

PA.NET International Quality Certification Protocol for blood pressure monitors

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Although standard validation protocols provide assurance of the accuracy of blood pressure monitors (BPMs), there is no guidance for the consumer as to the overall quality of a device. The PA.NET International Quality Certification Protocol, developed by the Association for Research and Development of Biomedical Technologies and for Continuing Medical Education (ARSMED), a nonprofit organization, with the support of the Italian Society of Hypertension-Italian Hypertension League, and the dabl Educational Trust denotes additional criteria of quality for BPMs that fulfilled basic validation criteria, published in full in peer-reviewed medical journals. The certification is characterized by three phases: (i) to determine that the device fulfilled standard validation criteria; (ii) to determine the technical and functional characteristics of the device (e.g. operativity, display dimension, accessory functions, memory availability, etc.) and (iii) to determine the commercial characteristics (e.g. price-quality ratio, after-sale service, guarantee, etc.). At the end of the certification process, ARSMED attributes a quality index to the device, based on a scale ranging from 1 to 100, and a quality seal with four different grades (bronze, silver, gold and diamond) according to the achieved score. The seal is identified by a unique alphanumeric code. The quality seal may be used on the packaging of the appliance or in advertising. A quality certification is released to the manufacturer and published on

www.pressionearteriosa.net and www.dableducational.org. The PA.NET International Quality Certification Protocol represents the first attempt to provide health care personnel and consumers with an independent and objective assessment of BPMs based on their quality. *Blood Press Monit* 13:285–289 © 2008 Wolters Kluwer Health | Lippincott Williams & Wilkins.

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Introduction

In recent years, rapid technological development has led to the availability on the market of several devices for home or office blood pressure (BP) monitoring, many of which are electronic and digital. However, although these instruments are widely used by doctors and patients, they are often inaccurate [1] or not easy to use in practice [2,3]. This gives the consumer the difficult task of first ensuring that the device is accurate and then deciding on whether its quality is sufficient for his or her needs. The choice of an electronic BP monitor is all too often influenced by the marketing policies of manufacturers, distributors and retailers, who usually focus more on their profit rather than on the ability of a device to provide the user with accurate blood pressure monitoring (BPM) coupled with minimum disturbance and at a reasonable price.

With the present large diffusion of automated and semi-automated BPM devices, there is an increasing need for potential purchasers to be easily informed on whether a given device has successfully passed an evaluation based on the agreed quality criteria [4]. With this need in mind, the Association for the Advancement of Medical Instrumentation published a document defining standard accuracy requirements for electronic or aneroid sphygmomanometers in 1987 [5], which included a protocol for the evaluation of the accuracy of devices, and this was followed in 1990 by the protocol of the British Hypertension Society [6]. The British Hypertension Society and the Association for the Advancement of Medical Instrumentation protocols were revised in 1993 and 2003, respectively [7,8]. These protocols, which differ in several details, had a common objective, namely the standardization of validation procedures to establish

minimum standards of accuracy and performance, and to facilitate comparison of one device with another [9]. In 2002, the Working Group on Blood Pressure Monitoring of the European Society of Hypertension published a new International Protocol for testing the accuracy of BPM devices, which greatly simplified the validation procedure, and which is now used for validating most of the available devices [10]. Whereas previously the state-of-the-market information in relation to the accuracy of devices was published in medical journals [4], BPM device accuracy and validation status is now regularly updated on the website of the dableducational advisory board at www.dableducational.org.

However, despite a progressive increase in the number of validated monitors, the issues of quality, performance and value for money are not commonly addressed. This prevents potential purchasers from obtaining the evaluation information required to choose the BPM instrument best suited to their needs from among the numerous products available on the market [10–17].

Purpose of quality certification

With the purpose of providing comprehensive information on BPM device quality and of enabling users, including patients of hypertension or healthcare personnel, to choose the device best suited to their requirements, Association for Research and Development of Biomedical Technologies and for Continuing Medical Education (ARSMED) (a nonprofit Italian association for research and development of biomedical technologies and for continuing medical education) has developed the PA-NET International Quality Certification Protocol, which has been supported by other nonprofit organizations, namely the Italian Hypertension Society, the Italian Hypertension League and the dabl Educational Trust. The specific purpose of the protocol is to certify the quality of the BPM devices that have fulfilled the accuracy criteria of the accepted international protocols, the results of which have been published in peer-reviewed medical/scientific journals, and posted on www.dableducational.org and on www.pressionearteriosa.net websites with a recommendation for clinical use.

Methodology

The PA.NET International Quality Certification Protocol is based on objective testing of the accuracy and the technical, functional and commercial characteristics of the BPM devices. All BPM devices classified as mercury, aneroid or electronic sphygmomanometers (manual, semi-automatic or automatic), which are to be used at home, in a clinical environment (hospital, doctor's office, pharmacy, etc.) or for 24-h ambulatory monitoring, can be certified following the request of the manufacturer or distributor. The certification is carried out independently by the nonprofit organizations

promoting the protocol. A minimum fee (2000 Euros) is charged to the manufacturer or distributor requesting the certification, to cover the costs of the certification process.

Briefly, the PA.NET certification process consists of four phases.

Phase I. The device must satisfy the validation or equivalence criteria of the dableducational website and be posted as recommended for clinical use [18,19]. ARSMED has reached an agreement with dableducational to provide this information through the www.pressionearteriosa.net website.

Phase II. The device is evaluated by ARSMED for its technical and functional characteristics.

Phase III. The device costing details are ascertained.

A standard evaluation grid allows each instrument to be evaluated by assigning a partial score to each phase of the check, and a global score, which is the sum of the partial scores, with a maximum value of 100. The certifier draws up a document summarizing the data obtained during the evaluation, broken down by checking specifications, and assigns the corresponding quality index, indicated by a number on a scale from 1 to 100 and a quality mark (or seal) with four different colours, depending on the score range awarded (Fig. 1). The manufacturer or distributor can use the seal on the packaging of the appliance or in advertising, subject to authorization by the certifying body ARSMED. Each certificate is also identified by a unique alphanumeric code. The applicant (manufacturer or distributor) receives a quality certificate, which is published in the public area of the online journal www.pressionearteriosa.net, together with the evaluation document and table summarizing the salient features of the instrument.

Phase 1: check on conformity of the validation study

The first phase of certification is based on analysis of the validation study, which must have been conducted in accordance with one or more of the validation protocols [7,8,10] and whose results must have been posted on the dableducational and [pressionearteriosa](http://www.pressionearteriosa.net) website. A maximum score of 53 points can be allocated at the first phase.

The check on the validation study is performed by an expert certifier (medical expert). In addition to analysis of the publication, the company or corresponding author is asked for details confirming that the study was correctly conducted whenever such information cannot be deduced or verified from the publication.

Fig. 1



PA.NET quality seals, distinguished on the basis of the global score obtained at the certification stage (bronze: lowest score, diamond: highest score).

Table 1 Information which must be included in the published validation study

Number and type of validation studies
Number of patients recruited
Number of measurements taken per patient or in total
Inclusion pressure range
Number of patients per pressure range
Type of patients studied
Posture of patients during validation
Demographic data (age, sex, weight and height)
Information about treatments
Distribution and range of arm circumference
Site of measurement
Dimensions of the cuffs used
Table of auscultatory pressures measured at the time of recruitment
Table of results in accordance with the specific protocol
Graph of results

Only studies classified as 'recommended' on the *dabl-educational* or on the *www.pressioenarteriosa.net* websites are accepted for certification. Analysis of the publication involves checking for the presence of a number of items of information, listed in Table 1.

This phase of certification is validated by the Italian Hypertension Society–Italian Hypertension League. The required documentation is listed in Table 2.

Phase 2: check on technical and functional characteristics

In addition to the prerequisite of proven accuracy of the device, the BPM device must possess technical and

Table 2 Documentation required to check conformity of validation study to validation protocols

Full name and address of study location
Name and address of principal investigator
Names and CVs of researchers involved in the validation study
Certification of researchers' training in validation study procedures
Name and CV of the person who performed the data entry and analysis (data management)
Origin of patients (hospital inpatients, referred from outpatient clinic, or other)
Certification of quality control on data entry (procedures for checking congruence of data and validating database)
Name and characteristics of analysis program used
Specifications of monitor used as reference for the validation
Brand, model and serial number of instrument tested
List or database (anonymous) of the data of individual patients (including those excluded from the study), with all the study variables
CV, curriculum vitae.

Table 3 List of technical/functional characteristics checked during PA.NET certification

Common to all blood pressure monitoring (BPM) devices
Compliance with the safety and quality legislation in force in the country of distribution (e.g. EU Directive 93/42/EEC for Europe, and Legislative Decree no. 46 of 24/02/1997, as amended, for Italy)
Possibility of operation in the absence of instructions (first measurement in ≤ 5 min)
Availability of an instruction manual in English
Availability of an instruction manual in the language of the country of distribution
Comprehensibility of instruction manual (≤ 10 pages and availability of comprehensible schemes and figures to help the users)
Accessibility and functionality of the system that operates the instrument (pushbutton in the case of an automatic monitor, or bulb in the case of a mercury or aneroid sphygmomanometer)
Easily read display (character's height ≥ 1.5 cm)
Simplicity of cuff application (application in ≤ 20 s)
Availability of cuffs for children (supplied as standard or on request)
Availability of cuffs for obese patients (supplied as standard or on request)
Degree of discomfort for patient during inflation and deflation of cuff (interview to three users)
Electronic monitors only
Degree of difficulty in operating monitor (operativity in ≤ 1 min)
Presence of additional functions which improve its accuracy and precision
Body movement sensors
Detection of irregular heart beats
Positioning sensor for wrist devices
Rapid blood pressure detection (fuzzy logic or similar)
Simple connection of cuff tube to monitor (≤ 10 s)
Time required to measure blood pressure (≤ 20 s)
Availability of memory, and number of measurements that can be stored if the monitor has a memory
Connection to PC
If connected to a PC, degree of difficulty in regulating software settings and transferring data, and user-friendliness
Possibility of real-time processing (e.g. averaging a number of measurements)
Heart-rate detection
Apparatus integrated into a telemedicine service

PC, personal computer.

functional characteristics, which make it safe, immediate and easy to use. A series of parameters, listed in Table 3, are evaluated for this check, which involves functionality tests conducted by suitably trained and certified ARSMED experts. This phase of certification involves the assignment of a maximum of 31 points.

Phase 3: check on commercial characteristics

This phase is designed to evaluate a series of characteristics associated with the commercial and after-sale

Table 4 Commercial characteristics checked during PA.NET certification

Manufacturer or distributor with physical premises in the country in which the instrument is marketed
Number of sales outlets per inhabitant (at least 1 every 4000 inhabitants)
Even distribution of sales outlets in the country (at least 90% of the territory covered)
Evaluation of price-quality ratio (overall score of phase 2 divided by price of the device)
Type of distribution (pharmacy and/or orthopaedic/sanitary appliances and/or mass distribution)
Statutory guarantee (2 years)
Extended guarantee (>2 years)
Level of packaging (battery, information about hypertension, blood pressure diary included in pack, etc.)
Availability of after-sales service
Response times to after-sales service requests (<24h)

aspects of the instrument, listed in Table 4. A maximum score of 16 points can be given at this third phase of PA.NET certification.

First and subsequent certifications

The first PA.NET quality certification for a given instrument can be based on a number of validation studies, conducted on patients with similar or different characteristics (e.g. children, elderly people, obese patients, diabetics, dialysed patients, etc.). The availability of a number of validation studies may increase the global evaluation score of the instrument.

The first certification must be renewed annually by the applicant, to prevent it from expiring. However, a fee (400 Euros) is charged to the manufacturer or distributor only if new validation studies become available, or improvements are made to the instrument or its commercial characteristics (e.g. reduction in retail list price), requiring recertification.

If a model already certified is updated in a way that could potentially affect its accuracy (Table 5), the instrument must undergo a new certification process, provided that a validation study has been published. This appliance will not be considered a variant of the model, but a new model for all purposes.

In the case of production of a new version of a BPM device model already validated, the manufacturer must provide a copy of the certificate of conformity with current legislation filed with the government agencies, or a 'Declaration of blood pressure measuring device equivalence' issued by the dabl Educational Trust [19].

Conclusion

The PA.NET International Quality Certification Protocol represents the first standardized attempt to subject BPM devices to quality certification on a large scale, allowing a strict, objective check on validation studies, which are often rather heterogeneous in terms of performance

Table 5 Criteria for definition of nonequivalence between variants of the same model of blood pressure monitoring (BPM) device

Updating of firmware (modification of measurement algorithm)
Modifications to the error or artefact detection system, if any
Modifications to the inflation, and especially the deflation mechanism
Modifications to the microphone, if any
Modifications to the pressure transducer
Modifications to the electronic components, except for solid-state memory, the system for connection to personal computers or peripherals, and software not designed to interpret the pressure signal

procedures and presentation of results. Moreover, it enables the functionalities and technology of the instrument, and the type of marketing, to be tested in practice on the background of manufacturer's declarations. This objective, standardized evaluation should allow purchasers to choose a BPM device with greater confidence, after obtaining detailed information on its overall quality in offering easy and accurate monitoring of BP levels, which is the prerequisite for a correct diagnosis of hypertension in accordance with the guidelines [12–17].

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