Model tested:** 740-2 (NIBP, SpO_2, temp)
• pressure range	good, SD ± 1.5 mmHg
• measurement consistency	good, SD ± 1.1 mmHg
• variable pulse rate	excellent, SD ± 0.9 mmHg
• susceptibility to artefact	gave no misleading readings
• variable pulse strength	gave no misleading readings
• overpressure[6]	pass
General	
• usability	good
Manuals	
• user manual	excellent
• service manual	good
Construction	case material: plastic
• mechanical	good
• electrical	good
• serviceability in house	good (main assembly replacement)
o battery	replaceable
• CE marking	CE_{0086}

Technical discussion

Construction
The monitor was supplied with a 3 m hose, an adult reusable cuff and a child size reusable cuff. The rear panel housed the battery and an attachment point for a variety of mounting options. An infrared data connection port was mounted on the lower panel: an optional interface unit provided a nurse call connector and an RS-232 port for connection to a PC.

Internally the monitor was well constructed, surface mount components were used on high quality circuit boards and all assemblies were securely mounted. The NIBP circuit board contained two pressure transducers.

Overpressure test
A maximum cuff pressure of 299 mmHg was recorded when a single fault condition was applied—below the permissible maximum limit.

Power supply
The monitor was powered from the mains, an external 12 V DC supply or a rechargeable 7.2 V NiMH battery with a specified capacity of 100 NIBP measurements when repeated at five-minute intervals. The battery was charged in-situ when AC mains was connected; the specified recharge time was four hours.

Serviceability
The user manual gave details on cleaning and maintenance of the unit, recommended intervals for pneumatic checks, calibration accuracy checks and replacement of the battery pack. A configuration menu enabled user preferences to be set. The service manual was good, enabling in-house servicing to main assembly replacement level.

Criticare VitalCare 506N3

Brief description

Eight models were available in the VitalCare range. The base model monitored NIBP including automatic timed measurements indicated for use on all patient categories (adult, paediatric and neonatal) and SpO_2. The seven other models provided different permutations of temperature, SpO_2 technology (Criticare or Nellcor) and printer.

The monitor (base model) was operated using ten front panel control buttons. Five numeric LED displays showed patient parameter information. A small LCD text panel showed status messages and menu information.

A further six LED icons indicated when AC power was connected, battery status, patient category and SpO_2 sensor off. An alarm silence indicator and an SpO_2 signal strength bar were provided.

NIBP measurements were performed during the cuff inflation phase, followed by immediate cuff deflation when the measurement was complete; this can be faster and more comfortable for patients than conventional measurement during deflation.

Summary

Validation
The manufacturer claimed clinical validation owing to similarity with the Criticare Poet Plus 8100 which meets the ANSI/AAMI SP10 protocol according to an unpublished report (supplied). From the data we derived its equivalent BHS grade to be A/B.

Good points
Well constructed. Good service facilities and documentation. 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
Poor measurement consistency at pulse rates below 60 bpm (SD ± 11.9 mmHg). Gave one misleading reading from 25 tests when subjected to varying degrees of tremor artefact. Failed the overpressure test.

Results

NIBP performance tests	**Model tested:** base model (NIBP, SpO_2)
• pressure range	good, (SD ± 2.0 mmHg)
• measurement consistency	excellent, (SD ± 0.6 mmHg)
• variable pulse rate	poor, (SD ± 11.9 mmHg)
• susceptibility to artefact	1 misleading reading from 25 tests
• variable pulse strength	no misleading readings
• overpressure	fail (> 400 mmHg)
General	
• usability	good
Manuals	
• user manual	excellent
• service manual	excellent
Construction	case material: plastic
• mechanical	good
• electrical	good
• serviceability in house	good (main assembly replacement)
o battery	user replaceable
• CE marking	CE_{0413}

Technical discussion

Construction
The monitor was supplied with an adult reusable cuff and a 3 m coiled hose. The unit's rear panel housed the battery, printer module (when specified) and an RS-232 port for connection to a PC. A roll stand/pole mounting point was provided.

Internally, all assemblies were securely mounted. Surface mount components were used on high quality circuit boards with good component labelling throughout. The NIBP components consisted of a single pressure transducer and two pressure release valves.

Overpressure test
The maximum cuff pressure achieved with a simulated single fault condition was 412 mmHg before the cuff was manually deflated to prevent damage—auto-cycling monitors are required to limit pressure to 330 mmHg under single fault conditions.

Power supply
The monitor was powered from the mains or a rechargeable 6 V SLA battery with an eight hour specified capacity with NIBP measurements repeating at five minute intervals. The battery was charged in-situ when AC mains was connected; the specified recharge time was four hours.

Serviceability
An excellent service manual covered configuration, planned maintenance, service testing and NIBP calibration accuracy checks. Service menus gave access to the NIBP calibration accuracy procedure using a PC connection and additional manufacturer's software (not supplied).

Datascope Accutorr Plus

Brief description

Five models were available in the Accutorr range. The base model monitored NIBP including automatic timed measurements and was indicated for use on all patient categories (adult, paediatric and neonatal). Other parameters available were SpO_2 (with a choice of Datascope, Nellcor or Masimo) and temperature modules. Four models included a trend display and a printer module was available on all models.

The monitor was operated by 15 control buttons in conjunction with seven numeric LED displays that showed patient parameter information, error codes and service information.

A set of indicator icons showed NIBP patient category, alarm status, AC power and battery status.

Models with trend option had an additional LCD—up to 100 readings were displayed.

Summary

Validation
The NIBP performance was clinically validated by independent studies using the ANSI/AAMI SP10 protocol and the British Hypertension Society (BHS) protocol, under which it was graded A/A. The work was supported by peer-reviewed publications [23, 24].

Good points
Well constructed with good documentation and service facilities. Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.5 mmHg). Good measurement consistency across a range of pulse rates (SD ± 2.0 mmHg). Gave no misleading readings when subjected to low pulse strengths.

Disadvantages
Gave two misleading readings from 25 tests when exposed to varying degrees of tremor artefact.

Results

NIBP performance tests	**Model tested:** base model (NIBP)
• pressure range	satisfactory, SD ± 2.1 mmHg
• measurement consistency	good, SD ± 1.5 mmHg
• variable pulse rate	good, SD ± 2.0 mmHg
• susceptibility to artefact	2 misleading readings from 25 tests
• variable pulse strength	gave no misleading readings
• overpressure	satisfactory (built-in self test—see below)
General	
• usability	excellent
Manuals	
• user manual	excellent
• service manual	good
Construction	case material: plastic
• mechanical	excellent
• electrical	excellent
• serviceability in house	good (main assembly replacement)
o battery	replaceable
• CE marking	CE_{0044}

Technical discussion

Construction
The monitor was supplied with a 3.5 m hose and a range of three adult reusable cuffs. The battery was housed in the monitor's base. On the rear panel was a pole/roll stand mounting point, a recessed carrying grip (not visible in photo) and an RS-232 port for connection to a PC. Internally, all assemblies were securely mounted. Surface mount components were used on high quality circuit boards with good component labelling.

Overpressure test
The service menu overpressure test gave a satisfactory result but we were unable to apply our standard simulated single fault to the NIBP assembly due to inaccessibility. It included two pressure transducers and two release valves that were broadly similar to those in the Duo (page 31), which we could test more easily and met the single fault requirements. We were therefore reasonably confident the Accutorr Plus also complied.

Power supply
The monitor was powered from the mains or a rechargeable 11.1 V Li-ion battery with a specified 9.5 hour capacity when measuring NIBP at five minute intervals. The battery was charged in-situ when AC mains was connected; the specified recharge time was 4 hours. Early models had an SLA battery option—now discontinued.

Serviceability
The service manual procedures were clearly described, including NIBP calibration accuracy checks and performance verification via a service diagnostics menu. Repair of the unit was to board/assembly replacement level—status and error codes were displayed to help identify faulty assemblies.

Datascope Duo

Brief description

Three models were available in the Duo range. The base model monitored NIBP, was indicated for use on adult and paediatric patient categories and was manually initiated only (i.e. no automatic timed measurements). The other two models included either Masimo or Nellcor SpO_2. A temperature display was built in to the front panel of the supplied model but this option was not available at the time of this report.

The monitor was operated by four control buttons below the display area.

A set of numeric LED displays showed patient parameter information and alongside them were LED indicators that gave additional information, e.g. pulse rate source (SpO_2 or NIBP), patient category, battery charging status, AC power, and NIBP start/stop.

The monitor had a battery power saving features:

- Standby invoked after 2-3 minutes of inactivity
- Auto shutoff after 13 minutes in standby

Summary

Validation
The NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. It was supported by means of an in-house study and an unpublished report (supplied). We were unable to derive a BHS grade from the data given in the supplied report.

Good points
Very well built. Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.5 mmHg) and varying pulse rates pulse rates (SD ± 0.9 mmHg). Good consistency across a range of pressures (SD ± 1.1 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	**Model tested:** NIBP, SpO_2
• pressure range	good, SD ± 1.1 mmHg
• measurement consistency	excellent, SD ± 0.5 mmHg
• variable pulse rate	excellent, SD ± 0.9 mmHg
• susceptibility to artefact	2 misleading readings from 25 tests
• variable pulse strength	gave no misleading readings
• overpressure	pass
General	
• usability	excellent
Manuals	
• user manual	good
• service manual	good
Construction	case material: plastic; rubber grip handle
• mechanical	excellent
• electrical	excellent
• serviceability in house o battery	good (main assembly replacement) replaceable
• CE marking	CE_{0044}

Technical discussion

Construction
The monitor was supplied with a 3.5 m hose and a range of three adult reusable cuffs. The battery was housed in the monitor's base and a roll stand mounting bracket was available. There was no RS-232 port for connection to a PC.

Internally all assemblies were securely mounted. Surface mount components were used on high quality circuit boards with good component labelling throughout. There were two pressure sensors and two pressure release valves.

Overpressure test (single measurement device*)
An overpressure test was performed with a simulated single fault condition applied. The monitor halted cuff inflation at 320 mmHg and an error message was displayed—a good result because standards do not require a single measurement device to comply with this test.

Power supply
The device was powered from the mains or a rechargeable 7.2 V Li-ion battery with a specified 14 hour capacity when measuring NIBP at seven minute intervals. The battery was charged in-situ when AC mains was connected; the specified recharge time was 4.5 hours.

Serviceability
The service manual procedures were clearly described and dismantling was straightforward. Diagnostic tests occurred when the monitor was switched on; if a failure occurred an error code was displayed to assist fault finding. Repair of the unit was to board/assembly replacement level. Configuration, calibration accuracy checks and testing were carried out from a menu accessible by pressing a combination of control buttons.

*Standards do not require a single measurement device to comply with this test.

GE Dinamap Pro

Brief description

Four models were available in the Dinamap Pro range. The base model (Pro 100V2) monitored NIBP including automatic timed measurements and was indicated for use on all patient categories (adult, paediatric and neonatal). The other three models included temperature, SpO_2 (Nellcor/Masimo) or both. All models had a trend display and a printer.

An LCD panel showed trends, alarms, control menus and user interface messages. A set of numeric LED displays showed patient parameter information. Other indicators included an alarm silence icon, a low battery warning and a battery charging indicator. LED intensity was controlled by automatic ambient light compensation.

The monitor was operated by four buttons and a rotary/push control knob to highlight/select menu items on the LCD panel. It detects the presence of neonatal cuffs/hoses and changes to neonatal mode automatically.

The monitor had a 'Clinician Mode', accessible by pass code, which allowed initial cuff inflation pressure to be set, NIBP calibration accuracy checks check and permanent silencing of alarms.

Summary

Validation
The NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. The work was an independent study described in a peer-reviewed publication [25]. The BHS grade was B/C. The publication acknowledged that the computational algorithm used by this device was derived and tested using intra-arterial blood pressure measurements.

Good points
Very well constructed with excellent documentation and service facilities. Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.3 mmHg). Good measurement consistency across a range of pulse rates (SD ± 1.6 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	**Model tested:** 400 V2 (NIBP,SpO_2, temp)
• pressure range	satisfactory, SD ± 3.3 mmHg
• measurement consistency	good, SD ± 1.3 mmHg
• variable pulse rate	good, SD ± 1.6 mmHg
• susceptibility to artefact	1 misleading reading from 25 tests
• variable pulse strength	gave no misleading readings
• overpressure	pass
General	
• usability	excellent
Manuals	
• user manual	good
• service manual	good
Construction	case material: plastic
• mechanical	excellent
• electrical	excellent
• serviceability in house	excellent (main assembly replacement)
o battery	replaceable
• CE marking	CE_{0086}

Technical discussion

Construction
The monitor was supplied with a 3.66 m hose and a wide range of cuffs was available; all were dual lumen. This feature was claimed to reduce measurement errors in the event of air hose kinking since both lumens were less likely to kink simultaneously. The monitor had an integrated carrying grip (not visible in the photo). The rear panel housed the battery and an integrated pole mounting rail with securing knob. Also on the rear panel was an RS-232 port for connection to a PC.

Internally, all assemblies were securely mounted. Two pressure transducers and two pressure release valves were present. All pneumatic components were encased in foam to reduce noise.

Overpressure test
We performed an overpressure test whilst applying a simulated single fault condition. The highest cuff pressure recorded was 301 mmHg, within the allowable limit.

Power supply
The device was powered from the mains, an external 24 V DC supply or a rechargeable 12 V SLA battery specified with a two hour minimum capacity. It was recharged in-situ when AC mains was connected; the specified recharge time was two hours (monitor off) or eight hours (monitor on).

Serviceability
The service manual dismantling procedure was straightforward and clear diagrams were provided. A troubleshooting guide and error codes helped to identify faults. A pass code protected service mode was similar to 'Clinician Mode' but with additional facilities including overpressure point adjustment and calibration accuracy verification.

GE Dinamap ProCare

Brief description

There were four models in the ProCare range. The base model (ProCare 100) monitored NIBP including automatic timed measurements and was indicated for use on all patient categories (adult, paediatric and neonatal). The other three models included temperature, SpO_2 (Nellcor/Masimo) or both. A printer module was optionally available on all models.

The monitor was operated by sets of buttons on both sides of the display area. A set of numeric LED displays showed patient parameter information. Other indicators included an alarm silence icon, a low battery warning and a battery charging indicator.

The monitor detects the presence of neonate cuffs/hoses and changes to neonatal mode automatically.

A protected access configuration mode included adjustments to date and time, initial inflation pressure and the alarm silence interval. Configuration changes can be saved no more than 90 times after which an error message is issued. This can be reset only by returning the monitor to a GE service centre.

A pull-out reference guide was slotted underneath the case.

Summary

Validation
The NIBP performance was clinically validated using the International Protocol of the European Society of Hypertension and ANSI/AAMI SP10. It was supported by an independent study and a peer-reviewed publication [26]. From the data we derived its equivalent BHS grade to be A/A.

Good points
Very well constructed with good documentation and service facilities. Good measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 1.5 mmHg). Good measurement consistency across a range of pressures (SD ± 1.9 mmHg). Gave no misleading readings in the presence of tremor artefact or low pulse strength.

Disadvantages
None identified.

Results

NIBP performance tests	**Model tested:** 400 (NIBP, SpO_2, temp)
• pressure range	good, SD ± 1.9 mmHg
• measurement consistency	good, SD ± 1.5 mmHg
• variable pulse rate	satisfactory, SD ± 3.5 mmHg
• susceptibility to artefact	gave no misleading readings
• variable pulse strength	gave no misleading readings
• overpressure	not tested
General	
• usability	excellent
Manuals	
• user manual	good
• service manual	good
Construction	case material: plastic
• mechanical	excellent
• electrical	excellent
• serviceability in house	good (main assembly replacement)
o battery	replaceable
• CE marking	CE_{0086}

Technical discussion

Construction
The monitor was supplied with a 3.66 m hose and a range of cuffs; all were dual lumen. This feature was claimed to reduce measurement errors in the event of an air hose kinking since both lumens were less likely to kink simultaneously. The rear panel housed the battery, a pole mounting bracket and an RS-232 port for connection to a PC. Internally, all the components were securely mounted with the NIBP assembly encased in foam to reduce noise.

Overpressure test
We were unable to apply our standard simulated single fault to the NIBP assembly due to inaccessibility. The NIBP assembly included two independent pressure sensors and two release valves that were broadly similar to those in the Dinamap Pro (page 33), which we could test more easily and met the single fault requirements. We were therefore reasonably confident the Dinamap ProCare also complied.

Power supply
The device was powered by an external 12 V mains adapter or a rechargeable 6 V SLA battery specified with a five hour minimum capacity. It was recharged in-situ when AC mains was connected; recharge time was five hours (monitor off) or eight hours (monitor on).

Serviceability
The service manual procedures were clearly described and dismantling was straightforward. Fault identification was assisted by error codes following self-tests. The service menu gave access to functional checks including pressure transducer calibration accuracy checks and leak tests. Any changes in this menu contributed to the tally of configuration changes referred to in the brief description (page 35).

Mindray VS-800

Brief description

The VS-800 monitor had five model variants of which four measured NIBP including automatic timed measurements and was indicated for use on all patient categories (adult, paediatric and neonatal). Other models monitored SpO_2 (Massimo, Nellcor or Mindray) and temperature. Options for all models included a printer and a choice of battery type.

The monitor was operated by up to 12 front panel buttons (depending on model) in conjunction with a set of LED displays that showed patient parameter information. A backlit LCD showed trend information, on-screen messages and SpO_2 waveform. Users could access simple configuration settings e.g. date and time through on-screen menus.

Other indicators included SpO_2 pulse strength, external/battery power LED, alarm silence, pressure units and patient category icons. A large alarm indicator was positioned centrally at the top of the case.

Summary

Validation
The NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. It was supported by means of an independent study and unpublished report (supplied). From the data we derived its equivalent BHS grade to be A/B for adult/paediatric patients.

Good points
Easy to use. Well constructed. Excellent measurement consistency across a range of pressures (SD ± 0.8 mmHg). Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.8 mmHg). Gave no misleading readings in the presence of tremor artefact or low pulse strength.

Disadvantages
None identified.

Results

NIBP performance tests	**Model tested:** NIBP, SpO_2
• pressure range	excellent, SD ± 0.8 mmHg
• measurement consistency	excellent, SD ± 0.8 mmHg
• variable pulse rate	satisfactory, SD ± 2.3 mmHg
• susceptibility to artefact	gave no misleading readings
• variable pulse strength	gave no misleading readings
• overpressure	pass
General	
• usability	excellent
Manuals	
• user manual	excellent
• service manual	good
Construction	case material: plastic
• mechanical	excellent
• electrical	good
• serviceability in house o battery	good (main assembly replacement) replaceable
• CE marking	CE_{0123}

Technical discussion

Construction
The monitor was supplied with a 3 m hose and an adult reusable cuff. The unit had an integrated carrying grip (not visible in the photo) and the printer (if specified) was installed in the left hand side panel. On the rear panel was a pole mounting point, an RS-232 port for connection to a PC, a nurse call connector and an Ethernet connector for use with a Mindray central monitoring system. The battery compartment was located underneath.

Internally, all assemblies were securely mounted; surface mount components were used on high quality circuit boards with good labelling throughout. Two pressure transducers were connected to a common manifold.

Overpressure test
A simulated single fault condition was applied and the resulting overpressure was measured whilst the monitor attempted to perform an NIBP determination. The maximum pressure recorded was 328 mmHg—an acceptable outcome.

Power supply
The monitor was powered from the mains or a rechargeable battery. Two types of battery were available depending on the monitor purchased: a 12 V SLA with a specified 4.5 hour capacity and an 8 hour charge time or 11.1 V Li-ion with a specified 10.5 hour capacity and an 8 hour charge time.

Serviceability
Monitor disassembly was very straightforward and was detailed in the service manual. Repair of the unit was to circuit board/assembly replacement level. A service menu gave access to pressure transducer calibration accuracy checks and a leak test.

Nissei DM-3000

Brief description

The Nissei DM-3000 was an NIBP device packaged to resemble a mercury sphygmomanometer and enabled a user to take blood pressure measurements by manual auscultation. It also had an 'automatic' setting in which the monitor measured blood pressure by the oscillometric method.

Cuff pressure was shown on a blue backlit LCD in the form of a 300 mm mercury column graduated in 2 mm steps. A separate numeric LCD showed systolic/diastolic pressure and pulse rate. A rotary knob with settings 100–280 mmHg adjusted the initial cuff inflation pressure. Once an NIBP determination had been performed the measurement readings were shown on both the column and the numeric LCD. The device had a single (last) reading memory—for automatic readings only. An LED indicator showed battery charge status: orange when charging and green when charged.

In manual auscultation mode, the cuff was inflated automatically and cuff deflation was via the monitor's internal bleed valve. The user could select a bleed rate of 2.5, 4.5 or 6.5 mmHg/sec.

A bulb inflator (not supplied) could be used with ‘pump off’ selected. This did not appear to disable the internal bleed valve but the instructions suggested that if the lowest bleed rate setting was selected, then the deflation valve on the bulb inflator could be used effectively.

Summary

Validation
At the time of writing this report studies to validate performance with respect to manual auscultation and oscillometric measurements using the ANSI/AAMI SP10 protocol and the International Protocol of the European Society of Hypertension (ESH) had been made but not yet published. The British Hypertension Society working party had approved and reviewed the auscultatory validation data. We were supplied with preliminary results from the ESH oscillometric validation, these indicated that the device passed and also met the ANSI/AAMI SP10 criteria. From this we derived an equivalent BHS grade to be A/A.

Good points
Manual auscultation facility. Excellent measurement consistency at a fixed pressure of 120/80 mmHg (SD ± 0.7 mmHg). Good measurement consistency across a range of pressures (SD ± 1.1 mmHg) provided that no tremor artefact was present. Good measurement consistency across a range of pulse rates (SD ± 1.3 mmHg) Gave no misleading readings when subjected to low pulse strengths. Inexpensive.

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

Results

NIBP performance tests	**Model tested:** DM-3000
• pressure range	good, SD ± 1.3 mmHg
• measurement consistency	excellent, SD ± 0.7 mmHg
• variable pulse rate	good, SD ± 1.3 mmHg
• susceptibility to artefact	10 misleading readings from 25 tests
• variable pulse strength	gave no misleading readings
• overpressure	> 370 mmHg
General	
• usability	oscillometric use: good manual auscultation: not assessed
Manuals	
• user manual	satisfactory
• service manual	not available
Construction	case material: plastic
• mechanical	good
• electrical	good
• serviceability in house	calibration accuracy checks only
o battery	replaceable
• CE marking	CE_{0123}

Technical discussion

Construction
The monitor was supplied with two reusable cuff sets: size adult and large adult each with a 1.5 m hose. The monitor is shown in its base unit (see photo) which included an accessory compartment and a pole mounting point. The case had a carrying grip (not visible in the photo).

Internally, surface mount components were used on high quality circuit boards with good component labelling. There was a single pressure transducer and two pressure release valves. There was no RS-232 port for connection to a PC.

Overpressure test (single measurement device*)
We tested the monitor for overpressure with a simulated single fault condition applied. We recorded a cuff pressure of 370 mmHg before releasing the pressure manually to prevent damage. The device had satisfactory means for the user to deflate the cuff immediately.

Power supply
The monitor could be powered by an external mains adaptor or a rechargeable 4.8 V NiMH battery but no operating time was specified. It was recharged in-situ when the AC mains adapter was connected with a recharge time of up to four hours.

Serviceability
No service manual was provided with the device, but the user manual contained some service information, including instructions for checking the accuracy of the pressure readings, cleaning procedures and advice stating that the monitor should be returned to the manufacturer or authorised supplier every two years for a calibration accuracy check.

*Standards do not require a single measurement device to comply with this test.

Nonin Avant 2120

Brief description

The Avant 2120 monitored NIBP with automatic timed measurements and SpO_2. The NIBP function was indicated for use on adult and paediatric patients only. There were no model variants although a compatible external printer was available.

The monitor was operated by 11 control buttons and a set of LED numerical displays. Five of them showed patient parameter information and a sixth showed a variety of other data including cuff pressure and timed measurement interval. An SpO_2 pulse strength bar graph doubled as a battery capacity indicator

A set of LED icon indicators included sensor data, alarm status and battery charging status.

The NIBP display was cleared five minutes after the last measurement. Up to 300 NIBP readings, 33.5 hours of SpO_2 and pulse rate data (not NIBP) were stored and available for download to a PC.

Summary

Validation
The NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. It was supported by means of an in-house study and an unpublished report (supplied). From the data we derived its equivalent BHS grade to be A/A.

Good points
Excellent measurement consistency across a range of blood pressures (SD ± 1.3 mmHg) and pulse rates (SD ± 0.8 mmHg). Gave no misleading readings when subject to varying degrees of tremor artefact and low pulse strengths.

Disadvantages
Failed overpressure test.

Results

NIBP performance tests	**Model tested:** Avant 2120
• pressure range	excellent, SD ± 1.3 mmHg
• measurement consistency	good, SD ± 1.2 mmHg
• variable pulse rate	excellent, SD ± 0.8 mmHg
• susceptibility to artefact	gave no misleading readings
• variable pulse strength	gave no misleading readings
• overpressure	fail
General	
• usability	good
Manuals	
• user manual	satisfactory
• service manual	not available
Construction	case material: plastic
• mechanical	good
• electrical	good
• serviceability in house	calibration accuracy checks only
o battery	replaceable
• CE marking	CE_{0123}

Technical discussion

Construction
The monitor was supplied with a 1.85 m hose and reusable cuffs of size small, standard and large. The case had a recessed carrying grip (not visible on photo) which doubled as a battery compartment cover. An RS-232 port the rear panel could be used with an external serial printer or for connection to a PC. There were facilities for a range of mounting options.

Internally, all assemblies were securely mounted. Surface mount components were used on high quality circuit boards with good component labelling throughout. There was a single pressure transducer and two pressure release valves.

Overpressure test
We tested the monitor for overpressure with a simulated single fault condition applied. The maximum cuff pressure recorded was 360 mmHg and would have continued increasing, but at this point we released the pressure manually to prevent damage—a poor result.

Power supply
The monitor was powered by an external mains adaptor or a rechargeable 7.2 V NiMH battery specified with a five hour minimum capacity. The battery was recharged in-situ when AC mains was connected; the specified recharge time was up to four hours (monitor off).

Serviceability
The user manual stated that repair was via manufacturer's agents only therefore no service manual was available. The monitor performed self-tests at power on with error codes and remedial action listed in the user manual. Also listed was a calibration accuracy check procedure for the NIBP module. Monitor configuration was via a set of miniature switches under the battery compartment cover.

Omron HEM-907

Brief description

The HEM-907 measures NIBP using the oscillometric method and had facilities for users to measure blood pressure by manual auscultation. There were no model variants.

In oscillometric mode it could be set to make a single measurement or provide an average of two or three readings taken at preset intervals (5 sec to 3 minutes). Initial inflation pressure could be set by the user or left for the device to determine for itself.

In its manual auscultation mode, inflation and deflation was not user controllable but occurred automatically while the user listens to the Korotkoff sounds. A rapid deflate button could be used as appropriate to conclude the process.

The device was operated by five front panel buttons (start, stop etc) and two rotary controls (initial pressure and function selector switch).

An LCD display was used to show systolic pressure, diastolic pressure and pulse rate. There were additional indicators for device ready, pulse level/number of irregular pulses, battery level, battery charging and external power source connected.

Summary

Validation
The performance of the HEM-907 in automated mode was clinically validated using the ANSI/AAMI SP10 protocol and the International Protocol of the European Society of Hypertension (ESH). It was supported by independent studies and peer-reviewed publications [27, 28]. From the data we derived its equivalent BHS grade to be A/B.

Good points
Excellent measurement consistency across a range of blood pressures (SD ± 0.6 mmHg) and pulse rates (SD ± 0.9 mmHg). Gave no misleading readings when subjected to low pulse strengths. Manual auscultation was possible. Inexpensive.

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

Results

NIBP performance tests	**Model tested:** HEM-907
• pressure range	excellent, SD ± 0.6 mmHg
• measurement consistency	excellent, SD ± 0.5 mmHg
• variable pulse rate	excellent, SD ± 0.9 mmHg
• susceptibility to artefact	1 misleading reading from 25 tests
• variable pulse strength	gave no misleading readings
• overpressure	see test below
General	
• usability	oscillometric mode: good manual auscultation : not assessed
Manuals	
• user manual	satisfactory
• service manual	not available
Construction	case material: plastic
• mechanical	good
• electrical	good
• serviceability in house	calibration accuracy checks only
o battery	replaceable
• CE marking	CE_{0197}

Technical discussion

Construction
The monitor was supplied with a 1 m hose and a medium size adult reusable cuff. The rear panel had a moulded grip (not visible in photo), a battery compartment and a pole/roll-stand mounting point.

Internally, the monitor was well constructed with surface mount components and high quality circuit boards. All assemblies were securely mounted. The device had a single pressure transducer and single release valve. There was no RS-232 port for connection to a PC.

Overpressure test (single measurement device*)
Standards do not require a single measurement device to comply with this test but the monitor addressed the possibility of complete transducer failure (and hence the risk of overpressure) by checking that a valid and increasing pressure reading occurred after a few seconds of inflation. Our test confirmed that this worked correctly.

Power supply
The monitor was powered from the mains or a 4.8 V rechargeable NiMH battery with a specified capacity of up to 300 NIBP tests. It was charged in-situ when AC mains was connected, taking up to 12 hours.

Serviceability
Repair was via manufacturer's agents therefore no service manual was available. However, the instruction manual gave a basic procedure (selected from the front panel 'mode' switch) to check accuracy against a calibrated pressure gauge. Cleaning instructions and battery maintenance were also provided.

*Standards do not require a single measurement device to comply with this test.

Philips SureSigns VS1

Brief description

The VS1 range comprised eight models. The base model monitored NIBP including automatic timed measurements and was indicated for use on all patient categories (adult, paediatric and neonatal). The other models added permutations of SpO_2, temperature and internal printer.

Six numeric LED displays showed patient parameter information and cuff pressure during inflation. An LCD panel showed trend data (400 data sets), control menus, user interface messages. There were eleven control buttons, five of which were used in conjunction with the LCD panel menus.

Other indicators/icons included patient category, alarm status, NIBP measurement underway, power on and battery charging—red when charging, green when charged.

The monitor had a battery power saving feature that invoked standby after five minutes of inactivity.

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
Gave no misleading readings when subjected to varying degrees of tremor artefact. Large trend data memory. Good service facilities.

Disadvantages
Poor measurement consistency at low (<60 bpm) pulse rates (SD ± 6.8 mmHg). Gave two misleading readings from 20 tests when subjected to low pulse strengths.

Note: This device range is discontinued and has been superseded by the SureSigns VS3 (page 47).

Results

NIBP performance tests	**Model tested:** NIBP, SpO_2, temp
• pressure range	satisfactory, SD ± 3.6 mmHg
• measurement consistency	satisfactory, SD ± 2.8 mmHg
• variable pulse rate	poor, SD ± 6.8 mmHg
• susceptibility to artefact	gave no misleading readings
• variable pulse strength	2 misleading readings from 20 tests
• overpressure	pass
General	
• usability	good
Manuals	
• user manual	good
• service manual	good
Construction	case material: plastic
• mechanical	good
• electrical	good
• serviceability in house	good (main assembly replacement)
o battery	replaceable
• CE marking	CE_{0123}

Technical discussion

Construction
The device was supplied with a 3.6 m hose and an adult reusable cuff. Neonatal cuffs required a different hose. On the monitor's rear panel was an integrated carrying grip (not visible in photo), the air hose connector and an RS-232 port for connection to a PC. The battery was housed in the bottom panel and the printer (when fitted) in a side panel.

Internally, all assemblies were securely mounted; surface mount components were used on high quality circuit boards with good component labelling throughout. There were two pressure transducers and two pressure release valves.

Overpressure test
A simulated single fault condition was applied and the resultant cuff pressure was measured whilst an NIBP determination was performed. The maximum pressure recorded was 304 mmHg—an acceptable outcome.

Power supply
The monitor was powered from the mains or a rechargeable 6 V SLA battery specified with a six hour operating time. It was charged in-situ when AC mains was connected; the specified recharge time was approximately four hours.

Serviceability
The service manual included a troubleshooting guide and a list of error messages. Repair of the unit was to board/assembly replacement level. Monitor configuration, performance tests and calibration accuracy checks were available from the service menu.

Philips SureSigns VS3

Brief description

The VS3 range comprised six models. The base model monitored NIBP including automated timed measurements and was indicated for use on all patient categories (adult, paediatric and neonatal). The other models added permutations of SpO_2, temperature and internal printer.

The monitor was controlled by six front panel buttons and a rotate/push 'navigation wheel' in conjunction with menus on the colour LCD panel. The panel displayed all patient parameter information and waveforms (depending on model) or trend information.

Other screen information included patient category, alarm status and battery gauge. Two LED indicators show mains and battery status information.

Summary

Validation
The NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. It was supported by means of an independent study and an unpublished report (supplied). From the data we derived its equivalent BHS grade to be B/A.

Good points
Excellent measurement consistency across a range of pressures (SD ± 0.9 mmHg). Good measurement consistency across a range of pulse rates (SD ± 1.7 mmHg). Gave no misleading readings when subjected to varying degrees of tremor artefact and low pulse strengths. Excellent build quality and serviceability.

Disadvantages
None identified.

Results

NIBP performance tests	**Model tested:** NIBP, SpO_2, temp
• pressure range	excellent, SD ± 0.9 mmHg
• measurement consistency	excellent, SD ± 0.8 mmHg
• variable pulse rate	good, SD ± 1.7 mmHg
• susceptibility to artefact	gave no misleading readings
• variable pulse strength	gave no misleading readings
• overpressure	not tested
General	
• usability	excellent
Manuals	
• user manual	good
• service manual	good
Construction	case material: plastic
• mechanical	excellent
• electrical	excellent
• serviceability in house	excellent (main assembly replacement)
o battery	replaceable
• CE marking	CE_{0123}

Technical discussion

Construction
The device was supplied with a 3 m hose and an adult reusable cuff. On the rear panel was a battery compartment, a USB port for connection to a PC and an Ethernet port for networking. On the base was a roll stand mounting point.

Internally, all assemblies were securely mounted on a metal chassis; surface mount components were used on high quality circuit boards with good component labelling throughout.

Overpressure test
The device incorporated two pressure transducers and two release valves necessary to fulfil this requirement but we were unable to carry out our standard over pressure test due to inaccessibility of the pneumatic components.

Power supply
The monitor was powered from the mains or a rechargeable11 V lithium-ion battery but no operating time was specified. It was recharged in-situ when AC mains was connected; the recharge time was not specified.

Serviceability
The monitor carried out self-tests when switched on. The service menu had a system diagnostic function and access to the pressure test /calibration accuracy check procedure. The service manual contained an extensive troubleshooting guide with a list and description of error messages.

Schiller Argus VCM

Brief description

The Argus VCM (as supplied in the UK) had four model variants. The base model monitored NIBP including automatic timed measurements and was indicated for use on all patient categories (adult, paediatric and neonatal). The other models added permutations of SpO_2 and internal printer.

The monitor was operated by nine control buttons (ten on models with printers) labelled with symbols instead of text. Patient parameter information was shown on a set of numeric LED displays. Other indicator icons included patient category, alarm status, mains connection status and battery status.

Summary

Validation
The manufacturer claimed 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 at a fixed pressure of 120/80 mmHg (SD ± 1 mmHg). Good measurement consistency across a range of simulated blood pressures (SD ± 1.7 mmHg) and across a range of pulse rates (SD ± 1.3 mmHg). Gave no misleading readings when subjected to varying degrees of tremor artefact and low pulse strengths.

Disadvantages
None identified.

Results

NIBP performance tests	**Model tested:** NIBP, SpO_2
• pressure range	good, SD ± 1.7 mmHg
• measurement consistency	excellent, SD ± 1.0 mmHg
• variable pulse rate	good, SD ± 1.3 mmHg
• susceptibility to artefact	gave no misleading readings
• variable pulse strength	gave no misleading readings
• overpressure	pass
General	
• usability	excellent
Manuals	
• user manual	excellent
• service manual	satisfactory
Construction	case material: plastic
• mechanical	excellent
• electrical	excellent
• serviceability in house	good (main assembly replacement)
o battery	replaceable
• CE marking	CE_{0434}

Technical discussion

Construction
The monitor was supplied with a 1.8 m hose and an adult reusable cuff. The rear panel had a battery compartment, an RS-232 port for connection to a PC and underneath was a roll stand mounting point. Alarm fault identification information was printed on the top panel.

Internally, all assemblies were securely mounted. Surface mount components were used on high quality circuit boards with good component labelling throughout. The NIBP assembly had two pressure transducer and two pressure release valves.

Overpressure test
We measured the cuff pressure with a simulated single fault condition applied. The maximum pressure recorded was 297 mmHg—an acceptable outcome.

Power supply
The monitor could be powered directly by mains or by a rechargeable 6 V SLA battery; operating time was stated (by the supplier) as two hours. It was recharged in-situ when AC mains was connected; the specified recharge time was up to 12 hours.

Serviceability
The manufacturer included a troubleshooting guide and an error code list. Repair of the unit was to board/assembly replacement level. The device had a dedicated service mode, entered by pressing a combination of buttons at switch-on. Facilities provided included NIBP calibration accuracy checks and pressure tests.

Smiths Mini-Torr Plus

Brief description

The Mini-Torr Plus monitored NIBP including automatic timed measurements and was indicated for use on all patient categories (adult, paediatric and neonatal). There were model variants that included SpO_2 and temperature; some models also had a built-in printer.

The monitor was operated by eleven control buttons in conjunction with six numeric LED displays (on fully equipped models) that showed patient parameter information.

Other indicator icons included an SpO_2 pulse strength bar, alarm condition with priority, alarm silenced, battery charge and low battery status.

Summary

Validation

The manufacturer claimed that the NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. However, no published evidence was found to verify this claim.

Good points

Excellent repeatability at a fixed blood pressure of 120/80 mmHg (SD ± 0.8 mmHg). Good measurement consistency across a range of simulated blood pressures (SD ± 1.5 mmHg) and a range of pulse rates (SD ± 1.3 mmHg). Gave no misleading readings when subjected to varying degrees of tremor artefact or low pulse strength settings.

Disadvantages

None identified.

Results

NIBP performance tests	from Evaluation report 01030 May 2001
• pressure range	good, SD ± 1.5 mmHg
• measurement consistency	excellent, SD ± 0.8 mmHg
• variable pulse rate	good, SD ± 1.3 mmHg
• susceptibility to artefact	gave no misleading readings
• variable pulse strength	gave no misleading readings
• overpressure	pass
General	
• usability	good
Manuals	
• user manual	excellent
• service manual	good
Construction	case material: plastic
• mechanical	satisfactory
• electrical	good
• serviceability in house	good (main assembly replacement)
o battery	replaceable (internal battery within enclosure)
• CE marking	CE_{0473}

Technical discussion

Construction
The monitor was supplied with a 3 m hose and an adult reusable cuff. The carrying handle (not visible in photo) 'flipped up' and was shaped to hook over a hospital bed rail. The case had a pole/ roll stand mounting point. On the rear panel was an RS-232 port for connection to a PC.

Internally, all assemblies were securely mounted. Surface mount components were used on high quality circuit boards with good component labelling throughout. The NIBP assembly had two pressure transducers and two pressure release valves.

Overpressure test
We tested the monitor for overpressure with a simulated single fault condition applied. The maximum cuff pressure achieved was 330 mmHg, meeting the requirements of the performance standard.

Power supply
The monitor was powered by a mains adaptor or an internal rechargeable 6 V NiCd battery with a specified capacity of six hours. It was charged in-situ when mains was connected; the specified recharge time was up to four hours.

Serviceability
The manufacturer provided a good service manual with the device. Repair was to board/assembly replacement level. If a problem was detected by self-tests, error codes were displayed to aid fault finding. The monitor had a 'system setting' mode that allowed NIBP calibration accuracy checks procedures.

Welch Allyn Spot Vital Signs

Brief description

Six models were available in the Spot Vital Signs range. The base model (4200B) monitored NIBP and was indicated for adult and paediatric patient categories, manually initiated only (i.e. no automatic timed measurements).The other five models included different permutations of SpO_2 (Nellcor or Massimo) and temperature.

The monitor was operated by five control buttons. in conjunction with a monochrome backlit LCD display. Other indicators included a battery level gauge and battery charging icon.

A configuration mode could be accessed to preset the initial cuff inflation pressure, change units of pressure (mmHg or kPa), change time of day etc.

Summary

Validation
The NIBP performance had been clinically validated using the ANSI/AAMI SP10 protocol; the results were also classified against the British Hypertension Society (BHS) protocol, under which an A/A rating was achieved. This was supported by an independent study and had been submitted for publication in a peer reviewed journal [29].

Good points
Excellent repeatability at a fixed blood pressure of 120/80 mmHg (SD ± 0.7 mmHg). Excellent measurement consistency across a range of pulse rates (SD ± 1.0 mmHg). Gave no misleading readings when subjected to low pulse strengths.

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

Results

NIBP performance tests	**Model tested:** 42N0B (NIBP, SpO_2)
• pressure range	good, SD ± 1.5 mmHg
• measurement consistency	excellent, SD ± 0.7 mmHg
• variable pulse rate	excellent, SD ± 1.0 mmHg
• susceptibility to artefact	4 misleading readings from 25 tests
• variable pulse strength	gave no misleading readings
• overpressure	> 400 mmHg
General	
• usability	good
Manuals	
• user manual	good
• service manual	satisfactory
Construction	case material: plastic
• mechanical	excellent
• electrical	satisfactory
• serviceability in house	good (main assembly replacement)
o battery	replaceable
• CE marking	CE_{0297}

Technical discussion

Construction
The monitor was supplied with a 1.5 m hose and a large adult reusable cuff. The rear panel housed the battery and had an attachment point for pole or wall mounting. A moulded carrying handle (partially obscured in photo) was integrated into the rear panel. There was no RS-232 port but an IR port enabled connection to a PC. Internally all assemblies were fixed securely. Surface mount components were used on high quality circuit boards with good component labelling throughout. The NIBP assembly had a single pressure transducer and a single release valve.

Overpressure test (single measurement device*)
We tested the monitor for overpressure with a simulated single fault condition applied. We recorded a cuff pressure of 400 mmHg before releasing the pressure manually to prevent damage. The device had satisfactory means for the user to deflate the cuff immediately.

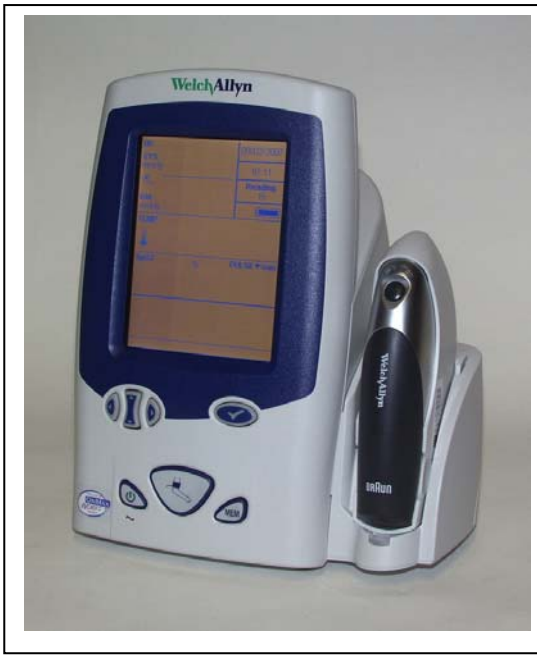
Power supply
The monitor was powered by a mains adaptor or a rechargeable 6 V SLA battery with a specified capacity of 130 NIBP measurements. It was charged in-situ when mains was connected; the specified recharge time was up to twelve hours.

Serviceability
The service manual described maintenance, calibration accuracy checks and repair procedures to board replacement level but advised they should be carried out only by personnel approved by Welch Allyn. The NIBP calibration accuracy procedure required manufacturer's separately available software and hardware.

*Standards do not require a single measurement device to comply with this test.

Welch Allyn Spot Vital Signs LXi

Brief description



Six models were available in the Spot Vital Signs LXi range. The base model (450T0) monitored NIBP and temperature. NIBP was indicated for adult and paediatric patient categories, manually initiated only (i.e. no automatic timed measurements). The other five models included different permutations of SpO_2 (Nellcor or Massimo) and temperature module. An external printer was also available.

The monitor was operated by seven control buttons in conjunction with a monochrome backlit LCD which showed patient parameter information. The user could scroll through the previous 50 NIBP readings. Other indications were a battery level gauge and mains/battery charge status. A Body Mass Index calculator was included on all models.

NIBP measurements were performed during the cuff inflation phase, followed by immediate cuff deflation when the measurement was complete; this can be faster and more comfortable to patients than conventional measurement during deflation. When pulse was weak or tremor artefact was present, it made the measurement during the cuff deflation phase.

Summary

Validation
The NIBP performance had been clinically validated using the ANSI/AAMI SP10 protocol; the results were also classified against the British Hypertension Society (BHS) protocol, under which an A/A rating was achieved. This was supported by an independent study and a peer reviewed publication [30].

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

Disadvantages
Poor response at higher (200/150 mmHg) simulated blood pressure settings (SD ± 8.0 mmHg). Gave three misleading readings from 25 tests when subjected to varying degrees of tremor artefact.

Results

NIBP performance tests	Model tested: 45NE0 (NIBP, SpO_2, temp)
• pressure range	poor, SD ± 8.0 mmHg
• measurement consistency	excellent, SD ± 0.7 mmHg
• variable pulse rate	satisfactory, SD ± 3.2 mmHg
• susceptibility to artefact	3 misleading readings from 25 tests
• variable pulse strength	gave no misleading readings
• overpressure	> 400 mmHg
General	
• usability	good
Manuals	
• user manual	good
• service manual	good
Construction	case material: plastic
• mechanical	excellent
• electrical	satisfactory
• serviceability in house	excellent (main assembly replacement)
o battery	replaceable
• CE marking	CE_{0050}

Technical discussion

Construction
The monitor was supplied with a 1.5 m hose and an adult cuff both of which were dual lumen. The rear panel housed the battery and had an attachment point for pole or wall mounting. A moulded carrying handle (partially obscured in photo) was integrated into the rear panel. Two RS-232 ports and a USB port were provided.

Internally, all assemblies were securely attached. Surface mount components were used on high quality circuit boards with good component labelling throughout. The NIBP assembly had a single pressure transducer and a single release valve.

Overpressure test (single measurement device*)
We tested the monitor for overpressure with a simulated single fault condition applied. We recorded a cuff pressure of 400 mmHg before releasing the pressure manually to prevent damage. The device had satisfactory means for the user to deflate the cuff immediately.

Power supply
The monitor was powered by a mains adaptor or a rechargeable 6 V SLA battery which was charged in-situ when mains was connected; the specified recharge time was up to six hours.

Serviceability
The service manual described maintenance, calibration accuracy checks and repair procedures to board replacement level but advised they should be carried out only by personnel approved by Welch Allyn. The NIBP calibration accuracy procedure required manufacturer's separately available software via the USB port.

*Standards do not require a single measurement device to comply with this test.

Welch Allyn VSM 300

Features and usability

Twelve models were available in the VSM range. The base model measured NIBP including automatic timed measurements and was indicated for use on all patient categories (adult, paediatric or neonatal). The other models included different permutations of SpO_2 (Masimo or Nellcor), temperature and printer. The monitor had a 99 NIBP reading memory with review facility.

The monitor was controlled by a set of up to nine control buttons (depending on model) in conjunction with LED displays which showed patient parameter information. A small LCD panel showed MAP (configuration option), NIBP timer interval, alarm limits, and status messages. Other indicator icons used were patient category, pressure units (mmHg or kPa) and battery status (low, charged or charging).

The configuration menu had facilities to enable the MAP display, select pressure units and set date and time.

Summary

Validation
The NIBP performance was clinically validated using the ANSI/AAMI SP10 protocol. It was supported by means of an in-house study and an unpublished report (supplied). From the data we derived its equivalent BHS grade to be A/A.

Good points
Excellent repeatability at a fixed blood pressure of 120/80 mmHg (SD ± 0.8 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 four misleading readings from 25 tests when subjected to varying degrees of tremor artefact.

Results

NIBP performance tests	**Model tested:** 53STP (NIBP, SpO_2, temp)
• pressure range	good, SD ± 1.5 mmHg
• measurement consistency	excellent, SD ± 0.8 mmHg
• variable pulse rate	good, SD ± 1.1 mmHg
• susceptibility to artefact	4 misleading readings from 25 tests
• variable pulse strength	gave no misleading readings
• overpressure	not tested
General	
• usability	excellent
Manuals	
• user manual	good
• service manual	satisfactory
Construction	case material: plastic
• mechanical	excellent
• electrical	excellent
• serviceability in house	good (main assembly replacement)
o battery	replaceable
• CE marking	CE_{0123}

Technical discussion

Construction
The monitor was supplied with a 1.85 m hose and an adult reusable cuff. In the rear of the case was a carrying slot (not visible in photo), a battery compartment, a nurse call connector, an RS-232 port for connection to a PC. On the base was a pole/wall-mount attachment point.

Internally, all assemblies were securely mounted to the case. Surface mount components were used on high quality circuit boards with good component labelling.

Overpressure test
The manufacturer specifies an overpressure limit of 295-330 mmHg. The design incorporated two pressure transducers and two release valves necessary to fulfil this requirement but we were unable to carry out our standard over pressure test due to inaccessibility of the pneumatic components.

Power supply
The monitor was powered by a mains adaptor or a rechargeable 6 V SLA battery with a specified minimum capacity of eight hours. It was charged in-situ when the mains was connected; the specified recharge time was up to twelve hours.

Serviceability
Error code information was given in the user manual and printed on the right hand side panel. The scope of the service manual was for preventative maintenance and repair procedures to board replacement level. A service menu gave access to an NIBP test routine and pressure measurement verification. Service utility software provided further NIBP performance tests and downloading of event logs.

Recommendations

Results

The results obtained for each device in the report are summarised in Table 3 (page 60). Three criteria were measured as described in Methods (page 13): accuracy, level of evidence and measurement repeatability.

To show which devices performed best against these criteria we have displayed the results diagrammatically in a Venn diagram, Figure 1 (page 62). It contains three overlapping circles labelled Accuracy, Level of evidence and Repeatability.

Every device is located on the diagram according to which of the criteria it satisfied. Those which satisfied all criteria are shown 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, should also be considered. Devices that satisfied only one criterion and devices which satisfied none of the criteria (those shown outside of the circles) are monitors we do not 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.

Recommended	**Automatic cycling**
Omron HEM 907	no
Welch Allyn Spot Vital Signs	no
Welch Allyn Spot Vital Signs LXi	no
Consider	
Criticare VitalCare 506N3	yes
Datascope Accutorr Plus	yes
GE Dinamap ProCare	yes
Mindray VS-800	yes
Nissei DM-3000	no
Philips SureSigns VS3	yes
Welch Allyn VSM 300	yes

> **Evaluator's note:** All of the above devices except the GE Dinamap ProCare, Mindray VS-800 and Philips SureSigns VS3 gave some misleading readings when subjected to varying degrees of tremor artefact using an NIBP simulator under test conditions—care should be taken when measuring patients' blood pressure in the presence of tremor.

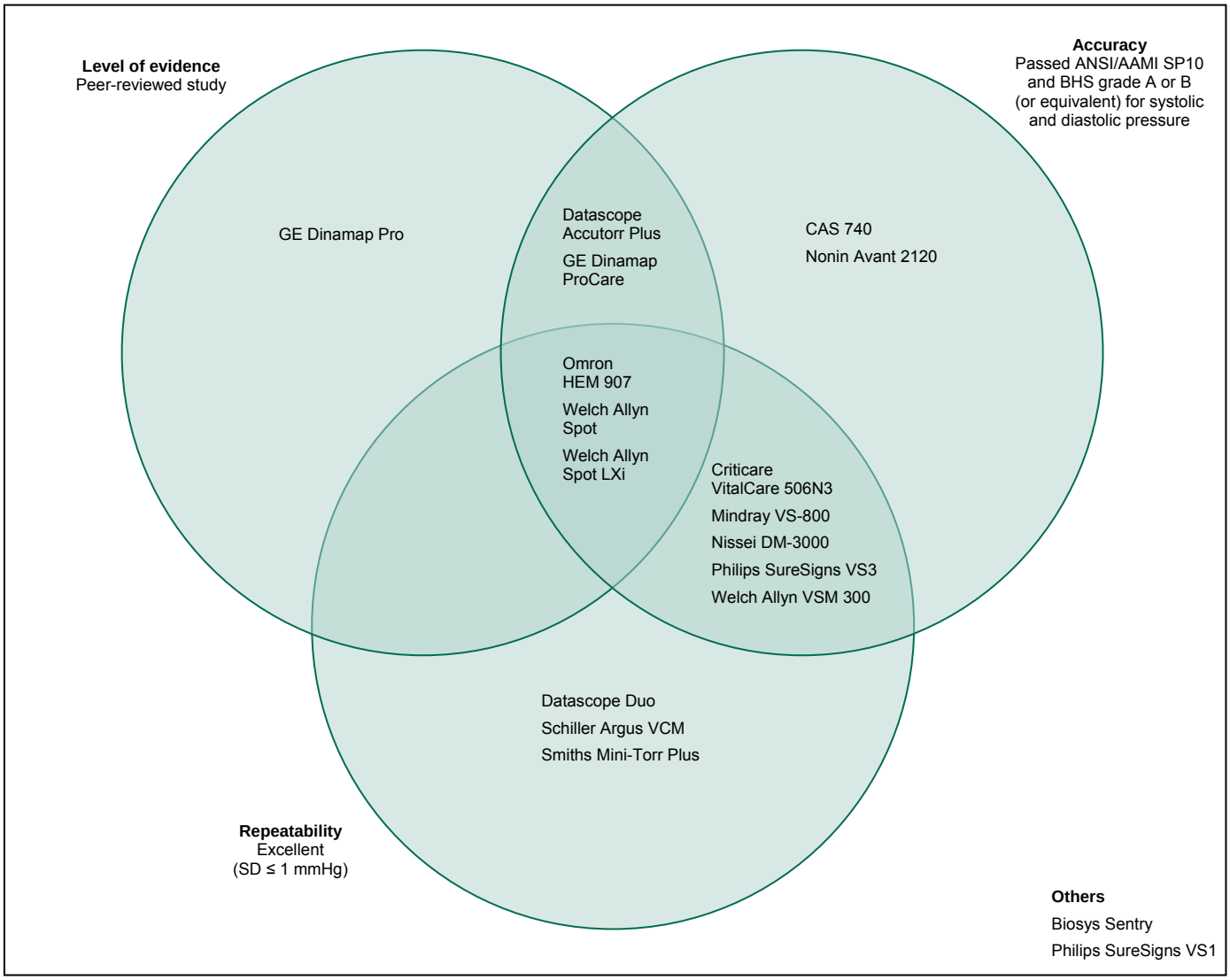
Not recommended	
Biosys Sentry (not currently available in UK - April 2008)	yes
CAS 740	yes
Datascope Duo	no
GE Dinamap Pro	yes
Nonin Avant 2120	yes
Philips SureSigns VS1 (discontinued)	yes
Schiller Argus VCM	yes
Smiths Mini-Torr Plus	yes

Table 3 Summary of results

Monitor	Accuracy	Level of evidence	Repeatability (mmHg) (30 measurements)
Biosys Sentry	n/a	We could find no evidence of a validation being performed on the device.	Satisfactory 121.0 ± 2.1 / 81.0 ± 0.8 (95.3 ± 1.0)
CAS 740	SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg Results: Pass 1.2 ± 5.8 / -1.4 ± 6.3 mmHg BHS grade A/A (derived from SP10 data)	ANSI/AAMI SP10. Unpublished independent report.	Good 124.4 ± 0.9 / 85.9 ± 1.0 (97.8 ± 1.1)
Criticare VitalCare 506N3	SP10: Mean difference less than ± 5mmHg SD less than ±8 mmHg Results: Pass -0.2 ± 5.5 / -0.4 ± 6.6 mmHg BHS grade A/B (derived from SP10 data)	Validation claimed due to similarity with Criticare Poet Plus 8100 which meets the ANSI/AAMI SP10 according to an unpublished independent report.	Excellent 118.0 ± 0.6 / 82.4 ± 0.6 (98.3 ± 0.6)
Datascope Accutorr Plus	SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg Results: Pass 0.0 ± 7.9 / 0.4 ± 5.8 mmHg BHS: A/A	ANSI/AAMI SP10 and BHS. Peer-reviewed publications [23, 24].	Good 120.0 ± 1.5 / 78.7 ± 0.9 (93.5 ± 1.0)
Datascope Duo	SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg Results: Pass 1.7 ± 5.9 / 0.2 ± 6.2 mmHg Unable to derive BHS grade from the SP10 data supplied.	The device uses a Mindray 630B NIBP module which meets the ANSI/AAMI SP10 according to an unpublished in-house report.	Excellent 125.6 ± 0.5 / 85.1 ± 0.3 (96.6 ± 0.5)
GE Dinamap Pro	SP10: Mean difference less than ± 5 mmHg SD less than ± 8mmHg Results: Fail -0.5 ± 9.8 / -2.9 ± 6.6 mmHg BHS: B/C	ANSI/AAMI SP10. Peer-reviewed published study [25] showed equivalent AAMI and BHS results.	Good 124.8 ± 1.3 / 85.8 ± 0.6 (98.7 ± 0.5)
GE Dinamap ProCare	SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg Results: Pass -2.5 ± 5.4 / 0.5 ± 4.5 mmHg ESH: phase 1 and phase 2 Results: Pass BHS grade A/A (derived from SP10 data)	ANSI/AAMI SP10 and International protocol (ESH). Peer-reviewed publication [26].	Good 124.2 ± 1.5 / 83.4 ± 1.3 (94.9 ± 0.7)
Mindray VS-800	SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg. Results: Pass -1.4 ± 5.1 / -0.2 ± 6.1 mmHg BHS: A/B (derived from SP10 data)	ANSI/AAMI SP10. Unpublished independent report.	Excellent 120.1 ± 0.8 / 84.2 ± 0.4 (94.2 ± 0.8)
Nissei DM-3000	SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg. Results: Pass -0.8 ± 6.0 / 0.8 ± 4.8 mmHg ESH: phase 1 and phase 2. Results: Pass BHS grade A/A (derived from ESH data)	At the time of writing this report the International protocol (ESH) validation study had not been published but we were supplied with preliminary results.	Excellent 121.1 ± 0.7 / 82.4 ± 0.6

Monitor	Accuracy	Level of evidence	Repeatability (mmHg) (30 measurements)
Nonin Avant 2120	SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg Results: Pass -2.3 ± 5.3 / -0.9 ± 4.5 mmHg BHS grade A/A (derived from SP10 data)	ANSI/AAMI SP10. Unpublished in-house report.	Good 121.1 ± 1.2 / 78.4 ± 0.9 (92.6 ± 0.9)
Omron HEM-907	SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg Results: Pass 1.6 ± 4.4 / 3.5 ± 4.6 mmHg ESH: phase 1 and phase 2 Results: Pass SP10 equivalent: Pass; -1.0 ± 7.0 / -5.0 ± 6.0 mmHg BHS equivalent grade A/B (stated in ESH validation paper)	ANSI/AAMI SP10 and International Protocol (ESH) Peer-reviewed publications [27, 28].	Excellent 120.5 ± 0.5 / 78.9 ± 0.4
Philips SureSigns VS1	SP10 results not supplied.	ANSI/AAMI SP10. FDA 510(k) K022537 summary states that the Colin OEM NIBP module has passed ANSI/AAMI SP10.	Satisfactory 119.1 ± 2.8 / 77.7 ± 2.1 (88.9 ± 1.9)
Philips SureSigns VS3	SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg Results: Pass 1.1 ± 6.0 / -0.5 ± 5.9 mmHg BHS grade B/A (derived from SP10 data)	The device uses a CAS NE OEM NIBP module which meets the ANSI/AAMI SP10 according to an unpublished independent report.	Excellent 125.8 ± 0.4 / 85.7 ± 0.5 (98.1 ± 0.8)
Schiller Argus VCM	n/a	Claimed validated to ANSI/AAMI SP10. We could find no evidence to substantiate the claim.	Excellent 122.3 ± 1.0 / 82.9 ± 0.8 (93.8 ± 0.5)
Smiths Mini-Torr Plus	n/a	Claimed validated to ANSI/AAMI SP10. We could find no evidence to substantiate the claim.	Excellent 112.6 ± 0.7 / 83.9 ± 0.8 (96.9 ± 0.6)
Welch Allyn Spot Vital Signs	SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg Results: Pass -1.0 ± 4.0 / -0.4 ± 6.1 mmHg BHS grade A/A	ANSI/AAMI SP10 and BHS. Submitted for publication in a peer-reviewed journal [29].	Excellent 119.6 ± 0.7 / 81.4 ± 0.5 (94.2 ± 0.4)
Welch Allyn Spot Vital Signs LXi	SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg Results: Pass -0.9 ± 7.2 / -2.2 ± 6.7 mmHg BHS: A/A	ANSI/AAMI SP10 and BHS. Peer-reviewed publication [30].	Excellent 123.4 ± 0.7 / 81.4 ± 0.5 (95.2 ± 0.4)
Welch Allyn VSM 300 Series	SP10: Mean difference less than ± 5 mmHg SD less than ± 8 mmHg Results: Pass -2.2 ± 7.0 / -1.4 ± 5.1 mmHg BHS grade A/A (derived from SP10 data)	ANSI/AAMI SP10. Unpublished in-house report.	Excellent 122.4 ± 0.8 / 84.7 ± 0.7 (94.9 ± 0.4)

Figure 1 Venn diagram of results



Acknowledgements

We would like to thank all the manufacturers and suppliers for providing information and samples for evaluation free of charge.

Glossary

Terms and abbreviations used in this report

AC	Alternating Current
BPM	Beats per minute
DC	Direct Current
IBP	Invasive Blood Pressure
NIBP	Non Invasive Blood Pressure
IR	Infrared
LCD	Liquid Crystal Display
	This type of display can be monochrome or colour.
LED	Light Emitting Diode
Li	Lithium
	A type of non-rechargeable battery cell.
Li-ion	Lithium ion
	A type of re-chargeable battery cell.
$LiMnO_2$	Lithium manganese dioxide
	A type of non-rechargeable battery cell.
NIBP	Non-invasive blood pressure
NiCd	Nickel cadmium
	A type of rechargeable battery cell.
NiMH	Nickel metal hydride
	A type of rechargeable battery cell.
MAP	Mean Arterial Pressure
PPM	Planned Preventative Maintenance
SD	Standard Deviation
SLA	Sealed Lead Acid.
	A type of rechargeable battery cell.
SMT	Surface Mount Technology
	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.
SpO_2	Oxygen saturation
STAT	An abbreviation of the Latin 'statim', meaning 'immediately'.

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36 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsProcurement/DH_4109316

Appendix 1

Supplier contact details

Biosys		
No UK supplier. At the time of writing the UK supplier had ceased supplying Biosys products.		

CAS and **Mindray**	Tel: +44 (0)1332 628877	
Artemis Medical Ltd Butterly Avenue Questor Business Park Dartford DA1 1JG	Fax: +44 (0)1322 628878	
	website:	www.artemismedical.co.uk
	email:	info@artemismedical.co.uk

Criticare and **Omron**	Tel: +44 (0)1786 446640	
R.L. Dolby & Co. Ltd. Monitor House Kerse Road Stirling FK7 7RZ	Fax: +44 (0)1786 446630	
	website:	www.dolby-ltd.co.uk
	email:	sales@dolby-ltd.co.uk

Datascope	Tel: +44 (0)1480 423600	
Datascope Medical Co. Ltd. Lakeview Court Ermine Business Park Huntingdon PE29 6XR	Fax: +44 (0)1480 423638	
	website:	www.datascope.com
	email:	uksales@datascope.com

GE Dinamap	Tel: +44 (0)1707 263570	
GE Healthcare 71 Great North Road Hatfield Hertfordshire AL9 5EN	Fax: +44 (0)1707 271013	
	website:	www.gehealthcare.com
	email:	via website

Nissei and **Omron**	Tel: +44 (0)1788 553904	
White Medical Meranti Lodge Hillmorton Lane Clifton upon Dunsmore Rugby, CV23 0BA	Fax: +44 (0)1788 560820	
	website:	www.white-medical.co.uk
	email:	enquiries@white-medical.co.uk

Appendix 1

Nonin	Tel: +44 (0)870 9097400	
Proact Medical Ltd. 9-13 Oakley Hay Lodge Great Folds Road Great Oakley Northamptonshire NN18 9AS	Fax: +44 (0)870 9097500	
	website:	www.proactmedical.co.uk
	email:	enquiries@proactmedical.co.uk

Philips	Tel: +44 (0)1625 878999	
Cardiac Services Ltd. The Acumen Centre First Avenue Poynton Manchester SK12 1FJ	Fax: +44 (0)1625 878880	
	website:	www.cardiac-services.com
	email:	via website

Schiller	Tel: +44 (0)161 7764336	
Amazon Medical Ltd. Carrington Business Park Carrington Manchester M31 4XL	Fax: +44 (0)161 7764339	
	website:	www.amazonmedical.co.uk
	email:	sales@amazonmedical.co.uk

Smiths	Tel: +44 (0) 1233 713070	
PULMOLINK Redwood House Canterbury Road Charing Kent TN27 0EU	Fax: +44 (0) 01233 713859	
	website:	www.pulmolink.co.uk
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Appendix 2

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 [32].

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 [33] and an illustrative example is provided in the NHS PASA Operational Purchasing Procedures Manual, Procedure 1-01 [34].

Appendix 2

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 [35].

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 [36].

Data collection pro-forma

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

Hospital grade NIBP devices – assessment protocol

Device details

Model & serial number:	Manufacturer:
UK Supplier:	Launch date (approx):

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

Completed acceptance testing ☐	Comments:

Production information – complete product information specification spreadsheet to include available cuff sizes (including disposables), cuff prices and supplier servicing/calibration costs

Completed product information spreadsheet ☐	Comments:

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

CE marking information	Comments
CE marking ID number: Notified body: Listed standards:	

Verification of claimed clinical validation – based on supplied information, scientific literature and reference to the www.dableducational.org website

Validation protocol claimed	Verified	Comments
BHS ☐ ANSI/AAMI SP-10 [2] ☐ DIN 58130 ☐ BS EN 1060-4 ☐ Other ☐	☐ ☐ ☐ ☐ ☐	
• Number of subjects • Where clinical validation carried out • Number of normal subjects • Number of patients in each clinical group		

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Appendix 3

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

Simulator testing - to include pressure range tests, measurement consistency test, variable pulse rate tests, artefact tests and pulse strength tests.

	Preset Simulator Setting							
Pressure Range Tests	Reading No.	60/30 (40) HR=80	80/50 (60) HR=80	100/65 (76) HR=80	120/80 (93) HR=80	150/100 (116) HR=80	200/150 (166) HR=80	255/195 (215) HR=80
	1							
	2							
	3							
	4							
	5							
	Average ± SD [3]							
Comments & rating [4]:								

Measurement Consistency Test [for a setting of 120/80 (93) HR=80]	1	2	3	4	5	6	7	8	9	10
	11	12	13	14	15	16	17	18	19	20
	21	22	23	24	25	26	27	28	29	30
Average ± SD [3]: Comments & rating [4]:										

	Simulator Heart Rate Setting (bpm)						
Variable Pulse Rate Tests [for a setting of 120/80 (93)]	Reading	40	60	80	120	160	200
	1						
	2						
	3						
	4						
	5						
	Average ± SD [3]						
Comments & rating [4]:							

Appendix 3

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

	Simulator Artefact Setting – **Tremor**					
	Reading	Level 1	Level 2	Level 4	Level 8	Level 16
Artefact Tests [for a setting of 120/80 (93) HR = 80]	1					
	2					
	3					
	4					
	5					
	Average ± SD [3]					
Comments & rating [4]:						

	Simulator Pulse Strength Setting						
	Reading	100%	75%	50%	25%	10%	100%
Pulse Strength Tests [for a setting of 120/80 (93) HR = 80]	1						
	2						
	3						
	4						
	5						
	Average ± SD [3]						
Comments & rating [4]:							

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

Assessed layout and performed overpressure test ☐	Comments:

User & Service manuals (if available) – complete checklist

Completed user & service manual checklist including cleaning and sterilization information ☐	Comments & ratings [4]:

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

Assessment of features and usability, construction & serviceability

	Rating [4]	Comments
Features and usability		
Mechanical construction including cuff & tubing		
Electrical construction		
Serviceability		

Photographs – take photographs for publication and to highlight features of interest ☐

Overall comments

Notes 1. ANSI/AAMI SP-10 Safety requirements.
2. ANSI/AAMI SP-10 Performance (validation) requirements.
3. Standard Deviation is a measure of repeatability.
4. Standard user assessment ratings: Excellent, Good, Satisfactory, Poor and Very Poor.

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Author and report information

Buyers' guide:
Hospital grade non-invasive blood pressure monitors

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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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