

Modification of blood-pressure-measuring devices and the protocol of the British Hypertension Society

Eoin O'Brien

The Blood Pressure Unit, Beaumont Hospital, Dublin, Ireland.

Correspondence and requests for reprints to Eoin O'Brien, The Blood Pressure Unit, Beaumont Hospital, Dublin 9, Ireland.

Editor's Note We would welcome responses from manufacturers and regulatory agencies regarding Professor O'Brien's concerns.

Blood Pressure Monitoring 1999, 4:53-54

The market for blood-pressure-measuring devices is enormous and growing. Devices are required in a number of areas in hospitals, in doctors' offices, in paramedical areas and in the transport of patients; and there is a vast demand for self-measuring devices from the public. In Germany, for example, 12 million such devices are sold annually [1]. Only a fraction of the many hundreds of models available worldwide has been subjected to independent validation, though the number of devices undergoing validation is growing [2]. However, one of the problems facing manufacturers who submit a device for independent validation according to the protocol of the British Hypertension Society (BHS) is that of being able to modify it thereafter without affecting its accuracy of operation.

The first BHS protocol emphasized the importance of manufacturers indicating by a change in model number any modifications made to blood-pressure-measuring devices [3]. The revised BHS protocol, published in 1993, went further by stipulating not only that manufacturers must indicate clearly all modifications to the technological and software components of automated devices by changing the device number but also that modified devices must be subjected to validation anew [4]. These stipulations were influenced by consequences that had resulted from changes made by manufacturers to the algorithms of devices for measuring ambulatory blood pressure [5,6].

In the first instance, examination of conflicting reports on the accuracy of the Takeda TM-2420 device (A&D Company Ltd., Tokyo, Japan) from a number of laboratories indicated that one could account for apparent differences

among laboratories in terms of different models having been submitted for validation by the manufacturers without the users being made aware that modifications might have been made to the device [5].

Another example of modification of a device affecting accuracy was that reported by Hansen and Orskov [7], who observed apparently inexplicable variations in mean arterial blood pressure in a longitudinal study, which were inconsistent with the observed changes in systolic and diastolic blood pressures. It became apparent that the SpaceLabs 90 202 (SpaceLabs Inc., Redmond, Washington, USA) monitors used at the beginning of the study, which had been sent for repair, had had their software programs updated by the manufacturers. Also, new devices supplied by the manufacturers during the course of the study, even though ostensibly of the same 90 202 model, also contained the updated software. The company readily admitted that it had modified the software program for mean arterial pressure to achieve greater accuracy and that the modification had resulted in mean arterial pressure being 3-4 mmHg higher according to the new program, but they had not disclosed this to the user [5].

The importance of device modification was also illustrated in the evaluation of the Profimat ambulatory system (Disetronic Medical Systems, Burgdorf, Switzerland) [8]. The Profimat device was developed for use in general practice by modifying the more expensive and elaborate CH-Druck ambulatory system [9]. During validation it became evident that the Profimat device was providing fewer valid measurements during ambulatory use than the parent CH-Druck device had done, because the facility for repeating measurements in the event of failure to obtain a measurement had been removed; when it was replaced, the modified recorders comfortably satisfied the protocol's requirements [8].

These incidents, which had come to attention by accident and had occurred with the most expensive devices on the market, influenced the authors of the BHS protocol to take the view that the practice of modifying algorithms might be more common than had been appreciated and that this was more likely to happen with less expensive blood-pressure-measuring devices. It was hoped that the provisions in the protocol requiring validation of modified devices would eliminate the likelihood of such an occurrence in the future [2].

Manufacturers, however, have from time to time expressed the view that the BHS stipulations were not only unreasonable, in that they oblige the manufacturer to go to the unnecessary expense of having a device that has undergone some design modifications without alteration of the algorithm re-evaluated, but also counterproductive, in that they prohibit beneficial modifications to device design, which need not involve adjusting an algorithm previously shown to satisfy the accuracy criteria of the protocol. It seems to me that this viewpoint is valid and, now that the BHS protocol is undergoing revision, it would seem timely to debate the issue.

Might it be reasonable to remove this stipulation from the BHS protocol if a manufacturer of a device that had satisfied the BHS accuracy criteria, and to which modifications were being made, was prepared to provide the following assurances: first, independent evidence that the algorithm in the modified device is identical to that in the originally validated model; second, evidence that the proposed modifications cannot alter the performance of the algorithm; third, a system of model numbering that would acknowledge a common algorithm and denote the features of the modification? Perhaps manufacturers of blood-pressure-measuring devices would be prepared to say how these objectives could be achieved.

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