Evaluation of the Tensioday ambulatory blood pressure monitor according to the protocols of the British Hypertension Society and the Association for the Advancement of Medical Instrumentation

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Background The validation of ambulatory blood pressure monitoring devices is necessary to obtain information on their accuracy. The objective of the present study was to evaluate the accuracy of the Tensioday oscillometric ambulatory blood pressure monitor according to the protocols of the British Hypertension Society and the Association for the Advancement of Medical Instrumentation (AAMI).

Design We followed the phases recommended by the British Hypertension Society protocol: before-use calibration, in-use assessment, after-use calibration, static device validation and report of the evaluation. However, we expanded on the protocol to accommodate features required by the AAMI.

Method The accuracy of calibration of three Tensioday devices was tested before and after the in-use phase when each of three devices was performing 10 24 h sessions of ambulatory monitoring. As all three devices passed these phases, the accuracy of blood pressure measurement was tested in one arbitrarily selected device on 85 subjects for systolic and 85 for diastolic blood pressure values. This was done by comparing three sequential same-arm blood pressure readings obtained by the device with three readings obtained by two observers using standard mercury sphygmomanometer. The comparisons were carried out while resting in the seated, supine and standing positions for all subjects. The results were used to grade the performance of the device according to the British Hypertension Society protocol and to calculate the mean $\pm$ standard deviation of the difference between the device and the observers, as required by the AAMI.

Results The Tensioday device achieved an overall grade of A for both the systolic and diastolic measurements, and had a mean difference compared with the observer-measured blood pressure of $1.4 \pm 5.3/1.0 \pm 4.7$ mmHg, which satisfies the AAMI criteria for accuracy. The British Hypertension Society grading did not change when patients with low, medium, and high blood pressure were analysed separately. The AAMI accuracy criteria were fulfilled in the standing and lying positions as well.

Conclusion On the basis of these results, the Tensioday ambulatory blood pressure monitoring device can be recommended for clinical use for ambulatory monitoring. The accuracy of the device needs, however, further testing in special situations, such as in pregnancy, in elderly patients and during exercise.
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Conflicts of interest: None.

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Introduction

Over the past decade, ambulatory blood pressure monitoring (ABPM) has become an integral part of the evaluation and follow-up of patients with hypertension [1]. Blood pressure values obtained using ABPM correlate better with hypertensive target-organ damage, and ABPM provides prognostic information over and above that provided by clinic measurements [2]. The use of ABPM in the evaluation of certain clinical situations, such as white-coat hypertension, drug-resistant hypertension, drug-induced hypotension, autonomic failure and treatment efficacy is endorsed by the Joint National Committee VI [3] and World Health Organization–International Society of Hypertension [4] guidelines for the evaluation and treatment of hypertension.

The expansion in the use of ambulatory monitoring has led to the design and production of a variety of ABPM devices [5]. Manufacturers are not currently obliged to submit their devices for an independent validation of accuracy despite the fact that inaccurate readings sometimes lead to

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inadequate therapy or unnecessary medication. Indeed, it has been suggested [6] that the most important factor influencing the choice of a particular device should be whether it has been validated independently according to the protocols of the British Hypertension Society (BHS) [7] and/or the Association for the Advancement of Medical Instrumentation (AAMI) [8]. In this study, the Tensioday ABPM device, produced by TensioMed Ltd in Hungary, was subjected to a validation of its accuracy according to the BHS and AAMI criteria.

Methods

The validation study was performed at the division of hypertension of the 1st Department of Medicine of the Semmelweis University, whose technical personnel are experienced in performing such validation studies [9,10]. The hearing acuity of the observers trained and experienced in blood pressure measurement was evaluated by audiometry. Observer agreement in measuring blood pressure was tested according to the requirements outlined in the Appendix of the BHS protocol prior to the study and repeated three times during and three times after the completion of the validation.

The Tensioday ABPM measures 12.8 × 7.75 × 4.55 cm and weighs 310 g including batteries. The accessories supplied along with the monitor are a pouch, belt, inflatable cuff, user manual, cable for infrared communication, and software. The unit is powered by four AA-size rechargeable batteries that come together with the accessories and a charger. Three Tensioday monitors were provided by the manufacturer for the study, along with cuffs with inflatable bladder sizes of 33 × 13 cm for normal, 22 × 10 cm for small and 44 × 15 cm for large arm circumferences. The manufacturer provided written confirmation that the three devices were selected at random from the production line. The device measures blood pressure with the oscillometric method using stepwise deflation, the pressure range being 30–280 mmHg. Pushing a button on the device once, twice or three times allows for the initiation of a manual measurement, indicating the taking of a pill and registering the times of going to bed and waking up, respectively.

The device is controlled by the software, the connection between the device and the computer being established by infrared communication. The software allows the device to be programmed to take measurements for up to 48 h at a frequency of between 5 and 90 min, and for defining individually set periods for daytime, night-time and a special period of interest. The report on the monitoring includes information on the patient, tabulated and graphical displays of the measured values and their times, and a statistical summary including the mean minimum and maximum blood pressure and heart rate values separately for daytime, night-time and the special period, the diurnal index, the blood pressure load and the hyperbaric impact.

Validation phases

The BHS protocol was modified to accommodate additional features required by the AAMI criteria. These included measurements made to the nearest mmHg, increasing the number of participants in the in-use phase to 30, increasing the measurement frequency during the daytime to every 15 min, performing the device validation in the supine and upright postures for all of the subjects and including the AAMI criteria in the analysis.

The objective of the '*before-use calibration*' phase was to test the accuracy of calibration of the three devices before any further procedures were undertaken. In this phase, the automated deflation system and blood pressure measuring mechanism of the Tensioday device was switched off by a service software provided by the manufacturer so that the device acted like a simple manometer. The evaluation of accuracy of calibration was accomplished by comparing the pressure values read from a recently calibrated mercury sphygmomanometer with those displayed on the device throughout the pressure range with the cuff wrapped around a cylinder and the tubing of the test device and the sphygmomanometer connected by a Y-connector. A third person (the controller), with a mercury sphygmomanometer whose tubing was also connected to the system, deflated the cuff at 2 mmHg/s and called 'Now' to denote the moment at which the two observers were to record pressures on the device and the sphygmomanometer, respectively. There were six deflations per device with five calls per deflation, giving a total of 30 device–observer pairs per device for comparison in the analysis. If a device is to pass the BHS criteria, at least 28 of the 30 pairs of values must lie within 3 mmHg of each other.

The objective of the '*in-use (field) assessment*' phase is to test the performance of the device in everyday clinical use. With each of the Tensioday monitors 10 24-h ABPM tests were performed over a 2-month period, measurements being programmed every 15 min during the daytime (0600–2259 h) and every 30 min at night. The BHS protocol requires that the performance of the device be assessed by determining how many monitoring days provide valid readings of more than 80, 70 and 50% of those expected. A subjective evaluation of the device was obtained from all the patients participating in this phase of the study.

The '*after-use calibration*' phase was performed as for the before-use calibration assessment to determine whether

there had been any change in the accuracy of calibration of the devices during use.

'*Static device validation*' was carried out using seven sequential same-arm measurements by the observers and by the device under resting conditions. It allowed for two different sequences of three paired comparisons between the test device- and observer-measured blood pressure values: 'observers first–device second' and 'device first–observers second'. The measurements were repeated in the supine and standing positions in all subjects. Analysis was undertaken separately for the two sequences of three paired readings, and separately for the two observers. As allowed by the BHS protocol, the sequence most favourable for the Tensioday device was used in grading the performance of the device. The same sequence was used in all three postures. The final grade for each systolic and diastolic blood pressure value was better than the corresponding grade obtained by the two observers.

As the accuracy of a device can differ according to the level of blood pressure, the accuracy of the device was also analysed in subgroups of patients in the low (<130/80 mmHg), medium (130–160/80–100 mmHg) and high (>160/100 mmHg) blood pressure ranges. For this subgroup analysis, each of the 102 patients were classified by the initial mercury sphygmomanometer measurement.

The BHS protocol recommends that devices be graded A to D according to their performance. To allocate a particular grade for the device, the percentage of test device measurements differing from the standard by 5, 10 and 15 mmHg or less were calculated separately for systolic and diastolic blood pressure. According to the BHS protocol, a device will pass validation if it achieves grade A or B both for systolic and diastolic blood pressure, and according to the AAMI protocol it passes if the mean difference between the test device and the observers does not exceed 5 mmHg with a standard deviation of not more than 8 mmHg. Static device validation during exercise was not performed.

Subjects involved in validating the Tensioday were recruited from the out-patient clinic of the department and the dialysis unit, some of the staff also being involved. All subjects gave consent for their participation. Validation studies were not performed with special populations such as pregnant women or systematically selected elderly subjects. Individuals were excluded if arrhythmias, including atrial fibrillation and frequent premature beats, were found. To comply with the blood pressure range and arm circumference requirements of the BHS and AAMI protocols, a total of 102 subjects were involved.

Results

Before-use calibration

The pressure calibration of all three devices lay within the accepted range of error: for device A 29 out of 30, for device B 28 out of 30 and for device C 30 out of 30 pressures fell within 3 mmHg of that recorded using the standard manometer.

In-use (field) assessment

Each of the three devices completed 10 24-h monitoring sessions on 30 subjects. There were a total of 2503 inflations, 2083 during the daytime and 420 during the night. Of the inflations, 12.7% of those occurring during the day and 3.3% of those made at night were invalid. The proportion of valid measurements was more than 80% in nine 24-h monitoring sessions with device A and in eight 24-h monitoring sessions with devices B and C. The proportion of valid measurements was more than 70% and less than 80% in one daytime measurement period with device C, in one night-time measurement period with device B and in both the daytime and night-time periods of one 24-h monitoring with device B. The proportion of valid measurements was more than 50% and less than 70% in one daytime measurement period with device A and in both the daytime and night-time periods of one 24-h monitoring with device C. No device failure or technical difficulty was noted.

The patients' subjective assessment of the device indicated that one-third of the participants experienced some, but none a considerable degree of, discomfort while using the monitor. Sleep was disturbed to some degree in 16 out of the 30 patients, only one patient noting a considerable degree of interference with sleep. One patient reported considerable and six some degree of anxiety caused by the device. No other problem perceived to be considerable in intensity was noted by the subjects. Overall, 13 patients rated the device as 'very good', 14 as 'good', 3 as 'fair' and none as 'bad'.

After-use calibration

Twenty-eight pressures read from devices A and B, and 30 pressures read from device C, fell within 3 mmHg of those 90 pressures read from the sphygmomanometer, indicating that the accuracy of calibration of the devices had not changed during use.

Static device validation

In order to comply with the BHS and AAMI criteria, the device was assessed on 102 patients. Both the systolic and diastolic blood pressure readings were analysed from 68 subjects, an additional 17 patients being involved in the systolic and diastolic pressure evaluation, respectively. For those involved in the systolic blood pressure evaluation,

their mean age was 56.6 ± 17.2 (range 22–90) years, weight 78.1 ± 20.4 (range 41–115) kg, height 169 ± 9.3 (range 146–186) cm, heart rate 75.6 ± 12.6 (range 52–117) per min and arm circumference 28.4 ± 4.7 (range 19.5–43.5) cm. For those included in the diastolic blood pressure evaluation, the corresponding values were 57.7 ± 16.5 (range 22–90) years, 79.8 ± 21.0 (range 41–115) kg, height 169 ± 9.8 (range 146–186) cm, heart rate 74.6 ± 11.3 (range 52–107) per min and 28.6 ± 4.8 (range 19.5–43.5) cm, respectively. The mean blood pressure and blood pressure distribution of the subjects are presented in Table 1. Device B was arbitrarily selected for the validation.

The results of the comparison of the 255 paired sitting blood pressure measurements between the device and the observers are presented in Table 2. The mean difference between the device and observer 1 was 1.4 ± 5.3/1.0 ± 4.7 mmHg, and that between the device and observer 2 1.1 ± 5.7/0.7 ± 5.1 mmHg. These pressure differences fulfil the accuracy criteria of the AAMI for both systolic and diastolic measurements. The percentages of measurements obtained by the device differing from the mercury standard by 5, 10 and 15 mmHg or less were 80, 96 and 97% for the systolic blood pressures, whereas for the diastolic pressure these percentages were 82, 96 and 98%, respectively. The overall grade achieved by the Tensioday device was, according to the BHS criteria for accuracy, A for both the systolic and diastolic measurements. The difference in blood pressure between the device and observer 1 for all 255 measurements was plotted against the mean of the device- and observer-obtained pressure (Figs. 1 and 2). Table 3 summarizes the results of the paired comparisons of blood pressure readings analysed separately for patients in the low, medium and high pressure ranges. The device achieved grade A/A in all three blood pressure ranges and passed the accuracy criteria of the AAMI protocol as well. The mean difference in blood pressure between the device and observer 1 in the standing and lying position was 1.2 ± 4.7/0.1 ± 4.6 mmHg and 1.9 ± 4.1/1.4 ± 4.0 mmHg, respectively, fulfilling the accuracy criteria of the AAMI protocol (Table 4).

Discussion

In this study, the validation of the accuracy of the Tensioday ABPM device was performed according to the BHS and AAMI protocols. The device, which measures blood pressure using the oscillometric method, achieved an overall grade of A/A according to the BHS criteria and also fulfilled the accuracy requirements of the AAMI protocol. Accuracy was not affected when the performance of the device was analysed separately in patients with low, medium and high blood pressure. The device passed the accuracy criteria during blood pressure measurement in the standing and supine positions as well. Based on these results the Tensioday device can be recommended for clinical use for ambulatory monitoring.

The accuracy of blood pressure measuring devices may, however, differ in special circumstances such as exercise or among special populations such as pregnant women, children or the elderly. As we did not involve pregnant women, and those subjects in our study who were above 65 years of age did not fulfil the age range criteria required by the BHS protocol, additional validation procedures need to be undertaken before the use of the device can be recommended for these subjects. Although our study included ABPM sessions during the 'in-use' phase, it was not intended to validate the device during exercise. Our results may therefore not apply to this situation.

In operational terms, the Tensioday was well accepted by the patients, as indicated by their overall 'good' to 'very good' rating. It should be noted, however, that one-third of patients experienced some degree of discomfort, probably representing interference with sleep during the monitoring period. This is of potential clinical significance as discomfort and sleep disturbance may affect the blood pressure readings. It was the operators' subjective impression that the software is user-friendly, allowing for quick individual programming and thorough analysis of the data.

Basic information on the manufacturer and the device is given in the Appendix to this paper. No instruction card is provided for patients, although the use of one might assist their familiarization with the device. The device has inbuilt editing criteria to reject impossible readings, but neither a clear description of nor a reference to these criteria is provided in the documentation. The effect of the automated artefact editing feature of the device can not be discerned from our data. The manual does not give information related to operation that might affect its accuracy with, for example, special populations, exercising subjects and those with an arrhythmia. As our study was

Table 1 Blood pressure and arm circumference distribution of the 102 subjects

			Range			Mean	SD
SBP (mmHg)	<90	90–129	130–160	161–180	>180	139.6	31.5
n	8	26	23	20	8		
DBP (mmHg)	<60	60–79	80–100	101–110	>110	82.4	19.5
n	9	24	24	20	8		

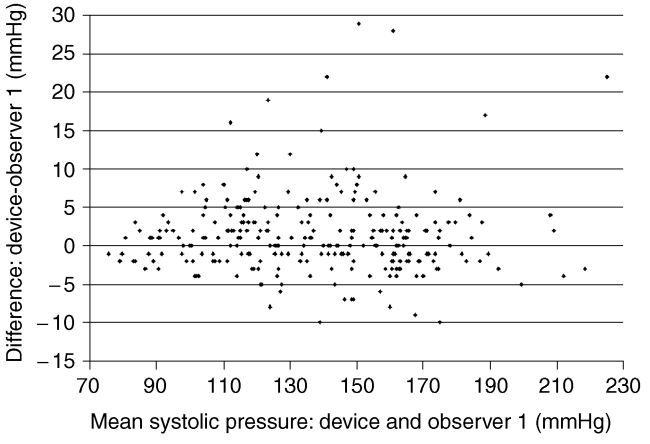
SD, standard deviation; SBP, systolic blood pressure; DBP, diastolic blood pressure.

Table 2 **Accuracy of the Tensioday device**

	Grade	Difference between test device and observer (mmHg)			Mean (SD) blood pressure (mmHg)	Mean (SD) difference (mmHg)
		≤5	≤10	≤15		
Observer 1						
SBP	A	80	96	97	137 (30)	1.4 (5.3)
DBP	A	82	96	98	82 (16)	1.0 (4.7)
Observer 2						
SBP	A	75	93	98	137 (30)	1.1 (5.7)
DBP	A	77	96	99	79 (17)	0.7 (5.1)
Final grading						
SBP	A	80	96	97	137 (30)	1.4 (5.3)
DBP	A	82	96	98	82 (16)	1.0 (4.7)
Observer comparison						
SBP	A	91	100	100		−0.3 (3.1)
DBP	A	93	100	100		−0.4 (2.6)

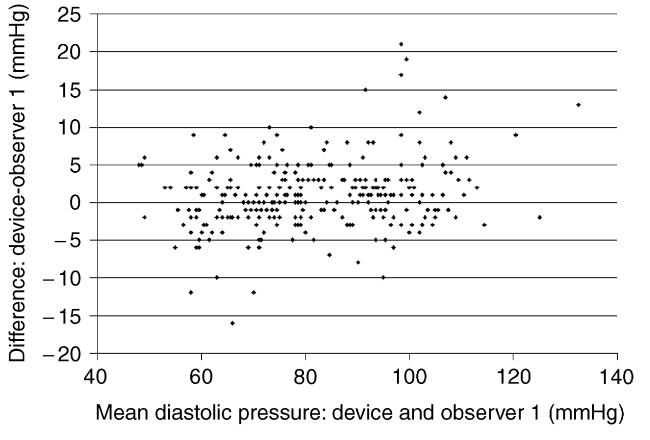
Numbers are percentage of measurements. SD, standard deviation; SBP, systolic blood pressure; DBP, diastolic blood pressure.

Fig. 1



Scatter plot of the difference in systolic pressure between the device and observer 1 against mean systolic pressures.

Fig. 2



Scatter plot of the difference in diastolic pressure between the device and observer 1 against mean diastolic pressures.

carried out under resting conditions and patients from these populations were not involved, we are unable to make recommendations on the accuracy of the device in such situations.

ABPM is being used more extensively in the management of hypertensive patients, and more and more devices are being marketed. As conclusions drawn from monitoring performed with devices of questionable accuracy may have serious consequences, an independent validation of any new devices is essential. The AAMI and BHS protocols were the first of the few national recommendations, including those from Germany [11] and Australia [12], that were developed with the objective of setting minimum standards for the validation of accuracy and facilitating a comparison of blood pressure measuring devices. Most validation studies have so far been performed according to the requirements of the AAMI and BHS criteria. The BHS and AAMI protocols are time-consuming to meet, and attempts are currently underway to reconcile and simplify them [13,14]. *Blood Pressure Monitoring* has assumed the task of being the depository of such validation studies, and the Working Group on Blood Pressure Monitoring of the European Society of Hypertension is publishing regular state-of-the-market reviews [5,15] to enhance information-sharing on validated devices through the medical community.

In summary, in this study we evaluated the accuracy of the Tensioday ABPM device, which passed the AAMI criteria for acceptance and achieved grade A for both systolic and diastolic measurements according to the BHS protocol. The BHS recommends devices for clinical use if they achieve a grade of at least B for both systolic and diastolic measurements, and the AAMI requires that the difference between the test device and the standard method should not exceed 5 mmHg, with a standard deviation of not more than 8 mmHg. As the Tensioday ambulatory blood pressure

Table 3 **Accuracy of the Tensioday device analysed according to the level of blood pressure**

	Grade	Difference between test device and observer 1 (mmHg)			Mean (SD) blood pressure (mmHg)	Mean (SD) difference (mmHg)	*n*
		≤5	≤10	≤15			
Low pressure range (<130/80 mmHg)							
SBP	A	86	97	100	108 (14)	1.4 (3.9)	102
DBP	A	81	97	99	67 (9)	0.3 (4.5)	99
Medium pressure range (130–160/80–100 mmHg)							
SBP	A	67	94	96	141 (13)	2.2 (6.6)	69
DBP	A	78	93	96	81 (10)	2.1 (5.6)	72
High pressure range (>160/100 mmHg)							
SBP	A	85	96	96	169 (17)	0.8 (5.5)	84
DBP	A	87	98	100	100 (9)	1.0 (3.9)	84

Numbers in the column 'Difference between test device and observer 1' represent the percentage of measurements. SD, standard deviation; SBP, systolic blood pressure; DBP, diastolic blood pressure.

Table 4 **Mean blood pressure and mean difference in blood pressure between the Tensioday device and the observers with the subject in the standing and supine positions**

	Mean (SD) blood pressure (mmHg)	Mean (SD) difference (mmHg)
Standing		
Test device–observer 1		
SBP	136 (30)	1.2 (4.7)
DBP	83 (16)	0.1 (4.6)
Test device–observer 2		
SBP	136 (30)	1.1 (5.8)
DBP	83 (16)	−0.3 (4.5)
Supine		
Test device–observer 1		
SBP	137 (29)	1.9 (4.1)
DBP	80 (18)	1.4 (4.0)
Test device–observer 2		
SBP	137 (29)	2.0 (4.9)
DBP	81 (18)	1.1 (4.5)

The measurements were performed on all 85 patients in both postures. SD, standard deviation; SBP, systolic blood pressure; DBP, diastolic blood pressure.

monitor fulfilled all these criteria, it can be recommended for clinical use. The device cannot be recommended for use in pregnancy, with elderly individuals or children, or during exercise, as testing was not carried out in these circumstances.

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Appendix

Basic information

Device identification. The manufacturer identifies the unit clearly on the front of the Tensioday. On the back, standard icons and text provide essential information on the device, including its version, the 'CE' marking that indicates the compliance of the device with European standards as listed below, and safety precautions.

Cost. The cost of the device, including all the accessories and the software, is 1060 Euros.

Compliance with standard. The operation of TensioMed and the production of the Tensioday device complies with the requirements of the following standards: ISO 9002, EN 46001, 93/42EEC, EN/60601-1, EN60601-1-2, EN1441, EN1060-1 and EN 1060-3.

Validation studies. There are no published validation studies using the Tensioday monitor.

Instructions for use. The user manual provides clear, step-by-step user instructions.

Patient instruction card. No instruction card is provided.

Precautions for use. The user manual provides a clear list of the precautions that need to be taken during the operation of the device.

Power supply. The unit is powered by four AA-size rechargeable NiCd or Ni-metal hybrid batteries with a capacity of 1500 mAh. The number of inflations that can be performed with fully charged batteries is not defined. The actual voltage of the batteries is shown on the display before each measurement.

Instructions for care and maintenance. The manual recommends that an approved agent service the device at least every 2 years to maintain its optimum performance and accuracy, and that the cuff can be cleaned by wiping it with a damp cloth. The warranty for the device lasts for 12 months.

Service facility. Repairs and check-ups on the device are performed at the Tensioday production site in Hungary, which can be contacted either directly or via the international office in England. Information on the cost of repairs and transport is not provided.

List of components, dimensions and method of blood pressure measurement. This information is given in the manual (see Methods).

Artefact editing. The device has inbuilt automated editing criteria, although these are not clearly stated. The software allows for further manual editing of the individual measurements.

Facility for device recalibration. The manual recommends that an approved agent service the device at least every 2 years.

Factors affecting accuracy. The manual lists the precautions that may affect accuracy that need to be taken during measurements, but no information is provided on the use of the device in special circumstances (e.g. arrhythmia).

Operator training requirements. The device is easy to operate, and the user manual is sufficient in this regard.

Computer analysis. The device is controlled by the Tensio-Win software, for which separate instructions are provided in the manual. The computer requirements are also listed in the manual. The software allows for an easy but extensive customization of device programming and data analysis. There is no facility to export the data to an external database.

Problem list and solutions. The list of error codes that can appear on the display of the device is provided in the manual.

Supplier names and addresses. The manual provides the following addresses: TensioMed Ltd, 163. Kétújfalu utca, Budapest, Hungary, 1182, tel.: +36 (1) 2960129, fax: +36 (1) 2952676, e-mail: tensiomed@tensiomed.com; TensioMed International, 5 Cheltenham House, The Square, Stow-on-the-Wold, Cheltenham, Gloucestershire, England, GL54 1AB, tel.: +44 (0) 1451 830197, fax: +44 (0) 1451 870755.