

# Development and application of a quality control procedure for short-wave diathermy units

N. Shields<sup>1</sup> N. O'Hare<sup>2</sup> G. Boyle<sup>2</sup> J. Gormley<sup>1</sup>

<sup>1</sup>School of Physiotherapy, Trinity College Dublin, Ireland

<sup>2</sup>Department of Medical Physics & Bioengineering, St James's Hospital, Dublin, Ireland

**Abstract**—Short-wave diathermy (SWD) is a form of radiofrequency (RF) radiation, operating at 27.12 MHz, that is used therapeutically by physiotherapists. Although this form of therapy is widely available, the management of the equipment is not often addressed by either physiotherapists or by medical physics/clinical engineering. A quality control protocol for SWD units, examining power output and electrical and mechanical condition, was developed and applied to 20 units used in clinical practice. In addition, an environmental assessment of where the units were used was also included. Results showed that the power output was generally stable (coefficient of variation range 0–8.8%) and reproducible (coefficient of variation range 0–6.8%). When the outputs from 12 similar units were compared, it was found that the relationship between the units' intensity settings and power output measurements was non-linear. Two units with mechanical timers were found to have inaccuracies that could contribute, under a 'worst-case' scenario, to a dosage error of up to 45%. Environmental analysis found that all treatment plinths in use contained metal parts, which could constitute a fire hazard, and no department examined was equipped with an RF screened room, a facility that would ensure that other persons in the vicinity were not exposed to excessive stray radiation.

**Keywords**—Short-wave diathermy, QC protocol, Safety

Med. Biol. Eng. Comput., 2003, 41, 62–68

## 1 Introduction

SHORT-WAVE DIATHERMY (SWD) is an electrotherapeutic agent applied by physiotherapists for the treatment of various conditions. It is a form of radiofrequency (RF) radiation that operates at 27.12 MHz and can be applied as either continuous short-wave diathermy (CSWD) or pulsed short-wave diathermy (PSWD). Either the electric or magnetic field component can be used to apply the treatment, the method of application being dependent on the electrode type chosen (Fig. 1). The physiological effects produced occur as the result of heat generated in the tissues or by athermal effects, depending on which mode of treatment is applied.

The management of SWD equipment is an issue not often addressed by either physiotherapists or by medical physics/clinical engineering personnel, possibly owing to a lack of knowledge in the area of equipment testing and servicing among physiotherapists. It may also be the result of insufficient medical physics/clinical engineering input into the maintenance of physiotherapy equipment by the relevant hospital department.

Only limited published literature is available on the servicing and quality control (QC) testing of electrotherapy equipment,

including SWD units (SHIELDS *et al.*, 2001a). The importance of QC testing in ultrasound units was highlighted by PYE and MILFORD (1994), who reported that, of the machines tested, 69% had power outputs differing by more than 30% from the expected values. High outputs from any malfunctioning electrotherapy unit could place the patient at an unnecessary risk of tissue damage, whereas low outputs could result in ineffective treatments that, not only waste the time of both physiotherapists and patients, but also incur substantial costs to the health service (PYE *et al.*, 1994).

Unfavourable responses to medical interventions, particularly to drug therapy, are widely reported in the literature. All forms of electrotherapy carry with them an inherent risk to the patient if applied incorrectly or if faulty equipment is used, although only limited information is available regarding their possible adverse effects. This is, in part, owing to a lack of trials investigating the effects of electrotherapy agents, as, unlike their counterparts in the pharmaceutical industry, manufacturers of electrotherapy equipment are not required to complete rigorous trials prior to marketing a new modality (HENDRICKS, 1991).

To date, only one study (PARTRIDGE and KITCHEN, 1999) has examined the adverse effects incurred through electrotherapy application. Over an 18 month period, 148 incidents were recorded by physiotherapists within the study sample. A large percentage of these incidents (32.4%) occurred as a result of the application of either CSWD or PSWD. The reported incidents included burns, increase in pain, nausea and vomiting, headaches and fainting. Of more serious concern was a report that, in 2001, two patients with implanted deep-brain stimulators

Correspondence should be addressed to Ms Nora Shields;  
email: shieldsn@tcd.ie

Paper received 19 March 2002 and in final form 24 September 2002  
MBEC online number: 20033730

© IFMBE: 2003



a



b

**Fig. 1** SWD units: (a) capacitive set-up with air-space electrodes, and (b) inductive set-up with drum electrode

suffered 'severe and permanent' brain damage leading to death after receiving SWD treatment (CSP, 2001). When compared with the total number of electrotherapy treatments undertaken on a daily basis in physiotherapy departments, the number of incidents is few. However, even a small number of patients experiencing adverse effects from electrotherapy treatment has major consequences for therapists in terms of litigation and clinical practice.

PARTRIDGE and KITCHEN's study (1999) documented the incidence of adverse effects from electrotherapy, but the cause of these effects was not established. It was suggested that they could have resulted from malfunctioning equipment, the use of inappropriate techniques or the incorrect application of treatment. It has been shown in ultrasound units that malfunctioning equipment can deliver excessive doses of treatment, sometimes over 50% of the indicated dose (LLOYD and EVANS, 1988). As yet, however, no comparative data for SWD units have been published in the literature.

One method of ensuring that adverse effects are not caused by malfunctioning SWD units is to evaluate their performance on a regular basis. Although SWD units are widely available (POPE *et al.*, 1995; SHIELDS *et al.*, 2001a), no QC protocol is available in the literature. This creates difficulties in ensuring reproducibility between treatment sessions within the same centre and also between treatment centres. This is significant in SWD treatment, owing to the manner of its application and dose selection. SWD dosage is set by the selection of various treatment parameters. The parameters selected depend on whether CSWD or PSWD is applied. CSWD dosage is selected through patient sensory feedback, with the level of intensity increased until the patient reports feeling a mild, comfortable heat. PSWD dosage is selected by choosing a combination of pulse repetition frequency, pulse width and peak pulse power to give an average power output reading. The pulse repetition frequency and pulse width vary between SWD models (see Table 1).

A review of the clinical trials on SWD (SHIELDS *et al.*, 2001b) noted the emphasis placed by researchers on the intensity setting values selected for various units. As the absorbed dose is not measured, the intensity level is reported as an arbitrary intensity setting value. This parameter is not an index for the energy absorbed by the patient and merely indicates the position of the intensity control on the unit. Equipment output and absorbed dose measurements are essential for clinical trials to ensure that units at different centres operate at a similar standard and that

*Table 1* SWD equipment included in the study

Model	Manufacturers	Frequency	Continuous or pulsed	Electrodes	Number of units	Pulse width	Pulse frequency, Hz
Curapuls 970	Enraf Nonius	27.12 MHz	Continuous and pulsed	Air-space drum	4	400 $\mu$ s	15–200
Curapuls 419	Enraf Nonius	27.12 MHz	Continuous and pulsed	Air-space drum	8	400 $\mu$ s	15–200
Thermatur 200	Elecktromedizin	27.12 MHz	Continuous and pulsed	Air-space	1	0.4 ms or 2 ms	70 or 250
Ultratherm 808i	Siemens	27.12 MHz	Continuous and pulsed	Air-space drum	1	400 $\mu$ s	20–180
Ultratherm 808	Siemens	27.12 MHz	Continuous	Air-space	1		
Megapulse	EMS	27.12 MHz	Pulsed	Drum	1	20–400 $\mu$ s	100–800
Curapuls 670	Enraf Nonius	27.12 MHz	Pulsed	Drum	1	65–400 $\mu$ s	26–400
Phyaction performa	Uniphy	27.12 MHz	Pulsed	Drum	1	65–400 $\mu$ s	26–400
Erbotherm 1100P	Erbe	27.12 MHz	Continuous and pulsed	Air-space	1		
Therpulse II	Chatlanooga Group Ltd	27.12 MHz	Continuous and pulsed	Drum	1	65 or 400 $\mu$ s	12.5–400

their performance is monitored to establish that treatment is within specified limits.

Three general reports on SWD equipment have been published (ECRI, 1979; HAYNE, 1984; DHSS, 1987). HAYNE's report (1984) provided a brief description of five SWD models, highlighting their principal advantages and disadvantages. The British Department of Health & Social Services (DHSS, 1987) evaluation report on SWD units was more comprehensive. Six models were assessed for compliance with the general and SWD-specific standards of the British Standards Institute current at that time (BS 5724-1, 1979; BS 5724-2-3, 1983), but no protocol for on-going equipment evaluation is described. The earliest of the reports (ECRI, 1979) described the evaluation criteria and test methods used to assess ten SWD models to enable the recommendation of equipment for purchase. Although the objective of the report was not to produce a QC protocol, many of the tests included could be incorporated into such a protocol.

The current study developed a QC protocol for SWD units and applied it to 20 SWD units in use in seven hospital-based physiotherapy departments and three private practices. The protocol (Table 2) examined the performance of these units and also included a basic assessment of the environment in which they operated to determine the presence of any significant risks to patient or operator safety.

## 2 Methodology

### 2.1 Quality control test procedure

The tests included were applicable to all SWD units emitting CSWD, PSWD or both. All measurements were carried out 'on-site' by the same investigator and using the same test equipment, as it was not feasible to transport units to a central laboratory for analysis.

**2.1.1 Mechanical checks:** SWD units were inspected to ensure that no deficiencies existed in their mechanical condition that would adversely affect patient or operator safety. The features inspected and acceptable findings are summarised in Table 2. Timer accuracy was measured using a stopwatch.

**2.1.2 Electrical safety testing:** SWD units are categorised as Class I type BF electrical equipment and are subject to compliance with the relevant IEC 601-2-3 requirements (IEC 60601-2-3, 1991) (see Table 2). An electrical safety tester operating in manual mode was used for testing. This was necessary as, although the unit switched on when power was supplied, there was no emission (as was required by some tests) until the timer circuit was activated and the intensity control was engaged. As type BF applied parts are intended to be non-conducting, it was necessary to wrap the electrodes in tin foil to measure the patient leakage currents.

**2.1.3 Output measurements:** No totally satisfactory method for measuring patient dosage exists (DHSS, 1987), but various methods have been suggested. These include the 'thigh' method, where a thermocouple measures tissue temperature 2 inches below the surface of the thigh after SWD is applied (ECRI, 1979). An 'acceptable' unit produces a temperature increase to at least 40°C. The 'phantom' method uses a saline-filled phantom as a substitute for the patient, and temperature change is again measured. Finally the 'light output' method measures the light emitted from one or more incandescent bulbs capacitively or inductively coupled to the applicator.

None of these methods, however, necessarily reflects the dose delivered to a patient (ECRI, 1979).

Test equipment for measuring output is available and can be used for routine assessment and standardisation of the outputs from 'identical' models (DHSS, 1987). For example, the Diathermy Analyser Model 901\* tests capacitive and inductive SWD using different pick-up electrodes attached to the unit by velcro straps (Fig. 2). This device was used in the current study to measure the power output linearity, stability, reproducibility and frequency while the unit operated in CSWD and PSWD modes and for the capacitive and inductive methods of application. The uncertainty of the tester was  $\pm 10\%$ . It was noted during testing that the inductive pick-up electrode was not suitable for testing two units in the normal manner. In both cases, the orientation of the coils in the treatment electrode and the pick-up electrode were the same. This gave poor linkage of the output field to the analyser and no detectable signal. When the pick-up electrode was orientated at an angle of 45° to the treatment electrode, linkage improved. In these cases, however, the measured output was an unknown factor, lower than the true output of the inductive coil.

The power output characteristics that were tested are summarised in Table 2. Output stability was measured over a 20 min period, as this was representative of an average treatment session (LOW and REED, 2000). Analysis of the output waveform from PSWD was performed using an oscilloscope with a scope probe attached that acted as a basic antenna. The parameters tested were pulse frequency and pulse width.

**2.1.4 Environmental survey:** The treatment environment was visually assessed to ensure that stray radiation from SWD units caused no interference with nearby equipment and that objects in the area would not cause a concentration of radiation. A review of the relevant literature identified three areas for inspection: furniture used, treatment area layout and the presence of warning signs (see Table 2).

Metal objects in the treatment area (including metal furniture) can cause a localised increase in RF radiation (DHW, 1983; APA, 1992), distortion of the RF field and an increase in the risk of RF burns. Metal objects can also constitute a fire hazard, as the concentration of RF fields can increase the temperature of that object and induce burning in nearby materials. Therefore the presence of any such objects near the SWD treatment area was noted.

An analysis of the treatment area layout was considered particularly important where SWD treatment was not carried out in RF screened rooms. The walls of such rooms are lined to ensure stray RF fields do not radiate outside, and the room acts as a Faraday cage, eliminating RF interference completely. The primary concern when SWD is operated in an open department is that other patients and staff in the vicinity could be exposed to excessive stray radiation from SWD. Accordingly, it was noted whether a specified area was designated for SWD treatments or nearby cubicles were of sufficient width to reduce this potential risk.

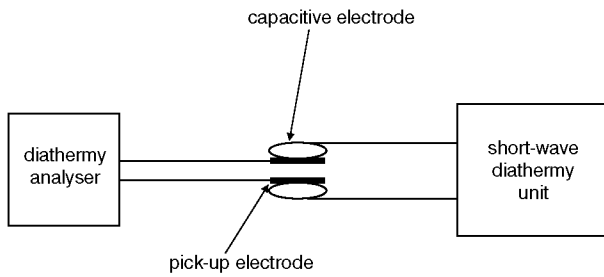
Stray RF radiation can also interfere with other operating electrotherapy equipment within 3–5 m, including low- and medium-frequency stimulators and laser equipment. Maintaining the required distances between equipment can prove difficult, depending on the departmental layout, and where this occurs it is recommended that arrangements be made that the relevant electrotherapy equipment be used at different times (CSP, 1992; CSP, 1994). Departments were observed for their practices in relation to electrotherapy use. Electrical interference can also be reduced through the introduction of a mains filter

\*BioTek Instruments Ltd

Table 2 Summary of QC protocol

Test section	Included tests	Acceptable criteria	Reference
Mechanical tests	Secure casing	Access to internal components is only through panels removable with tools	—
	Functioning castors	All surfaces are in good condition	—
	Operating castor brakes	Unit is portable	—
	Movable treatment arms	Brakes immobilise unit	—
	Treatment arms lock	Treatment arms are securely attached and freely movable	—
	Interchangeable electrodes	Treatment arms lock in place	—
	Condition of electrodes	Range of electrodes are available	—
	Functioning control	Electrodes lock in place	ANHMRC (1985)
	Operation of patient circuit breaker	Inspect for signs of deterioration or damage	—
	Timer accuracy	Air-space electrodes are adjustable	—
Output tests	Linearity	Rubber on pad electrodes has not broken down	—
	Stability	Dials are fixed and click at correct interval	—
	Reproducibility	Lamps and controls are operational	—
	Waveform analysis	Power output stops when operated	IEC 60601-2-3 (1991)
	Visual inspection	Unit is only energised by timer	—
	Earthing tests	Output switches off when timer is zeroed	—
	Insulation tests	Timer testing: <5 min: $\pm 30$ s; 5–10 min: $\pm 10\%$ ; >10 mins: $\pm 1$ min	DHW (1983)
	Leakage current tests	Power output varies by no more than $\pm 30\%$ of rated output power*	IEC 60601-2-3 (1991)
	Auxiliary current tests	Maximum power output does not exceed 500 W	—
	Furniture	Power output does not vary by more than $\pm 20\%$	—
Electrical safety	Visual inspection	Power output is reproducible to $\pm 20\%$	—
	Earthing tests	Frequency lies within 26.96–27.28 MHz band	IEC 60601-2-10 (2001)
	Insulation tests	Pulse frequency and pulse width measurements lie within 30% of actual value	—
	Leakage current tests	Obvious physical damage is ruled out	IEC 601-2-3 (1991)
	Auxiliary current tests	200 m $\Omega$	IEC 601-2-3 (1991)
	Furniture	>50 M $\Omega$	IEC 601-2-3 (1991)
	Treatment area layout	Earth leakage	IEC 601-2-3 (1991)
	Warning signs	Enclosure leakage	—
	Other modalities in area	Patient leakage (AC)	—
		Patient leakage (DC)	—
Environmental survey	Warning signs	AC	IEC 601-2-3 (1991)
	Other modalities in area	DC	—
	Warning signs	Treatment plinths and chairs are non-metallic	DHW (1983); ANHMRC (1985); APA (1992); CSP (1992); CSP (1994); ENRAF NONIUS (1997)
	Other modalities in area	Large metal objects not closer than 3 m	DHW (1983); APA (1992)
	Warning signs	Mains filter present	ANHMRC (1985); ENRAF NONIUS (1997)
	Other modalities in area	Danger to patients with pacemakers	—
	Warning signs	Regarding use of mobile phones	—
	Other modalities in area	Other electrotherapy equipment at 5 m	—
	Warning signs		CSP (1992); CSP (1994)
	Other modalities in area		—

\*This criterion refers to accuracy of unit's output reading; where no reading was given, a comparison of output power with intensity setting was performed



**Fig. 2** Diathermy analyser set-up to measure power output linearity, stability, reproducibility and frequency from an SWD unit operating using the capacitive method

on the power source of SWD equipment (ANHMRC, 1985; ENRAF NONIUS, 1997). Interference from SWD units can also cause mobile phones and cardiac pacemakers to malfunction. Accordingly, the presence of warning signs and mains filters was noted in the survey.

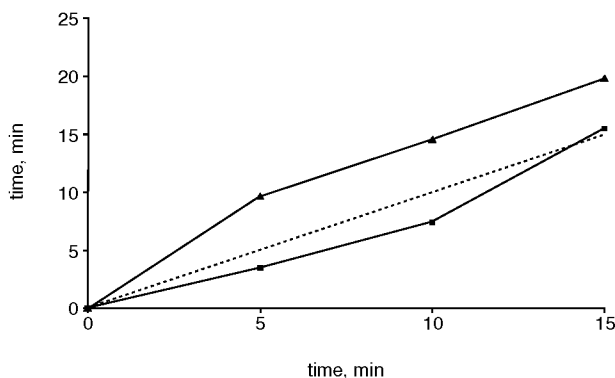
### 3 Results

Seven hospital-based departments and three private practices took part in the study. Two hospital departments had SWD units available at two different sites within the hospital. In total, 20 units were examined at 12 sites.

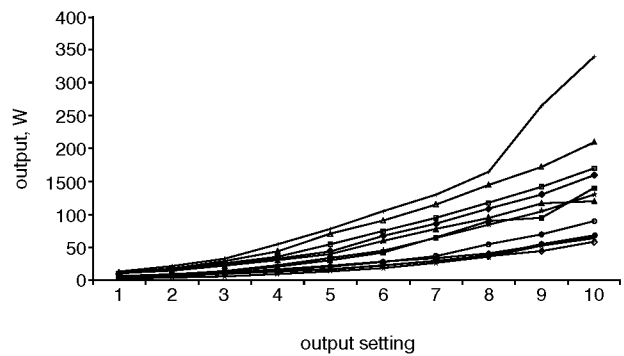
#### 3.1 Mechanical checks

The majority of units tested were mechanically sound. Three units had no brakes on their castors to fix the unit during treatment, but all other units possessed operational brakes. Most units (80%) had no patient circuit breaker incorporated into their design, but where this feature was present it operated correctly. These features should be considered by the manufacturers for inclusion as standard in future equipment designs. In one unit, the treatment arms did not lock into position. Inspection of available electrodes found two cases where they were not in good condition. In one instance, a loose connection was found on an inductive electrode adaptor, and, in another case, the electrodes were old and worn, and the metal plate was non-adjustable. All unit controls operated correctly, with one exception where the control did not select the correct setting.

A significant result was found when the operation of the timer circuits was analysed. Eighteen digital timers were examined, and all operated correctly (average coefficient of variation <0.01%). Only two mechanical timers were examined, and both were inaccurate: the first by an average of 4.5 min too long, and the second by an average of 2 min too short (Fig. 3).



**Fig. 3** Timer inaccuracy for two mechanical timers tested. (●) unit A; (▲) unit B; (---) line of unity

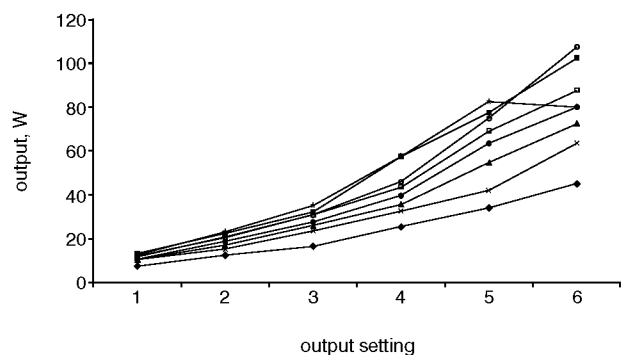


**Fig. 4** Variation in output linearity measurements for 12 SWD units from the same manufacturers (Enraf Nonius) operated using air-space electrodes (capacitive method) in continuous mode. (—) Unit 1; (●) Unit 2; (▲) Unit 3; (◊) Unit 4; (◐) Unit 5; (◑) Unit 6; (◒) Unit 7; (◓) Unit 8; (◔) Unit 9; (◕) Unit 10; (◖) Unit 11; (◗) Unit 12. Units 1 and 4–6 are model Curapuls 970; all other units are model Curapuls 419

These errors represent a dose increase of 82.4 kJ or 45% and a dose decrease of 61.2 kJ or 26%, respectively, when a 'worst-case' treatment dose error was calculated, based on the maximum output of each unit over 10 min.

#### 3.2 Power output measurements

Linearity tests found that the power output increased in a non-linear fashion, regardless of the method of application (Figs 4 and 5). Analysis of the data found an exponential relationship between the intensity setting values and the power output. Furthermore, a large disparity was noted between measured outputs on 12 different units that were set to the same nominal output intensity level (Fig. 4). For example, at the maximum intensity setting (setting 10), the output measured ranged from 59 to 340 W. In four of the units tested, the unit gave a reading of the power output in watts. These readings were compared with the readings taken by the diathermy analyser. In two cases, a comparison was not possible. For one unit, the output reading was for the peak power output, whereas the diathermy analyser measured the average power output. In the second case, a difficulty arose when the output from the inductive electrode was measured, owing to the orientation of the electrode coils, as previously discussed. Of the two cases where direct comparison between the unit's output reading and the diathermy analyser



**Fig. 5** Variation in output linearity for eight SWD units from the same manufacturer (Enraf Nonius) operated using air-space electrodes (capacitive method) in continuous mode. (Manufacturers recommend that, with this set-up combination, the intensity setting is kept below 6.) (◆) Unit 1; (●) Unit 2; (▲) Unit 3; (◊) Unit 4; (◐) Unit 5; (◑) Unit 6; (◒) Unit 7; (◓) Unit 8. Units 1–3 are model Curapuls 970; all other units are model Curapuls 419

was possible, the difference between the readings was within the 30% accuracy level set by the IEC 601-2-3 standard (IEC 60601-2-3, 1991).

Measurements of output stability showed the output to be generally stable for both the capacitive method of application (average coefficient of variation 2%; range 0.4–6.1%) and the inductive method (average coefficient of variation 4.3%; range 0–8.8%) (Fig. 6). Tests for reproducibility found that output power levels were reproducible (average coefficient of variation for the capacitive method 0.8%; range 0–2.4%; average coefficient of variation for the inductive method 2.3%; range 0–6.8%). Frequency, pulse frequency and pulse width readings were all within the  $\pm 30\%$  accuracy level adopted from an equivalent standard for nerve and muscle stimulators (IEC 60601-2-10, 2001) (see Table 2).

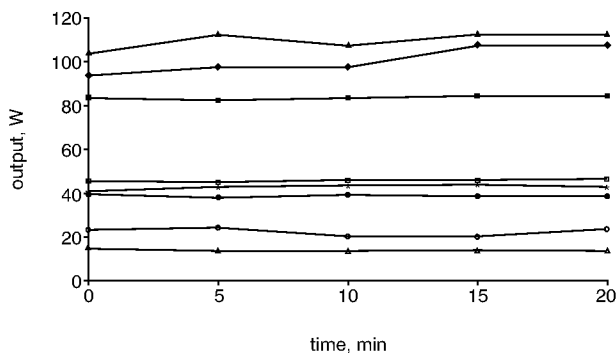
### 3.3 Electrical safety testing

All electrical safety tests were found to be within normal limits.

### 3.4 Environmental survey

Manufacturers of SWD units specify that the furniture used with this equipment should be absolutely metal-free (ENRAF NONIUS, 1997). However, in the departments assessed, none of the treatment plinths was completely metal free. All had a wooden frame that contained various metal components, including screws and hinges. Of similar concern was the presence of large metallic objects, including radiators and wire mesh, within 3 m of SWD equipment in most departments. Another significant finding was the observation that, where a patient call bell or alarm was unavailable, the patient used a metal bell to attract attention.

Electrotherapy equipment was generally not used within 3 m of SWD equipment. Although most departments displayed warning signs regarding the use of mobile phones and alerting patients with pacemakers (69.2% and 76.9%, respectively), a significant number of departments did not. These should be standard for all treatment areas where electrotherapy equipment is used. Finally, no department operated SWD equipment in an RF screened room, although one department used a separate room, and most others nominated a specific area for SWD treatment. In the case of private practices, each patient was treated in a separate room.



**Fig. 6** Variation in output stability over a 20 min period for eight SWD units from the same manufacturer operated using a drum electrode (inductive method) in continuous mode. (Power output reading taken every 5 min over a 20 min period.) (♦) Unit 1; (●) Unit 2; (▲) Unit 3; (△) Unit 4; (○) Unit 5; (◐) Unit 6; (◑) Unit 7; (◒) Unit 8. Units 1–3 are model Curapuls 970; all other units are model Curapuls 419

## 4 Discussion

The QC protocol described is useful in determining whether an SWD unit is functioning to the required specifications and for comparing its performance over a period of time. For example, if equipment is serviced under contract, part of the contract could be to determine reference output data for each unit that could be used for comparison during subsequent services to note trends in output levels. The protocol would be particularly useful when a new SWD unit is introduced into a physiotherapy department. The IEC 601-2-3 standard document (IEC 60601-2-3, 1991) and the Canadian Department of Health & Welfare (DHW, 1983) recommend departments perform QC testing on their units at yearly intervals. The Australian Physiotherapy Association (APA, 1992) and the Chartered Society of Physiotherapy in Britain (CSP, 1992; 1994), however, suggest that equipment used daily be tested every 6 months. Routine checking of mechanical tests and analysis of the treatment environment could be performed by trained physiotherapy staff. Electrical safety testing and output measurements require assessment by technical staff. Of the tests included in the protocol, electrical safety testing, output measurements and timer accuracy are the most important.

The results highlighted the importance of checking mechanical timer accuracy. Although only two mechanical timers were tested, both were unreliable and deviated significantly from normal. This finding is clinically significant in terms of dosage error. Basic research on the actual SWD dose received by the patient is scarce, primarily owing to difficulties in determining reliably the amount of RF energy absorbed by human tissues. As the exact dose absorbed is unknown, estimated theoretical and real 10 min doses were calculated for the two units with mechanical timers, and results found large differences of up to 45%. Based on the guidelines issued by the Canadian Department of Health & Welfare (DHW, 1983), it is recommended that the timer error should be within  $\pm 10\%$ . Units that do not conform to this criterion should be replaced. Furthermore, the use of mechanical timers is no longer acceptable in ionising radiation units, and, in the light of the current results, it is recommended that all SWD units with mechanical timers should be replaced.

Although the output measurement testing was generally unremarkable, the non-linear nature of output measurements is noteworthy. CSWD dose is based on a patient's thermal sensation, with the operator increasing the intensity until a mild, comfortable heat is felt. Operators should be aware that, although the intensity settings are described using an interval scale, the power output produced is exponential under experimental conditions. This finding and the differences in actual power delivered for the same setting on different machines are relevant to comparisons of treatment efficacy between machines and centres and during clinical trials. Future research should focus on developing a reliable method of measuring patient dosage, so that treatment is accurate and reproducible. Power output and reproducibility varied by no more than 8.8%. None of the documents published on SWD units suggests an acceptable limit for variation in these parameters. Standards for other electrotherapy modalities were consulted, but no limits were found from which to extrapolate. Therefore it was considered that a limit of  $\pm 20\%$  was reasonable, based on the data collated and the uncertainty of the diathermy analyser used to take the measurements. Future research in the areas of dosage, physiological change from treatment and risk assessment will enable these criteria to be refined.

The environmental survey of the SWD treatment areas found that the treatment plinths used in all departments, although made from wooden frames, contained various metal components, contrary to advice given by the manufacturers (ENRAF NONIUS, 1997). The danger presented by such furniture has not been assessed scientifically, but an increased risk of patient burns is

possible. Such furniture can also constitute a fire hazard, as reported incidents have involved cases of output cables overheating when situated close to metal objects including screws (DHSS, 1987). Of similar concern were the large amounts of metal located close to SWD units. Metallic objects in the vicinity of operating SWD equipment can act as antennae and cause a concentration of radiofrequency radiation in an area, producing an unnecessary hazard both in terms of burns and excessive exposure from stray radiation (ENRAF NONIUS, 1997; ANHMRC, 1985; DHW, 1983; APA, 1992). In addition, the use of metal bells to attract the physiotherapist's attention is also discouraged, as it too places the patient at an unnecessary risk of sustaining a burn.

No department operated SWD equipment in an RF-screened room. This facility is important, but not essential, in ensuring that other people in the vicinity of operating equipment are not exposed to excess amounts of stray radiation, as directed by international guidelines (IRPA, 1988). In the absence of this facility, steps should be in place to avoid unnecessary exposure. Future research should investigate how rigorously this is enforced.

## 5 Conclusions

A quality control procedure has been presented for SWD units that should enable personnel to evaluate and monitor the performance of this equipment over time and ensure it is functioning to the required specifications. The protocol includes tests to monitor mechanical and electrical safety, to examine the power output characteristics and to assess the environment within which these units operate. The protocol was completed on 20 SWD units currently in use, and 18 were found to be within the acceptable limits. Two units were deemed unacceptable owing to inaccurate mechanical timers that would, under worst-case scenarios, deliver in one case a treatment dose 45% higher than the selected dose and in another case a dose 26% lower than expected.

This protocol can be used to verify whether a unit is functioning within normal limits and also as a periodic review of a unit's performance. In this way, those operating such equipment can be assured of reproducible treatments. Equipment analysis is important, as the use of faulty equipment in electrotherapy treatment can cause adverse effects. Future research in this area could be incorporated into this procedure, particularly in the area of output analysis.

*Acknowledgments*—The financial support of the following organisations is acknowledged: Enterprise Ireland, the Trinity Trust Foundation and the Coyle Hamilton Bursary.

The contributions to the study of Fran Hegarty and Angela Donohoe, of the Medical Physics & Bioengineering Department, St James's Hospital, Dublin, and Karl Casey, student in the School of Physiotherapy, Trinity College, Dublin, are acknowledged.

The support of the physiotherapy departments and private practices that participated in the study is acknowledged.

The authors would also like to thank the two anonymous reviewers for their very helpful comments.

## References

- AUSTRALIAN NATIONAL HEALTH & MEDICAL RESEARCH COUNCIL (1985): 'Code of practice for the safe use of shortwave (radio-frequency) diathermy units' (Australian Government Publishing Service, Canberra, Australia, 1985)
- AUSTRALIAN PHYSIOTHERAPY ASSOCIATION (1992): 'Clinical standards for the use of electrotherapy agents' (Australian Physiotherapy Association, Victoria, 1992)
- BRITISH STANDARD BS 5724-1 (1979): 'Medical electrical equipment. Specification for general safety requirement' (British Standards Institution, London, UK, 1979)

- BRITISH STANDARD BS 5724-2-3 (1983): 'Section 2.3 Specification for shortwave therapy equipment' (British Standards Institution, London, UK, 1983)
- CHARTERED SOCIETY OF PHYSIOTHERAPY (1992): 'Guidelines for the safe use of continuous shortwave therapy equipment', *Physiother.*, **78**, pp. 755–757
- CHARTERED SOCIETY OF PHYSIOTHERAPY (1994): 'Guidelines for the safe use of pulsed shortwave therapy equipment', *Physiother.*, **80**, pp. 233–235
- CHARTERED SOCIETY OF PHYSIOTHERAPY (2001): 'Physios warned of diathermy danger', *Frontline*, **7**, p. 9
- DEPARTMENT OF HEALTH & SOCIAL SERVICES (1987): 'Evaluation report: shortwave therapy units', *J. Med. Eng. Technol.*, **11**, pp. 285–298
- DEPARTMENT OF HEALTH & WELFARE (1983): 'Safety code 25, short-wave diathermy: guidelines for limiting radiofrequency exposure' (Canadian Environment Health Directorate 83-EHD-98)
- EMERGENCY CARE RESEARCH INSTITUTE (1979): 'Shortwave diathermy units', *Health Devices*, pp.175–192
- ENRAF NONIUS (1997): 'Curapuls 970 operating instructions manual' (Enraf Nonius, Delft, The Netherlands, 1997)
- HAYNE, C. (1984): 'Pulsed high frequency energy—its place in physiotherapy', *Physiother.*, **70**, pp. 458–466
- HENDRICKS, O. (1991): 'Developments in electrotherapy', *Physiother. Ireland*, **12**, pp. 18–21
- IEC 60601-2-3 (1991): 'Section 2.3 Specification for shortwave therapy equipment' (International Electrotechnical Commission, Geneva, Switzerland, 1991)
- IEC 60601-2-10 (2001): 'Section 2.10 Particular requirements for the safety of nerve and muscle stimulators' (International Electrotechnical Commission, Geneva, Switzerland, 2001)
- INTERNATIONAL RADIATION PROTECTION ASSOCIATION (1988): 'Guidelines on limits of exposure to radiofrequency electromagnetic fields in the frequency range from 100 kHz–300 GHz', *Health Phys.*, **54**, pp. 115–123
- LLOYD, J. J., and EVANS, J. A. (1988): 'A calibration survey of physiotherapy equipment in North Wales', *Physiother.*, **74**, pp. 593–600
- LOW, J., and REED, A. (2000): 'Electrotherapy explained: principles and practice' (Butterworth Heinemann, Oxford, 2000)
- PARTRIDGE, C. J., and KITCHEN, S. S. (1999): 'Adverse effects of electrotherapy used by physiotherapists', *Physiother.*, **85**, pp. 298–303
- POPE, G., MOCKETT, S., and WRIGHT, J. (1995): 'A survey of electrotherapeutic modalities: ownership and use in the NHS in England', *Physiother.*, **81**, pp. 82–91
- PYE, S., HILDERSLEY, K., SOMER, E., and MUNRO, V. (1994): 'A simple calorimeter for monitoring the output power of ultrasound therapy machines', *Physiother.*, **80**, pp. 219–223
- PYE, S., and MILFORD, C. (1994): 'The performance of ultrasound physiotherapy machines in Lothian Region Scotland', *Ultrasound Med. Biol.*, **20**, pp. 347–359
- SHIELDS, N., GORMLEY, J., and O'HARE, N. (2001a): 'Short-wave diathermy in Irish physiotherapy departments', *Br. J. Ther. Rehabil.*, **8**, pp. 331–339
- SHIELDS, N., GORMLEY, J., and O'HARE, N. (2001b): 'Short-wave diathermy: a review of existing clinical trials', *Phys. Ther. Rev.*, **6**, pp. 101–118

## Authors' biographies

Ms NORA SHIELDS is a post-graduate physiotherapy student in Trinity College Dublin and has undertaken this work as part of her PhD. Her current area of interest is clinical and safety issues in SWD application. Dr NEIL O'HARE is the Assistant Head of Department of Medical Physics and Bioengineering in St James's Hospital, Dublin and is supervisor to Ms SHIELDS. He has a specific interest in the area of non-ionising radiation including RF and UV radiation. Dr GERARD BOYLE is a Principal Physicist in St James's Hospital, Dublin and has been closely involved in the development of Quality Assurance and maintenance protocols for physiotherapy equipment. Dr JOHN GORMLEY is a lecturer in Electrotherapy in the School of Physiotherapy, Trinity College Dublin and is also a supervisor to Ms SHIELDS.