

## In-use effect of electrolysed water on transcutaneous oxygen sensors

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**Abstract.** Reusable clinical equipment should be decontaminated between patients in order to reduce risk of pathogen transmission. Manufacturers are obliged to offer advice regarding decontamination but occasionally insufficient guidance is provided. Tissue oxygen sensors are reusable, costly and vulnerable to disinfectants. This pilot study describes an in-use protocol using neutral electrolysed water aimed at eliminating infection risk during transcutaneous oxygen monitoring of diabetic feet. Sensor components were screened for microbial contamination before, during, and after monitoring healthy and diabetic volunteers. Exposure to electrolysed water removed original skin commensals and alleviated the risk of transmitting microbial flora without affecting test results. The product is non-toxic, inexpensive and may be useful for decontaminating a wide range of sensitive clinical equipment.

Received 8 August 2015, accepted 7 September 2015, published online 1 October 2015

### Introduction

Diabetic patients are at risk from developing foot ulcers due to neurovascular deficits.<sup>1</sup> It is important to distinguish between critical limb ischaemia as opposed to neurosensory loss in order to optimise management of the non-healing diabetic ulcer.<sup>1</sup> One method of ascertaining vascular insufficiency is to measure tissue oxygenation using a transcutaneous oxygen monitor (TOM) (Fig. 1a).<sup>2</sup> This is performed by connecting membrane-covered sensors to fluid-filled coupling holders attached to the skin by adherent pads. The membrane itself is costly, highly sensitive and permeable and forms an integral part of the sensor (Fig. 1b). Electrical leads connect the sensors to the monitoring unit.

TOM equipment is used across the western world for neonatal oxygen monitoring, tissue vascularity assessment, and the diagnosis of sepsis, diabetes and anaemia, amongst other conditions.<sup>3</sup> Several companies manufacture this type of monitoring unit, and general decontamination advice is offered for most of the components. Users are advised not to handle the membrane, however, with a kit supplied for replacing the membrane after a specified number of tests.

Manufacturer's guidance on decontamination of the TOM (TCM400) model was provided excluding the electro-membrane on the sensor. We were told that this component should not be handled or exposed to cleaning agents because

they might affect the integrity and function of the sensor. Since diabetic feet (and surrounding skin) may harbour a wide range of microbes, there is a risk of cross transmission between patients. TOM sensors are not dissimilar to ultrasound transducers, which also contact broken skin, and are considered to be semi-critical devices needing high-level disinfection.<sup>4</sup> It was felt that we should find a decontamination method that would allay any concerns of cross-transmission without affecting the function and longevity of the TOM equipment.

We chose to audit the effect of neutral electrolysed water during clinical use in a diabetic foot clinic.<sup>5</sup> While this product has been approved as an environmental disinfectant, it has not been evaluated for decontamination of sensitive clinical equipment.<sup>6–8</sup> Electrolysed water (also known as super-oxidised water) is produced by ion-exchange electrolysis of saline, and contains a significantly higher level of available hypochlorous acid than can be delivered via chemical formulation.<sup>5</sup> It is effective against a range of microorganisms following contact times of <1 min.<sup>5</sup> Salvesan<sup>®</sup> is a commercial product in which hypochlorous acid has been stabilised, allowing it to be bottled and stored for periods in excess of 1 year.<sup>7</sup> Sensitivity and toxicology studies have demonstrated that the product is environmentally friendly and non-toxic for mammals.<sup>5,7</sup>

### Implications

- Decontaminating reusable clinical equipment between patients reduces the risk of pathogen transmission.
- Some equipment cannot be easily decontaminated and thus represents an infection risk to patients.
- Neutral electrolysed water was used to decontaminate sensitive electrical probes without compromising monitoring data. The product could be useful for decontaminating similar clinical equipment.

### Methods

#### Validity monitoring

Two sensors 10 cm apart were attached to the dorsum of the foot of one healthy volunteer. One sensor was immersed in neutral electrolysed water (Salvesan<sup>®</sup>; Aqualution Ltd, Histon, Cambridgeshire, UK) for 10 to 15 s between tissue pO<sub>2</sub> readings while the other was not. Measurements were taken from both sensors over a 3-h time period. One sensor was then repeatedly immersed in 20 mL electrolysed water for 20 cycles, with background readings from the monitor compared against those from an unexposed sensor. Since electrolysed water exposure did not affect volunteer or background readings, an in-use protocol was devised for patients requiring assessment of tissue pO<sub>2</sub>.

#### Participants

Ten volunteers were recruited, comprising two healthy staff members and eight diabetic patients with chronic ulcers on the lower limbs. All volunteers received a patient information leaflet and explanation of the study before providing consent. Overall, six men and four women participated, with ages ranging from 49 to 79 years (mean age: 61 years). The study received prior ethical approval from NHS Lanarkshire.

#### Decontamination protocol

All components of the TOM equipment were cleaned and disinfected using electrolysed water before use. Investigators washed and dried hands before donning sterile gloves. Skin on the dorsum of the foot (4 cm<sup>2</sup>) proximal to the first digital interspace was sampled with a swab moistened in sterile saline (swab 1). The area was then cleaned with an alcohol wipe and allowed to dry. Other monitoring sites were ankle (above lateral malleolus) and thigh (3–4 cm above knee), depending upon site of an active ulcer in the patient group. One sensor per volunteer was used for repeat sampling throughout the study. A disposable coupling holder was then placed on the cleaned skin using an adhesive pad (Fig. 1). The holder cup was filled with coupling fluid before being connected to the sensor, which was itself attached to a monitor with leads and allowed to equilibrate.

A second swab was moistened with sterile saline and wiped over the entire surface of the sensor and coupling unit while

the monitor was operating (swab 2). The time interval before pO<sub>2</sub> tension stabilised ranged from 20 to 40 min. Directly after disconnection, a dry swab was immersed in the coupling fluid (swab 3) in the coupling holder. A further moistened swab was gently applied to the membrane of the sensor (swab 4). The coupling holder and pad were then removed from the skin. The sensor and overlying membrane was immersed in electrolysed water for 10 to 15 s and allowed to dry naturally.

The membrane was re-sampled after 15 min using a moistened swab (swab 5) and a final swab was applied to skin at the monitoring site (swab 6). The two staff members underwent the study protocol using sites on both feet, which with eight patients, supplied results for 12 sets of six swabs.

### Microbiology

Swabs were processed by a CPA accredited laboratory in accordance with standard operating procedures for wound swabs. Swabs were plated onto Columbia blood agar incubated in CO<sub>2</sub> and anaerobically, and aztreonam Columbia and CLED agars in O<sub>2</sub>. All plates were incubated for 24 to 48 h at 37°C. Microbial growth was quantified as follows: scanty growth: 1–10 cfu/swab; light growth: 11–50 cfu/swab; moderate growth: 51–100 cfu/swab; and heavy growth: >100 cfu/swab. Staphylococci were subjected to coagulase testing and positive isolates identified and characterised for methicillin resistance (Vitek<sup>®</sup>22 AST P-634 Cards; bioMérieux UK Ltd, Basingstoke, Hampshire, RG22 6HY). Bacillus colonies were plated onto *Bacillus cereus* selective agar and coliforms were identified using MacConkey agar, oxidase and Vitek<sup>®</sup>2 GN ID cards. Cutaneous fungi were not sought. Supplied coupling fluid was independently tested against laboratory cultures of methicillin-susceptible *Staphylococcus aureus* (MSSA), coagulase-negative staphylococci (CNS), *Escherichia coli* and *Bacteroides fragilis* to determine antibacterial activity. Briefly, 1 mL aliquots of coupling fluid were inoculated with 0.5 McFarland dilutions of laboratory cultures for each test organism and incubated at 37°C in air and anaerobically for at least 5 days. Cultures were subbed onto Columbia blood (staphylococci and *B. fragilis*) and MacConkey (*E. coli*) agars and incubated for 24 to 48 h at 37°C in CO<sub>2</sub>, anaerobically and O<sub>2</sub>, respectively. Sterile distilled water and electrolysed water were used as positive and negative controls.

### Results

Skin and faecal-type flora in varying quantities (1 to >100 cfu/swab) were recovered from the lower limbs of all 10 participants before transcutaneous oxygen monitoring (swab 1; Table 1). In addition to mixed CNS varying from a few colonies (scanty growth) to heavy growth (>100 cfu/swab), one volunteer was colonised with *S. aureus* (11–50 cfu/swab), one patient had scanty growth of *B. cereus* (<10 cfu/swab) and a third had moderate growth of two different coliforms (51–99 cfu/swab). No anaerobes, enterococci or streptococci were recovered.

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