附件4

试验报告

《高频呼吸机》校准规范

编写组

2023年10月

1. **试验目的**

验证《高频呼吸机》校准规范（征求意见稿）的可行性与适用性。

1. **试验地点**

上海德尔格医疗器械有限公司设备技术部，湖南省儿童医院新生儿科，湖南省人民医院新生儿科，湖南省妇幼保健院新生儿科，长沙市妇幼保健院新生儿科

1. **环境条件**

试验过程中，环境温度控制在（20~25）℃，相对湿度不超过85%

1. **试验标准及其他设备**

呼吸机质量检测仪、模拟肺

1. **试验对象**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 序号 | 生产厂家 | 型号 | 产品编号 | 试验地点 |
| 1号机 | Drager | Infinity-C500 | ASBD-0001 | 上海德尔格设备技术部 |
| 2号机 | Drager | Babylog 8000 plus | ASCE-0030 | 长沙市妇幼保健院新生儿科 |
| 3号机 | Stephan | Sophie | S0381500984 | 湖南省儿童医院新生儿科 |
| 4号机 | Stephan | Sophie | S03819001759 | 湖南省人民医院新生儿科 |
| 5号机 | Stephan | Sophie | S03816001105 | 湖南省妇幼保健院新生儿科 |
| 6号机 | Stephan | Christina | S0390800628 | 长沙市妇幼保健院新生儿科 |

注：高频呼吸机实际生产在售在用的的厂家品牌较少，德尔格（Drager）和史蒂芬（Stephan）基本占据95%以上的市场，因此本试验报告覆盖这两个厂家的主流型号，分别在不同使用地点进行试验，取得各个参数的试验结果以期验证本规范的可行性与适用性。

1. **试验结果**

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| **序号** | **生产厂家** | **型号** | | | **产品编号** | | | | **试验地点** | | | | |
| **1号机** | **Drager** | **Infinity-C500** | | | **ASBD-0001** | | | | **上海德尔格设备技术部** | | | | |
| 校准项目 | 技术要求 | 校准结果 | | | | | | | | | | | |
| 设定值 | 监测值 | | | | 平均值 | 测量值 | | | | 平均值 | 示值误差 |
| 潮气量（mL） | ±15% | / | 15 | 15 | | 15 | 15 | 14 | | 14 | 14 | 14 | / |
| / | 62 | 62 | | 62 | 62 | 61 | | 61 | 61 | 61 | 1.6% |
| / | 149 | 149 | | 149 | 149 | 147 | | 147 | 147 | 147 | 1.4% |
| 通气频率  （次/min） | ±1次/分或  设定值的±10%  （取绝对值大者） | 60 | 60 | 60 | | 60 | 60 | 60.3 | | 60.3 | 60.3 | 60.3 | -0.5% |
| 100 | 100 | 100 | | 100 | 100 | 100.8 | | 100.8 | 100.8 | 100.8 | -0.8% |
| 150 | 150 | 150 | | 150 | 150 | 150.0 | | 150.0 | 151.9 | 150.6 | -0.4% |
| 300 | 300 | 300 | | 300 | 300 | 300 | | 307.7 | 300 | 302.6 | -0.9% |
| 600 | 600 | 600 | | 600 | 600 | 600 | | 600 | 615.4 | 605.1 | -0.8% |
| 900 | 900 | 900 | | 900 | 900 | 900 | | 923.1 | 900 | 907.7 | -0.8% |
| 气道峰压  （mbar） | ±(2%FS+4%  ×实际读数)  FS= 80 mbar | 10 | 10.0 | 10.0 | | 10.0 | 10.0 | 9.9 | | 9.9 | 9.9 | 9.9 | 0.1 |
| 20 | 20.0 | 20.0 | | 20.0 | 20.0 | 19.8 | | 19.8 | 19.8 | 19.8 | 0.2 |
| 30 | 30.0 | 30.0 | | 30.0 | 30.0 | 29.4 | | 29.4 | 29.4 | 29.4 | 0.6 |
| 呼气末正压  （mbar） | ±(2%FS+4%  ×实际读数)  FS= 35 mbar | 1 | 1.2 | 1.2 | | 1.2 | 1.2 | 1.1 | | 1.1 | 1.1 | 1.1 | 0.1 |
| 2 | 2.1 | 2.1 | | 2.1 | 2.1 | 2.0 | | 2.0 | 2.0 | 2.0 | 0.1 |
| 5 | 5.0 | 5.0 | | 5.0 | 5.0 | 4.9 | | 4.9 | 4.9 | 4.9 | 0.1 |
| 吸气氧浓度（%） | ±5%  （体积分数） | 21 | 21 | 21 | | 21 | 21 | 19.5 | | 19.9 | 19.9 | 19.9 | 1.1 |
| 40 | 40 | 40 | | 40 | 40 | 38.5 | | 38.5 | 38.6 | 38.5 | 1.5 |
| 60 | 60 | 60 | | 60 | 60 | 58.6 | | 58.7 | 58.7 | 58.7 | 1.3 |

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| **序号** | **生产厂家** | **型号** | | | **产品编号** | | | | **试验地点** | | | | |
| **2号机** | **Drager** | **Babylog 8000 plus** | | | **ASCE-0030** | | | | **长沙市妇幼保健院新生儿科** | | | | |
| 校准项目 | 技术要求 | 校准结果 | | | | | | | | | | | |
| 设定值 | 监测值 | | | | 平均值 | 测量值 | | | | 平均值 | 示值误差 |
| 潮气量（mL） | ±15% | / | 13 | 13 | | 13 | 13 | 12 | | 12 | 12 | 12 | / |
| / | 65 | 65 | | 65 | 65 | 62 | | 62 | 61 | 62 | 4.8% |
| / | 153 | 152 | | 152 | 152 | 144 | | 146 | 145 | 145 | 4.8% |
| 通气频率  （次/min） | ±1次/分或  设定值的±10%  （取绝对值大者） | 60 | 60 | 60 | | 60 | 60 | 60.3 | | 60.3 | 60.3 | 60.3 | -0.5% |
| 100 | 100 | 100 | | 100 | 100 | 100.8 | | 100.8 | 100.8 | 100.8 | -0.8% |
| 150 | 150 | 150 | | 150 | 150 | 151.9 | | 151.9 | 151.9 | 151.9 | -1.3% |
| 300 | 300 | 300 | | 300 | 300 | 300.0 | | 307.7 | 307.7 | 305.1 | -1.7% |
| 600 | 600 | 600 | | 600 | 600 | 615.4 | | 615.4 | 615.4 | 615.4 | -2.5% |
| 900 | 900 | 900 | | 900 | 900 | 923.1 | | 923.1 | 923.1 | 923.1 | -2.5% |
| 气道峰压  （mbar） | ±(2%FS+4%  ×实际读数)  FS= 80 mbar | 10 | 10.0 | 10.0 | | 10.0 | 10.0 | 9.7 | | 9.7 | 9.7 | 9.7 | 0.3 |
| 20 | 20.0 | 20.0 | | 20.0 | 20.0 | 19.6 | | 19.6 | 19.6 | 19.6 | 0.4 |
| 30 | 30.0 | 30.0 | | 30.0 | 30.0 | 29.3 | | 29.3 | 29.3 | 29.3 | 0.7 |
| 呼气末正压  （mbar） | ±(2%FS+4%  ×实际读数)  FS= 25 mbar | 1 | 1.4 | 1.4 | | 1.4 | 1.4 | 1.2 | | 1.2 | 1.2 | 1.2 | 0.2 |
| 2 | 2.2 | 2.2 | | 2.2 | 2.2 | 2.0 | | 2.0 | 2.0 | 2.0 | 0.2 |
| 5 | 5.3 | 5.3 | | 5.3 | 5.3 | 5.0 | | 5.0 | 5.0 | 5.0 | 0.3 |
| 吸气氧浓度（%） | ±5%  （体积分数） | 21 | 21 | 21 | | 21 | 21 | 18.9 | | 18.9 | 19.0 | 18.9 | 2.1 |
| 40 | 40 | 40 | | 40 | 40 | 37.5 | | 37.5 | 37.6 | 37.5 | 2.5 |
| 60 | 60 | 60 | | 60 | 60 | 57.4 | | 57.3 | 57.3 | 57.3 | 2.7 |

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| **序号** | **生产厂家** | **型号** | | | **产品编号** | | | | **试验地点** | | | | |
| **3号机** | **Stephan** | **Sophie** | | | **S0381500984** | | | | **湖南省儿童医院新生儿科** | | | | |
| 校准项目 | 技术要求 | 校准结果 | | | | | | | | | | | |
| 设定值 | 监测值 | | | | 平均值 | 测量值 | | | | 平均值 | 示值误差 |
| 潮气量（mL） | ±15% | / | 15 | 15 | | 15 | 15 | 14 | | 14 | 14 | 14 | / |
| / | 61 | 61 | | 61 | 61 | 56 | | 56 | 56 | 56 | 8.9% |
| / | 155 | 156 | | 156 | 156 | 147 | | 147 | 148 | 147 | 6.1% |
| 通气频率  （次/min） | ±1次/分或  设定值的±10%  （取绝对值大者） | 60 | 60 | 60 | | 60 | 60 | 60.0 | | 60.3 | 60.3 | 60.2 | -0.3% |
| 100 | 100 | 100 | | 100 | 100 | 100.0 | | 100.0 | 100.0 | 100.0 | 0.0% |
| 150 | 150 | 150 | | 150 | 150 | 150.0 | | 151.9 | 150.0 | 150.6 | -0.4% |
| 300 | 300 | 300 | | 300 | 300 | 307.7 | | 300.0 | 307.7 | 305.1 | -1.7% |
| 600 | 600 | 600 | | 600 | 600 | 600.0 | | 600.0 | 600.0 | 600.0 | 0.0% |
| 900 | 900 | 900 | | 900 | 900 | 900.0 | | 923.1 | 923.1 | 915.4 | -1.7% |
| 气道峰压  （cmH2O） | ±(2%FS+4%  ×实际读数)  FS= 60 cmH2O | 10 | 10.0 | 10.0 | | 10.0 | 10.0 | 9.7 | | 9.7 | 9.7 | 9.7 | 0.3 |
| 20 | 20.0 | 20.0 | | 20.0 | 20.0 | 19.8 | | 19.8 | 19.8 | 19.8 | 0.2 |
| 30 | 30.0 | 30.0 | | 30.0 | 30.0 | 29.6 | | 29.6 | 29.6 | 29.6 | 0.4 |
| 呼气末正压  （cmH2O） | ±(2%FS+4%  ×实际读数)  FS= 30 cmH2O | 1 | 1.0 | 1.0 | | 1.0 | 1.0 | 0.9 | | 0.9 | 0.9 | 0.9 | 0.1 |
| 2 | 2.0 | 2.0 | | 2.0 | 2.0 | 1.7 | | 1.7 | 1.7 | 1.7 | 0.3 |
| 5 | 5.0 | 5.0 | | 5.0 | 5.0 | 4.7 | | 4.7 | 4.7 | 4.7 | 0.3 |
| 吸气氧浓度（%） | ±5%  （体积分数） | 21 | 21 | 21 | | 21 | 21 | 20.1 | | 20.1 | 20.1 | 20.1 | 0.9 |
| 40 | 40 | 40 | | 40 | 40 | 38.9 | | 38.9 | 38.9 | 38.9 | 1.1 |
| 60 | 60 | 60 | | 60 | 60 | 58.8 | | 58.8 | 58.8 | 58.8 | 1.2 |
| **序号** | **生产厂家** | **型号** | | | **产品编号** | | | | **试验地点** | | | | |
| **4号机** | **Stephan** | **Sophie** | | | **S03819001759** | | | | **湖南省人民医院新生儿科** | | | | |
| 校准项目 | 技术要求 | 校准结果 | | | | | | | | | | | |
| 设定值 | 监测值 | | | | 平均值 | 测量值 | | | | 平均值 | 示值误差 |
| 潮气量（mL） | ±15% | / | 14 | 14 | | 14 | 14 | 14 | | 13 | 13 | 13 | / |
| / | 64 | 64 | | 64 | 64 | 62 | | 62 | 61 | 62 | 3.2% |
| / | 157 | 157 | | 156 | 157 | 151 | | 151 | 152 | 151 | 4.0% |
| 通气频率  （次/min） | ±1次/分或  设定值的±10%  （取绝对值大者） | 60 | 60 | 60 | | 60 | 60 | 60.0 | | 60.0 | 60.3 | 60.1 | -0.2% |
| 100 | 100 | 100 | | 100 | 100 | 100.0 | | 100.8 | 100.0 | 100.3 | -0.8% |
| 150 | 150 | 150 | | 150 | 150 | 150.0 | | 151.9 | 150.0 | 150.6 | -0.4% |
| 300 | 300 | 300 | | 300 | 300 | 307.7 | | 300.0 | 300.0 | 302.6 | -0.9% |
| 600 | 600 | 600 | | 600 | 600 | 600.0 | | 600.0 | 600.0 | 600.0 | 0.0% |
| 900 | 900 | 900 | | 900 | 900 | 900.0 | | 900.0 | 923.1 | 907.7 | -0.8% |
| 气道峰压  （cmH2O） | ±(2%FS+4%  ×实际读数)  FS= 60 cmH2O | 10 | 10.0 | 10.0 | | 10.0 | 10.0 | 9.8 | | 9.8 | 9.8 | 9.8 | 0.2 |
| 20 | 20.0 | 20.0 | | 20.0 | 20.0 | 19.8 | | 19.8 | 19.8 | 19.8 | 0.2 |
| 30 | 30.0 | 30.0 | | 30.0 | 30.0 | 29.9 | | 29.9 | 29.9 | 29.9 | 0.1 |
| 呼气末正压  （cmH2O） | ±(2%FS+4%  ×实际读数)  FS= 30 cmH2O | 1 | 1.0 | 1.0 | | 1.0 | 1.0 | 0.9 | | 0.9 | 0.9 | 0.9 | 0.1 |
| 2 | 2.0 | 2.0 | | 2.0 | 2.0 | 1.9 | | 1.9 | 1.9 | 1.9 | 0.1 |
| 5 | 5.0 | 5.0 | | 5.0 | 5.0 | 4.9 | | 4.9 | 4.9 | 4.9 | 0.1 |
| 吸气氧浓度（%） | ±5%  （体积分数） | 21 | 21 | 21 | | 21 | 21 | 20.5 | | 20.5 | 20.5 | 20.5 | 0.5 |
| 40 | 40 | 40 | | 40 | 40 | 39.4 | | 39.4 | 39.5 | 39.4 | 0.6 |
| 60 | 60 | 60 | | 60 | 60 | 59.2 | | 59.1 | 59.2 | 59.2 | 0.8 |

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| **序号** | **生产厂家** | **型号** | | | **产品编号** | | | | **试验地点** | | | | |
| **5号机** | **Stephan** | **Sophie** | | | **S03816001105** | | | | **湖南省妇幼保健院新生儿科** | | | | |
| 校准项目 | 技术要求 | 校准结果 | | | | | | | | | | | |
| 设定值 | 监测值 | | | | 平均值 | 测量值 | | | | 平均值 | 示值误差 |
| 潮气量（mL） | ±15% | / | 13 | 13 | | 14 | 13 | 13 | | 12 | 11 | 12 | / |
| / | 67 | 67 | | 67 | 67 | 68 | | 69 | 69 | 69 | -2.9% |
| / | 155 | 155 | | 156 | 155 | 159 | | 160 | 160 | 160 | -3.1% |
| 通气频率  （次/min） | ±1次/分或  设定值的±10%  （取绝对值大者） | 60 | 60 | 60 | | 60 | 60 | 60.0 | | 60.0 | 60.0 | 60.0 | 0.0% |
| 100 | 100 | 100 | | 100 | 100 | 100.0 | | 100.0 | 100.0 | 100.0 | 0.0% |
| 150 | 150 | 150 | | 150 | 150 | 150.0 | | 151.9 | 150.0 | 150.6 | -0.4% |
| 300 | 300 | 300 | | 300 | 300 | 300.0 | | 300.0 | 300.0 | 302.6 | 0.0% |
| 600 | 600 | 600 | | 600 | 600 | 600.0 | | 600.0 | 600.0 | 600.0 | 0.0% |
| 900 | 900 | 900 | | 900 | 900 | 900.0 | | 900.0 | 923.1 | 907.7 | -0.8% |
| 气道峰压  （cmH2O） | ±(2%FS+4%  ×实际读数)  FS= 60 cmH2O | 10 | 10.0 | 10.0 | | 10.0 | 10.0 | 10.1 | | 10.1 | 10.1 | 10.1 | -0.1 |
| 20 | 20.0 | 20.0 | | 20.0 | 20.0 | 20.2 | | 20.2 | 20.2 | 20.2 | -0.2 |
| 30 | 30.0 | 30.0 | | 30.0 | 30.0 | 30.4 | | 30.4 | 30.4 | 30.4 | -0.4 |
| 呼气末正压  （cmH2O） | ±(2%FS+4%  ×实际读数)  FS= 30 cmH2O | 1 | 1.1 | 1.1 | | 1.1 | 1.1 | 1.3 | | 1.3 | 1.3 | 1.3 | -0.2 |
| 2 | 2.1 | 2.1 | | 2.1 | 2.1 | 2.0 | | 2.0 | 2.0 | 2.0 | 0.1 |
| 5 | 5.1 | 5.1 | | 5.1 | 5.1 | 5.2 | | 5.2 | 5.2 | 5.2 | -0.1 |
| 吸气氧浓度（%） | ±5%  （体积分数） | 21 | 21 | 21 | | 21 | 21 | 20.1 | | 20.1 | 20.1 | 20.1 | 0.9 |
| 40 | 40 | 40 | | 40 | 40 | 38.7 | | 38.7 | 38.7 | 38.7 | 1.3 |
| 60 | 60 | 60 | | 60 | 60 | 59.0 | | 59.1 | 59.0 | 59.0 | 1.0 |

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| **序号** | **生产厂家** | **型号** | | | **产品编号** | | | | **试验地点** | | | | |
| **6号机** | **Stephan** | **Christina** | | | **S0390800628** | | | | **长沙市妇幼保健院新生儿科** | | | | |
| 校准项目 | 技术要求 | 校准结果 | | | | | | | | | | | |
| 设定值 | 监测值 | | | | 平均值 | 测量值 | | | | 平均值 | 示值误差 |
| 潮气量（mL） | ±15% | / | 17 | 17 | | 17 | 17 | 15 | | 16 | 15 | 15 | / |
| / | 66 | 66 | | 66 | 66 | 64 | | 64 | 64 | 64 | 3.1% |
| / | 159 | 159 | | 158 | 159 | 156 | | 156 | 157 | 156 | 1.9% |
| 通气频率  （次/min） | ±1次/分或  设定值的±10%  （取绝对值大者） | 60 | 60 | 60 | | 60 | 60 | 60.0 | | 60.0 | 60.0 | 60.0 | 0.0% |
| 100 | 100 | 100 | | 100 | 100 | 100.8 | | 100.8 | 100.8 | 100.8 | -0.8% |
| 150 | 150 | 150 | | 150 | 150 | 150.0 | | 151.9 | 151.9 | 151.3 | -0.9% |
| 气道峰压  （cmH2O） | ±(2%FS+4%  ×实际读数)  FS= 60 cmH2O | 10 | 10.0 | 10.0 | | 10.0 | 10.0 | 10.4 | | 10.4 | 10.4 | 10.4 | -0.4 |
| 20 | 20.0 | 20.0 | | 20.0 | 20.0 | 20.3 | | 20.3 | 20.3 | 20.3 | -0.3 |
| 30 | 30.0 | 30.0 | | 30.0 | 30.0 | 30.4 | | 30.4 | 30.4 | 30.4 | -0.4 |
| 呼气末正压  （cmH2O） | ±(2%FS+4%  ×实际读数)  FS= 30 cmH2O | 1 | 1.0 | 1.0 | | 1.0 | 1.0 | 1.3 | | 1.3 | 1.3 | 1.3 | -0.3 |
| 2 | 2.0 | 2.0 | | 2.0 | 2.0 | 2.2 | | 2.2 | 2.2 | 2.2 | -0.2 |
| 5 | 5.0 | 5.0 | | 5.0 | 5.0 | 5.2 | | 5.2 | 5.2 | 5.2 | -0.2 |
| 吸气氧浓度（%） | ±5%  （体积分数） | 21 | 21 | 21 | | 21 | 21 | 19.1 | | 19.1 | 19.1 | 19.1 | 1.9 |
| 40 | 40 | 40 | | 40 | 40 | 36.6 | | 36.6 | 36.6 | 36.6 | 3.4 |
| 60 | 60 | 60 | | 60 | 60 | 57.2 | | 57.2 | 57.2 | 57.2 | 2.8 |

1. **试验结论**

根据以上试验结果得出各个校准项目测量结果范围如下：

|  |  |  |
| --- | --- | --- |
| 校准项目 | 技术要求 | 试验结果范围 |
|
| 潮气量 | ±15% | -3.1% ~ 8.9% |
|
|
| 通气频率 | ±1次/分或设定值的±10%  （取绝对值大者） | -2.5% ~ 0.0% |
|
|
| 气道峰压 | ±（2%FS+4%×实际读数） | （-0.04 ~ 0.07）kPa |
|
|
| 呼气末正压 | ±（2%FS+4%×实际读数） | （-0.03 ~ 0.03）kPa |
|
|
| 吸气氧浓度 | ±5%  （体积分数） | 0.5% ~ 3.4% |

试验结果表明：本规范规定的校准项目及校准方法实用性强，具有可操作性，计量特性指标规定科学合理，适用于现场校准工作。