Technologie Institut Medizin GmbH (TIM)

Information sheet:

TIM offers primary HME tests according to DIN EN ISO 9360-1:2009 (ISO 9360-1:2000) and DIN EN ISO 9360-2:2009 (ISO 9360-2:2001) (for Tracheostoma HME). Tests for HME, dedicated for patients with a tidal volume below 250 mL, are not defined in the standard. Tests with these HME are performed by using a special test system developed by TIM with defined test procedures based on the HME standard DIN EN ISO 9360-1:2009 (ISO 9360-1:2000).

As required in the standard, TIM performs moisture loss tests according to chapter 6.2 of this standard and pressure drop tests according to chapter 6.3 for HME. We are also able to perform pressure drop tests with breathing filters according to DIN EN ISO 23328-2:2009 (ISO 23328-2:2002), chapter 5.2.

Evaluation of the test result is not part of the testing service. Please contact TIM via e-mail (hme@tim-gmbh.de) to get an offer in case you need consulting service regarding the test methods and test results.

Kinds of HMEs we are able to test:

Kind of HME	Tidal volume in mL	Moisture loss	Pressure drop
HME	≥ 250	Yes	Yes
HMEF	≥ 250	Yes	Yes
Tracheostoma	≥ 250	Yes	Yes
Filter	≥ 250	No	Yes
HME	< 250	Yes	Yes
HMEF	< 250	Yes	Yes
Tracheostoma	< 250	No	No
Filter	< 250	No	Yes

Forms for tests:

TIM has created four different forms for you with which the desired test conditions can be clearly selected. In addition, the forms already show the expected bid amount.
Please note that this is a non-binding offer. Prices and feasibility are subject to change and can only be confirmed by TIM after a thorough examination.

These forms can be found on our homepage (www.tim-gmbh.de).

According to the standard:

- Form 1: HME and Filters dedicated for tidal volumes ≥ 250 mL

Based on the standard:

- Form 2: HME and Filters dedicated for tidal volumes < 250 mL

Individual tests:

- Form 3: HME and Filters dedicated for tidal volumes ≥ 250 mL
- Form 4: HME and Filters dedicated for tidal volumes < 250 mL

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HME test requests: hme@tim-gmbh.de

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Adult tests according to standard (Form 1)

Moisture loss tests:

The following list shows the test conditions for moisture loss measurements as defined in table 2 and in chapter 6.2.3.2 of the standard.

Test condition	Tidal volume in mL	Breathing rate in 1/min	Test duration in h
#1	1000	10	24 / 48 / 72
#2	750	12	24 / 48 / 72
#3	500	15	24 / 48 / 72
#4	250	20	24 / 48 / 72
Chapter 6.2.3.2	1500	10	24 / 48 / 72

The test system is calibrated with a calibration HME according to the requirements in the standards.

If your sample has to be tested for more than 24h (one day) please select extra test day in the form. Each sample of one type will be tested with the same test duration.

Pressure drop tests:

Following flows for pressure drop measurements of adult HME are defined in table 4 of the standard:

Flow in L/min
30
60
90

The HME pressure drop is taken initially and after moisture loss test. This means that it is measured immediately before the moisture loss measurement starts with a dry test subject and immediately after the moisture loss measurement with a moistured and tempered subject.

The pressure drop of breathing filters will be measured with the same flows even if 30 L/min (adult) is the only value which is required in DIN EN ISO 23328-2:2009 (ISO 23328-2:2002).

Although the HME standards stipulate pressure drop measurement only in combination with moisture loss tests, TIM offers also single HME pressure drop test with dry samples (initial) so you will only get one result instead of two.

Please note: if the order value is less than 1000€, we reserve the right to charge an expense allowance of 250€.

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Neonatal and pediatric tests based on the standard (Form 2)

Moisture loss tests:

The following list shows the test conditions for moisture loss measurements which TIM has predefined for HME dedicated for tidal volumes below 250 mL.

Test condition	Tidal volume in mL	Breathing rate in 1/min	Test duration in h
#1	10	60	24 / 48 / 72
#2	25	40	24 / 48 / 72
#3	50	30	24 / 48 / 72
#4	75	30	24 / 48 / 72
#5	100	30	24 / 48 / 72

As there is no standardized calibration process for these tests TIM provides for every test condition the resulting moisture loss value when performing the test without a connected HME.

If your sample has to be tested for more than 24h (one day) please select extra test day in the form. Each sample of one type will be tested with the same test duration.

Pressure drop tests:

Following flows for pressure drop measurements of neonatal/pediatric HME are predefined by TIM:

Flow in L/min
10
15
20

The pressure drop is taken initially and after moisture loss test. This means that it is measured immediately before the moisture loss measurement starts with a dry test subject and immediately after the moisture loss measurement with a moistured and tempered subject.

The pressure drop of breathing filters will be measured with the same flows even if 15L/min (neonatal/pediatric) is the only required flow of DIN EN ISO 23328-2:2009 (ISO 23328-2:2002).

Although the HME standards stipulate pressure drop measurement only in combination with moisture loss tests TIM offers also single HME pressure drop test with dry samples (initial) so you will only get one result instead of two.

Please note: if the order value is less than 1000€, we reserve the right to charge an expense allowance of 250€.

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Individual tests (Form 3 and Form 4)

As this is not enough, we want to fulfil customer wishes as long as they are technical realizable.

Moisture loss tests:

For adult HME you can choose a tidal volume between 150 mL and 1500 mL - for neonatal/pediatric it is between 10 mL and 100 mL. The breathing rate for adult HME can be chosen between 5 /min and 30 /min depending on the chosen tidal volume (the higher the selected volume, the lower the breathing rate must be). The same is valid for neonatal/pediatric HME, which can be tested with rates between 10 /min and 60 /min.

Please find below two tables of possible combination for different tidal volumes and the maximal possible rates.

HME dedicated for tidal volumes ≥ 250 mL:

Tidal volume in mL	Max. breathing rate in 1/min
150	30
200	30
250	30
300	30
350	30
400	30
450	30
500	30
550	30
600	30
650	30
700	30
750	28
800	24
850	22
900	20
950	19
1000	18
1100	17
1200	16
1300	14
1400	12
1500	10

HME dedicated for tidal volumes < 250 mL:

Tidal volume in mL	Max. breathing rate in 1/min
10	60
15	60
20	60
25	60
30	60
35	60
40	60
45	58
50	56
55	54
60	52
65	46
70	34
75	32
80	30
85	30
90	30
95	30
100	30

Test duration can be selected. TIM offers tests with 24 h (zero extra time), with 48 h (one extra day) and 72 h (two extra days).

Pressure drop tests:

You can choose flows for a pressure drop test on your own. For this, you have to select three flows with different values. The first input should be the lowest value and the last input the highest.

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In the following, you will find the selectable flows:

Flow	Adult	Neonatal/pediatric
Flow 1 in L/min	10 - 80	5 - 18
Flow 2 in L/min	20 - 90	6 - 19
Flow 3 in L/min	30 - 100	7 - 20

For neonatal/pediatric measurements, you can select flows in steps of minimum 1 L/min, for adult measurements the minimal step is 10 L/min.

If both – pressure drop and moisture loss- are chosen, we measure pressure drop initial and after moisture loss, as it is described in the standard.

TIM offers also single HME pressure drop test with dry samples (initial) so you will only get one result instead of two.

Please note: if the order value is less than 1000€, we reserve the right to charge an expense allowance of 250€.

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