

Recommendations for blood pressure measuring devices for office/clinic use in low resource settings

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This paper, which summarizes the conclusions of a WHO Expert meeting, is aimed at proposing indications to develop technical specifications for an accurate and affordable blood pressure measuring device for office/clinic use in low resource settings. Blood pressure measuring devices to be used in low resource settings should be accurate, affordable, and easily available worldwide. Given the serious inherent inaccuracy of the auscultatory technique, validated and affordable electronic devices, that have the option to select manual readings, seem to be a suitable solution for low resource settings. The agreement on the technical specifications for automated blood pressure measuring devices for office/clinic use in low resource settings included the following features: high accuracy, adoption of electronic transducers and solar batteries for power supply, standard rates of cuff inflation and deflation, adequate cuff size, digital display powered by solar batteries, facilities for adequate calibration, environmental requirements, no need of memory function, resistance to shock and temperature changes, and low cost. Availability of a device with these features should be accompanied by adequate training of health care personnel, who should guarantee

Introduction

Hypertension is as prevalent in many developing countries as in developed countries, and is an increasingly common health issue worldwide [1]. It is a major risk factor for heart attacks and strokes: approximately 62% of cerebrovascular disease (CVD) and 49% of ischaemic heart disease are attributable to sub-optimal blood pressure [2]. Worldwide, high blood pressure is estimated to cause 7.1 million deaths, with close to 4.2 million of these occurring in developing countries [2].

Blood pressure measurement in low resource settings

The treatment of hypertension has been associated with an approximate 40% reduction in the risk of stroke and 15% reduction in the risk of myocardial infarction [3]. However, in developing countries the detection of major cardiovascular risk factors, such as hypertension, is often missed. Failure to identify hypertension is largely due to the unavailability of suitable blood pressure measurement devices (BPMD) and limited attention paid to the

implementation of the procedures recommended in recent European and American Guidelines for accurate blood pressure measurement. *Blood Press Monit* 10:3–10 © 2005 Lippincott Williams & Wilkins.

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techniques and procedures necessary to obtain accurate blood pressure readings [4] (Annex I & II).

There are several barriers to accurate and affordable blood pressure measurement, particularly in developing countries. These include:

- the absence of accurate, easily-obtainable, inexpensive devices for blood pressure measurement;
- marketing of non-validated blood pressure measuring devices;
- high cost of blood pressure devices given the limited resources available;
- limited awareness of the problems associated with conventional blood pressure measurement techniques and;
- a general lack of trained manpower and limited training of personnel.

To fulfil requirements related to blood pressure measurement in low resource settings, a blood pressure measuring device should therefore be affordable and extremely simple to use, but at the same time be accurate and

robust so that it can be easily used for repeated blood pressure measurements.

World Health Organization initiatives Meeting of experts on integrated management of cardiovascular risk

In July 2002, WHO held a meeting to develop a package of tools for integrated cardiovascular risk assessment and management [5]. The resulting WHO CVD-risk management package for low- and medium-resource settings consists of clinical protocols for the management of cardiovascular risk, primarily in individuals detected to have hypertension or diabetes through opportunistic screening [6]. The availability of a reliable BPMD was considered to be a prerequisite for implementation of the package under all levels of resource availability.

The July 2002 meeting included deliberations on BPMDs. The experts supported the use of affordable, independently validated electronic devices in clinical practice. However, when the use of such devices is not feasible, there may be no alternative to the use of mercury and aneroid devices, which are inexpensive and easily portable. It was recommended that WHO, in collaboration with relevant professional associations and industry, explore the development of an accurate and affordable automated BPMD suitable for low resource settings.

Meeting of experts on accurate and affordable BPMDs for office/clinic use in low resource settings

The WHO convened a meeting of experts on 3 December 2003 in Geneva, Switzerland, to develop technical specifications for an accurate and affordable BPMD for office/clinic use in low resource settings. A list of meeting participants is provided in Annex III. The objectives of the meeting were two-fold:

1. to elaborate on the preferred type of BPMD for office/clinic use in low resource settings and;
2. to develop technical specifications for such a device.

The meeting participants addressed a variety of issues, including the future of the mercury sphygmomanometer [7,8], the importance of device accuracy and validation [4,9–11], and the current state-of-the-market [4,12,13]. From these discussions, which are summarized in Annexes I and II, recommendations and technical specifications for a BPMD for office/clinic use in low resource settings, were developed.

Recommendations on blood pressure measuring devices for office/clinic use in low resource settings

The following general recommendations were considered to be fundamental requirements that should be fulfilled

before a manufacturer gave consideration to the technical requirements for a BPMD for low resource settings.

- Blood pressure measuring devices to be used in low resource settings should be accurate, affordable, and easily available worldwide.
- Given the serious inherent inaccuracy of the auscultatory technique, validated and affordable electronic devices, that have the option to select manual readings, are the preferred option for low resource settings.
- In light of the toxicity of mercury, it is recommended that mercury blood pressure measuring devices be gradually phased out in favour of affordable, validated, professional electronic devices as these become available. However, in certain low resource settings it may be difficult to replace all mercury devices with automated devices within a short time frame. In addition, some mercury devices will need to be kept for calibration purposes. In these cases, special precautions should be taken in servicing mercury devices, in avoiding mercury spills, and in ensuring the safe disposal of non-functioning devices. Mercury devices should be serviced and calibrated at regular intervals.
- In circumstances where aneroid devices are already being used, their continued use is appropriate, provided they have been shown to be accurate not only at the time of manufacture, but also after a period of time in use. Aneroid devices should be considered only if calibrated at regular intervals (e.g., every 6 months). The need for periodic calibration, and the recommended time period between calibrations, should be clearly labelled on the device. A simple flow-chart of calibration instructions should also be provided.
- Regardless of the type of BPMD, appropriate cuff sizes should be available.
- If the BPMD uses the auscultatory technique, users should receive appropriate training and be assessed for accuracy.

Technical specifications for automated blood pressure measuring devices for office/clinic use in low resource settings

The technical specifications for automated blood pressure measuring devices for office/clinic use in low resource settings address the following features.

1. *Accuracy.* Blood pressure measuring devices should undergo a validation procedures aimed at achieving both technical and clinical validation.
 - a. Technical validation should be independently obtained by institutions identified by WHO Headquarters, and should be based on international requirements, such as those

- defined by the European Community, in order to get a CE label.
- b. Clinical validation should be independently obtained according to international protocols, such as those released by the European Society of Hypertension Working Group on Blood Pressure Measurement [11] or the Association for the Advancement of Medical Instruments [9] by comparison with blood pressure readings yielded by the conventional approach according to highly standardised procedures. Information on the state of the market and on devices that have passed a validation test according to such protocols is available on www.dableducational.com [13].
2. *Transducers and power.* Measurement should ideally derive from an electronic transducer, which can function on low power. Electronic transducers can be incorporated in semi-automatic devices, in which cuff inflation is manual, and energy is provided by solar chargers to the electronic transducer itself and to a digital display. Semi-automatic devices should allow the user to disable the automated mode and measure blood pressure manually using the auscultatory method. This is an important feature to allow clinicians to measure blood pressure in patients in whom oscillometric automatic BP measurement is inaccurate or impossible. Power should be solar charged, sufficiently for the digital display and electronic transducer, and there should be an electronic indicator that the power is adequate as well as a warning system for impending power exhaustion (e.g., a digital display should disappear if there is not enough power). The use of batteries is not recommended due to difficulties in supply and maintenance.
 3. *Cuff inflation and deflation.* Cuff inflation should be manual to save power. The cuff deflation rate should be 2–3 mmHg/s.
 4. *Cuff size.* A range of cuff sizes, or preferably a universal cuff to suit all arm circumferences, should be provided.
 5. *Digital display.* The digital display should be large and easily legible.
 6. *Calibration.* All blood pressure measurement devices require regular calibration. Calibration for devices subjected to intensive use should be repeated at regular intervals (e.g., every six months). Manufacturers should provide a simple methodology to check calibration without the need for tools or equipment. Information should be clearly provided on the need for periodical calibration of the device, and on the recommended time period or approximate number of measurements (recorded) between calibrations.
 7. *Environmental requirements.* Devices should include a temperature-stabilizing system, which allows for use in extreme weather conditions.
 8. *Memory function.* This function is not required.
 9. *Performance requirements.* The following performance requirements should be met:
 - a. durability and robustness: should allow for 10–20,000 cycles;
 - b. temperature: accurate up to 50°C;
 - c. humidity: 85%, well sealed devices;
 - d. drop test of 1 m satisfied;
 - e. vibration test satisfied.
 10. *Cost.* Cost of production should be less than 20 (euros) for validated automated/semi-automated devices.
 11. *Additional requirements.* Instructions for the use of the device, as well as information on customer service assistance, should be readily available. Manufacturers of blood pressure measuring devices for low resource settings should be able to provide distribution outlets to developing countries.

Conclusion

The purpose of this WHO initiative and publication is straightforward: it is an invitation to the world's manufacturers of BPMDs to meet a challenge, namely that of producing an affordable accurate semi-automated BPMD for use in the developing world. The requirements are clearly stated but it is recognized that the detail on technical specifications may need to be discussed further and elaborated upon. It is now up to the manufacturing industry to meet the challenge of providing the developing world with the means of accurately measuring blood pressure, so as to diagnose and manage hypertension, which is the major cause of stroke and heart attack worldwide.

Annex I

Summary of guidelines of the European Society of Hypertension for clinic blood pressure measurement (The full text and references can be obtained in reference [4])

Blood pressure measurement is the basis for the diagnosis, management, treatment, epidemiology, and research of hypertension and the decisions affecting these aspects of hypertension will be influenced for better or worse by the accuracy of measurement. An accurate blood pressure reading is a prerequisite, therefore, regardless of which

technique is used, yet all too often the accuracy of measurement is taken for granted or ignored.

Aspects of blood pressure measurement common to all techniques

Factors affecting the technique

- *Selecting an accurate device.* An accurate device is fundamental to all blood pressure measurement techniques. All devices used for blood pressure measurement should be subjected to independent evaluation according to one of the recognized protocols. Details of devices and their validation status can be obtained on www.dableducational.com—a website devoted to blood pressure measurement. This website links to other websites (such as the British Hypertension Society—www.bhsoc.org) which also give information on blood pressure measuring devices.
- *Variability of blood pressure.* No matter which measurement device is used, blood pressure will always be a variable haemodynamic phenomenon, which is influenced by many factors that include the circumstances of measurement itself, emotion, exercise, meals, tobacco, alcohol, temperature, respiration, bladder distension, and pain, and blood pressure is also influenced by age, race and diurnal variation, usually being lowest during sleep.
- *White-coat hypertension, also termed Isolated office hypertension.* White-coat hypertension (WCH) is a condition in which a subject is hypertensive during repeated clinic blood pressure measurement, but pressures measured outside the medical environment by ambulatory or self measurement techniques, are normal.
- *White-coat effect.* This is the term used to describe the rise in pressure that occurs in the medical environment regardless of the daytime ABPM level. In other words the term indicates the phenomenon found in most hypertensive patients whereby CBPM is usually higher than the average daytime ABPM, which is nonetheless elevated above normal.
- *Masked hypertension (Isolated ambulatory hypertension).* This phenomenon refers to patients in whom CBPM is normal but ABPM is elevated; in other words, hypertension is hidden until ABPM is performed.

The procedure

- *Explanation to subject.* The first step, in blood pressure measurement is adequate explanation of the procedure in an attempt to allay fear and anxiety, especially in nervous subjects.
- *Attitude of observer.* Before taking the blood pressure, the observer should be in a comfortable and relaxed position, and should not rush the procedure, otherwise, the cuff may be deflated too rapidly,

Table 1 Mismatching of bladder and arm

Bladder too narrow or too short Under-cuffing	Overestimation of BP—'cuff hypertension' Range of error: 3.2/2.4 to 12/8 mmHg, as much as 30 mmHg in obesity
Bladder too wide or too long Over-cuffing	Underestimation of BP Range of error: 10 to 30 mmHg
Under-cuffing more common than over-cuffing	

BP, blood pressure.

Table 2 Recommended bladder dimensions for adults

British Hypertension Society	
Standard cuff	Bladder 12 × 26 cm for the majority of adult arms
Large cuff	Bladder 12 × 40 cm for obese arms
Small cuff	Bladder 12 × 18 cm for lean adult arms and children
American Heart Association	
Small adult cuff	Bladder 10 × 24 for arm circumference 22–26 cm
Adult cuff	Bladder 13 × 30 for arm circumference 27–34 cm
Large adult cuff	Bladder 16 × 38 for arm circumference 35–44 cm
Adult thigh cuff	Bladder 20 × 42 for arm circumference 45–52 cm

resulting in underestimation of systolic and overestimation of diastolic pressures.

- *Attitude of patient.* Patients should be encouraged to relax and advised that neither they nor the observer should talk to each other for the few minutes before and during the blood pressure measurement.
- *Posture of subject.* Blood pressure should be measured with the subject sitting with back support, legs uncrossed and the arm should be supported at heart level. Some patients may exhibit postural hypotension, especially with certain antihypertensive drugs. When this is likely, blood pressure should be measured standing.
- *Which arm.* Bilateral measurements should be made on first consultation and if persistent differences greater than 20 mmHg for systolic or 10 mmHg for diastolic pressure are present on consecutive readings, the patient should be referred to a cardiovascular centre for further evaluation with simultaneous bilateral measurement and the exclusion of arterial disease.
- *The cuff and bladder.* However sophisticated a blood pressure measuring device may be, if it is dependent on cuff occlusion of the arm (as are the majority of devices), it will then be prone to the inaccuracy induced by miscuffing, whereby a cuff contains a bladder that is either too long or too short relative to arm circumference (Table 1). The recommendations of the British Hypertension Society and the American Heart Association are shown in Table 2.

Factors common to the subject

Certain groups of people merit special consideration for blood pressure measurement. These include children; the elderly, who often have isolated systolic hypertension or autonomic failure with postural hypotension; obese people in whom the inflatable bladder may be too small for the arm size leading to 'cuff hypertension'; patients with arrhythmias in whom blood pressure measurement may

be difficult and the mean of a number of measurements may have to be estimated; pregnant women in whom the disappearance of sounds (fifth phase) is the most accurate measurement of diastolic pressure except when sounds persist to zero when the fourth phase of muffling of sounds should be used; and subjects during exercise.

Clinic (conventional/office) sphygmomanometry

Basic requirements for auscultatory blood pressure measurement

The accurate measurement of blood pressure in clinical practice by the century-old technique of Riva Rocci/Korotkoff is dependent on the subject, the equipment used and the observer. Errors in measurement can occur at each of these interaction points of the technique, but by far the most fallible component is the observer.

- *Observer error.* Observer error, which can greatly affect accuracy of measurement falls into three categories (Table 3).
- *Mercury and aneroid sphygmomanometers.* The mercury sphygmomanometer is a reliable device, but all too often its continuing efficiency has been taken for granted, whereas the aneroid manometer is not generally as accurate. An inflation/deflation system, an occluding bladder encased in a cuff, and auscultation using a stethoscope are features common to these devices, any of which may introduce error. Users should be aware of the hazards of mercury, which may soon be banned from use in clinical medicine. Aneroid sphygmomanometers register pressure through a bellows and lever system, which may become inaccurate with everyday use, usually leading to falsely low readings with the consequent underestimation of blood pressure. A stethoscope should be of a high quality with clean, well-fitting earpieces.
- *Automated alternative devices to the mercury sphygmomanometer.* Given the increasing concern for mercury toxicity, mercury sphygmomanometers are likely to be banned from clinical practice in the near future. Alternative solutions need therefore to be explored, among which a

Table 3 Observer error

Systematic error	Intra- and inter-observer error
Terminal digit preference	Rounding to digit preference—often zero
Observer prejudice or bias	Adjustment of pressure to suit observer

Table 4 Auscultatory sounds

Phase I	The first appearance of faint, repetitive, clear tapping sounds which 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.
Auscultatory gap	In some patients sounds may disappear altogether for a short time.
Phase III	The return of sharper sounds, which become crisper to regain, or even exceed the intensity of phase I sounds. The clinical significance, if any, to phases II and III has not been established.
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.

role has been suggested for automated blood pressure measuring devices. An accurate automated sphygmomanometer capable of providing print-outs of systolic and diastolic blood pressure, together with heart rate and the time and date of measurement should eliminate errors of interpretation and abolish observer bias and terminal digit preference, and should be used when possible. Moreover, the need for elaborate training as described above would no longer be necessary, although a period of instruction and assessment of proficiency in using the automated device will always be necessary.

Performing auscultatory measurement

- The observer should ensure that the manometer is no more than 3 feet away so that the scale can be read easily, that the mercury column is vertical, that the bladder dimensions are accurate and if the bladder does not completely encircle the arm its centre must be over the brachial artery.
- The stethoscope should be placed gently over the brachial artery at the point of maximal pulsation; the cuff should then be inflated rapidly to about 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 auscultatory phenomena described in Table 4 will be heard.
- Disappearance of sounds, or the first mmHg level at which the sounds are no longer audible (phase V) should be taken as diastolic pressure except when sounds persist down to zero, when muffling of sounds (phase IV) should be recorded for diastolic pressure.
- The points listed in Table 5 should be recorded.

Table 5 What to note when measuring blood pressure

Patient state—	anxious, relaxed
Time of drug	ingestion
Note position—	lying, sitting or standing
Note arm—	right or left
Note bladder	size
Auscultatory	gap
Diastolic BP—	phases IV and V
Measurements	made to the nearest 2 mmHg
BP should not	be rounded off to the nearest 5 or 10 mmHg—digit preference
BP should be	written down as soon as it has been recorded
Take at least	two measurements at 1 min intervals

BP, blood pressure.

Annex II

Overview of blood pressure measurement techniques and devices

Blood pressure measuring techniques

The auscultatory technique

The auscultatory technique for measuring blood pressure consists of the transmission and interpretation of a signal (Korotkoff sound) from a subject via a device (mercury or aneroid sphygmomanometer) to an observer [15]. This technique requires that observers be trained and assessed for accuracy and auditory acuity, and requires a good quality stethoscope. Although the auscultatory technique has remained essentially unchanged for over a century, there is now widespread acknowledgement that it is an inherently inaccurate method [4,16,17]. In particular, the estimation of diastolic blood pressure using the auscultatory technique is limited in accuracy. Moreover, the auscultatory approach is subject to observer error such as digit preference and observer bias [18].

The oscillometric technique

The oscillometric technique is based on the detection of variations in pressure oscillations due to arterial wall movement beneath an occluding cuff. Empirically derived algorithms are utilized, which calculate systolic and diastolic blood pressure.

The palpatory technique

The use of the simple palpatory technique for the identification of systolic blood pressure may have a role in low resource settings.

Blood pressure measuring devices

Current options for blood pressure measuring devices include mercury sphygmomanometers, aneroid manometers, semi-automatic devices and fully automatic electronic devices.

Mercury sphygmomanometers

Historically, blood pressure measurements have been obtained through the use of mercury column sphygmomanometers, which rely on the auscultatory technique. In spite of the accuracy and affordability of mercury devices, these may have a limited future due to increasing concerns about the toxicity of mercury for users and/or service personnel, and for the environment in general [7,8]. Some countries have recommended that mercury sphygmomanometers be replaced, while others have banned the use of mercury altogether. However, to ensure that new devices conform to recommended validation protocols, the mercury sphygmomanometer will have to be retained as a gold standard in designated laboratories.

Aneroid sphygmomanometers

Aneroid devices are inexpensive and portable, and as such have been proposed as an alternative to mercury sphygmomanometers. However, the accuracy of the

bellow-and-lever system through which aneroid manometers register pressure is subject to the jolts and bumps of everyday use, often leading to false readings and the consequent under- or overestimation of blood pressure. Thus, they are less accurate than mercury sphygmomanometers [15]. There are shockproof aneroid sphygmomanometers available, however these are substantially more expensive. Aneroid sphygmomanometry is also limited by the problems common to the auscultatory technique, such as observer bias and terminal digit preference.

Aneroid devices require regular calibration, namely they should be checked at regular intervals (e.g., every 6 months) against an accurate mercury sphygmomanometer over the entire pressure range. This can be achieved by connecting the aneroid sphygmomanometer, via a Y-piece, to the tubing of the mercury sphygmomanometer and inflating the cuff around a bottle or cylinder. Aneroid devices can also be calibrated against a water column, where 1.6 m of water = 120 mmHg.

As mercury sphygmomanometers are removed from clinical practice there is a tendency to replace them with aneroid devices on the false assumption that, because both can be used to measure blood pressure by means of the auscultatory technique, they can be interchanged. However, there is remarkably little literature on the accuracy of aneroid devices, and what does exist is generally negative.

Automated blood pressure measuring devices

Given the inherent inaccuracy of the auscultatory technique irrespective of the sphygmomanometer used, there is a need to replace it with accurate automated methods of measurement using the oscillometric technique. An accurate automated sphygmomanometer eliminates errors of interpretation, observer bias and terminal digit preference. Moreover, elaborate training in using the automated device is not required, although a period of instruction and an assessment of proficiency will always be necessary. Another advantage of automated devices is the ability to store readings and transmit them electronically or telephonically.

A transition toward automated blood pressure measurement is underway. However, the advent of accurate automated devices as an alternative to the mercury manometer, although welcomed, is not without limitations [12]. Automated devices are notoriously inaccurate, although more accurate devices are now appearing on the market. In addition, most have been designed for the self-measurement of blood pressure, and as such it cannot be assumed that they will be suitable for professional use in the office/clinic setting. Another disadvantage of automated devices is that oscillometric techniques

cannot measure blood pressure in all situations, particularly in patients with arrhythmias such as atrial fibrillation with a rapid ventricular response, as well as in other individuals for reasons that are not always apparent.

Automated blood pressure measuring devices should only be considered as an alternative for low resource settings if validated and affordable. Currently, the feasibility of using automated blood pressure measuring devices in such settings may be limited by their relatively high capital and maintenance costs. Furthermore, of the more than 500 automatic blood pressure measuring devices on the market, less than 10% have been independently validated [5]. Thus, there is a need to increase the supply and distribution of validated automated blood pressure measuring devices that are affordable for low resource settings. Additional important considerations in the selection of a device are durability, the need for regular servicing, and the need for a power source or frequent battery replacements. In light of the difficulties associated with frequent battery replacement, semi-automatic devices appear to be more suitable than fully automatic devices, particularly in low resource settings. Semi-automatic devices are battery powered, however they do not require frequent battery replacement as the cuff is inflated manually using a hand bulb.

Hybrid sphygmomanometers

Another alternative to the mercury sphygmomanometer is the hybrid sphygmomanometer, which combines features of both electronic and mercury devices. Hybrid devices use an electronic pressure gauge and display as a substitute for the mercury column, while blood pressure is taken in the same way as with a mercury device—using a stethoscope and listening for the Korotkoff sounds. The cuff pressure is displayed both as a simulated mercury column using an array of LCDs, and as a digital LCD readout. The cuff is deflated in the normal way. When systolic and diastolic pressures are heard, a button next to the deflation knob on the digital device is pressed, freezing the digital display to show measurements. This feature has the potential to eliminate terminal digit preference, a major problem with the clinical use of any auscultatory monitor. Hybrid devices allow the physician to measure blood pressure using the traditional auscultatory technique, without necessarily relying on automated readings, but without the problems associated with mercury columns. A hybrid device with LED display that has passed the International Protocol for device validation is commercially available [19]. The hybrid manometer's durability, ability to withstand shock, and calibration requirements, are not yet known.

Validation of blood pressure measuring devices

Accuracy is of prime importance when selecting a blood pressure measuring device. Thus, regardless of the type

of device used, standardized validation procedures are essential [4]. In this regard it is important to define standards and refine specifications to be sent to industries, as well as to provide information to assist consumers in selecting reliable devices.

International protocols for blood pressure measuring device validation have been released and the European Society of Hypertension Working Group on Blood Pressure Measurement [11], the Association for the Advancement of Medical Instrumentation [9], and the British Hypertension Society [10]. However, only a very small number of the blood pressure measuring devices available worldwide have been validated [12]. Information on the state of the market and on devices that have passed a validation test according to international protocols is available in a number of publications, including one that appeared in 2001 [12]. Since then, such information is being regularly updated by dabl[®] Educational Trust, an independent, not for profit educational organisation (www.dableducational.com) [13], as well as by the French agency of medical devices (AFSSAPS) (<http://afssaps.sante.fr>).

Annex III

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