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A Test Protocol and Evaluation of the Moisture Return of the Intersurgical Hydro-Trach T HME, code 1873000

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Introduction

The supplied gases available to patients with bypassed upper airways often lack the required moisture to enable the respiratory tract to meet the physiological demands.

Heat and Moisture exchangers (HMES) are used to raise the water content and the temperature of the gas delivered to the respiratory tract of patients. They are primarily intended for use with tracheostomised or intubated patients, independently or as part of a breathing system.

HME output is tested with protocols based on international standards, using a rig to simulate breathing under a variety parameters. This test apparatus consist of a sine wave pump and a humidifier to deliver warm humidified gas towards the HME during expiration. During inspiration dry gas at ambient temperature passes through the HME thereby transporting the accumulated heat and moisture back towards the humidifier.

The HME moisture output is the total amount of water in milligrams per litre, in the inspired gas leaving the HME patient port under specified test conditions, expressed in mg/L.

Apparatus

The Moisture Return rig according to ISO standards consists of the following (Figure 1):

Sine Wave Pump: Delivers the minute volume at the frequencies stated.
Temperature probes: At various points to measure test gas, water bath, and HME patient port.
Tubing and connections: Between the sine wave pump and HME isolate the length of tubing between the HME and point of separation of the inspiratory and expiratory limbs.
Temperature controlled water bath: Regulated to give a maximum temperature measured at the HME patient port of 34°C ±1°C, 100% humidity, when averaged over 20 expirations.
Reservoir bag: Capacity of which is greater than the tidal volume.
Balance: With an accuracy of ±0.1g or better in the range of mass to be measured.
Test gas: The test gas is air-having humidity not exceeding 0.88mg/L equivalent to a dew point of 20°C at atmospheric pressure.
Gas flow measuring equipment: Calibrated to an accuracy of ±5% of the reading in the range 1L/min to 100L/min.
Respirometer: to check the volumes at the piston and HME connection (±4%).
One-way valves: To direct inspiratory and expiratory flows.

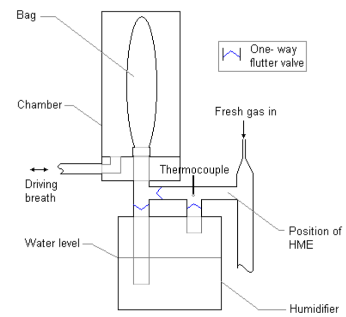

Figure 1: The patient model and its connections (rig)

Method

The HME is connected to the patient model and ventilator (rig) as shown in Figure 1. Table 1 shows the ventilator parameters.
The flow meter (fresh gas) is set at 20L/min (for all adult HMEs). This represents the fresh gas supply used on machine side during long-term ITU treatment. The ambient temperature for the duration of the test is 23°C ±2°C.

The apparatus was run for 60 minutes, without the HME, in order to perform a calibration and evaluate the set-up performance. The pre and post weights of the patient model were recorded.

The system was run for 60min to precondition the HME and stabilise the test system. The patient model was then disconnected and the HME removed. The weight of the patient model was then measured. With the HME reconnected, the patient model was replaced. The test apparatus was run for 2 hours.

After 2 hours the patient model was disconnected carefully so that any condensation that had occurred was retained in situ within the patient model, and the HME carefully removed. The model was then reweighed. This is the final weight.

Tidal Volume (ml)	Fresh Gas (l/min)	Breaths per min	I:E
500	20	20	1:2

Table 1: Ventilator Parameters.

Calculation of Moisture Return

Equation 1 is used to calculate the weight loss after the calibration run and the test run with the HME in place.

(1) $$W_l = \frac{1000\times(W_{Start}-W_{Finish})}{B_T - V_T}$$

(2) $$Efficiency = \frac{100\times(W_{Calibration}-W_{Test})}{W_{Calibration}}$$

The weight loss values calculated from equation 1 are then used to calculate the efficiency (Equation 2). The efficiency is then put into equation 3 to calculate the moisture return.

(3) $$Moisture\ Return = \frac{37.6\times Efficiency}{100}$$

Where: W_l = Weight Loss
W_{Start} = Start Weight
W_{Finish} = Finish Weight
$W_{Calibration}$ = Weigh loss after calibration run.
W_{Test} = Weight loss after test run with HME.
B_t = Total Breaths
V_T = Tidal Volume

Results

Filter	Moisture return (mg/L)
1873000	26.0[3]

Table 2: Moisture return of 1873000 filter.

References:
1. ISO 9360 – 1: 1992
2. ISO 9360 – 2: 2001
3. Final test results HME efficiency