Requirements for the admission of CPAP devices
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Introduction

Status:
- Positive Airway Pressure (PAP) therapy established
- Requirements defined and must be fulfilled
- PAP devices per therapy form free exchangable

Patients:
- „PAP devices (same therapy form/setting) have different pressure properties“
- „Unsuitable PAP device leads to interruption of treatment“

Do PAP-devices have an appropriate quality and are exchangeable per therapy form?
**CPAP devices: Requirements (German Health Aid List)**

**PAP-therapy forms**
- CPAP
- APAP
- Bilevel
- Auto Bilevel
- Bilevel ST
- Special therapy

**Selection of CPAP device**

**Price**
- All-inclusive prices based on call for tender (health insurances)

**Quality**
- Pressure stability
- Noise level
- Humidification

**Performance**
- CE marking
- Operating voltage
- Pressure adaptable by physician in 0.5 hPa steps
- Display actual pressure, service and therapy hours
- Adaptable insp./exsp. support and ramp functions
- Instruction manual + identification plate
- Delivery of tube system and connectable humidifier
- Declaration service live, maintenance freedom re-use

**Pressure stability is the key KPI in PAP-therapy.** DIN EN ISO 17510-1
## CPAP devices: Test methods

<table>
<thead>
<tr>
<th>Name</th>
<th>Short-term accuracy (pressure stability)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>Stability of dynamic airway pressure accuracy</td>
</tr>
</tbody>
</table>

### Test set-up

1. PAP device  
2. Breathing gas pathway  
3. Standard resistance  
4. Flow meter  
5. Pressure measuring device  
6. Pump  
7. Patient connection port

### Result

\[ \Delta p = p_{\text{max}} - p_{\text{min}} \]

### Set value**

- \( \Delta p \leq 0.5 \text{ hPa} \) (set pressure < 10 hPa)
- \( \Delta p < 1 \text{ hPa} \) (set pressure \( \geq 10 \text{ hPa} \))

### Example

- \( \Delta p < 1 \text{ hPa} \)
- Test passed

### Settings*

- \( E/I = 1 \)
- Tidal volume: 500 ml
- Sinusoidal flow
- Breaths/min: 10, 15, 20
- Set pressure: \( (\frac{1}{3}, \frac{2}{3}, 1) \) of \( p_{\text{max,device}} \cdot 10 \text{ hPa} \)

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**Based on test method 14-4 03/2007 MDS-Hi

** Minimum requirement in German Health Aid List.

Performance Indicators, set values, test methods given in German Health Aid List.
CPAP devices: Test methods

Test set-up

- Based on DIN EN ISO 17510-1: 2009-07, test method 14-4 03/2007 MDS-Hi
- Software based expiration support deactivated

Test

- Short-term accuracy (screening) with
  - Set pressure: 10 hPa
  - Respiration frequency: 15 breaths /min

Tested devices

- 3 different marketable CPAP-devices (brands)
- Each brand 10 identical devices

Evaluation

- Short-term accuracy (service hours, construction year)
- Mean respiration pressure

Test of of several CPAP devices of the same design.
CPAP devices: Pressure stability, mean pressure

<table>
<thead>
<tr>
<th>Device</th>
<th>Pressure stability</th>
<th>Mean set pressure in hPa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test passed</td>
<td></td>
</tr>
<tr>
<td>30 %</td>
<td>100 %*</td>
<td>100%</td>
</tr>
<tr>
<td>9,3 - 12,9</td>
<td>9,3 - 10,1</td>
<td>9,4 - 10,6</td>
</tr>
</tbody>
</table>

* Partly spikes

Manufacturer-dependent quality differences.
Aging effects are not clearly detectable.
CPAP devices: Pressure stability, construction year

- Manufacturers 1: No construction year dependent change of pressure stability
- Manufacturer 2.3: Better pressure stability of new devices

Manufacturer dependent quality improvement.
Auto-CPAP devices: Requirements (German Health Aid List)

PAP-therapy forms
- CPAP
- APAP
- Bilevel
- Auto Bilevel
- Bilevel ST
- Special therapy

Selection of Auto-CPAP-device

Price
- All-inclusive prices based on call for tender (health insurances)

Quality
- Pressure stability
- Noise level
- Humidification

Performance
- CE marking
- Operating voltage
- Pressure adaptable by physician in 0,5 hPa steps
- Display actual pressure, service and therapy hours
- Adaptable insp./exsp. support and ramp functions
- Instruction manual + identification plate
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Automatic pressure control has no minimum requirement.
APAP devices: Test methods

2. Connection with real Simulator

3. Simulation of respiration with obstructions

1. Simulation of human lung with computer

4. Connection of Auto CPAP device

Parameters:
- Expiration/inspiration: 1,5
- Respiration frequency: 14 breaths/min
- Tidal volume: 500 ml

Technical test of APAP-devices.
**APAP devices: Test methods**

**Test 1: Simulation 20 obstruktive events* (15s, 30s, 120s)**

<table>
<thead>
<tr>
<th>Time in s</th>
<th>Normal respiration</th>
<th>Severe obstruktion</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 500</td>
<td></td>
<td></td>
</tr>
<tr>
<td>500 - 1000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1000 - 2000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2000 - 2500</td>
<td></td>
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<tr>
<td>2500 - 3000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3000 - 3500</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3500 - 4000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4000 - 4500</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Obstructions fully opened with 10 hPa pressure

**Test 2: Simulation 10 central hypopnoeas with 70 % flow reduction (2 min each)**

<table>
<thead>
<tr>
<th>Time in s</th>
<th>Central hypopnoea</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 500</td>
<td></td>
</tr>
<tr>
<td>500 - 1000</td>
<td></td>
</tr>
<tr>
<td>1000 - 1500</td>
<td></td>
</tr>
<tr>
<td>1500 - 2000</td>
<td></td>
</tr>
<tr>
<td>2000 - 2200</td>
<td></td>
</tr>
</tbody>
</table>

**Test 3: Simulation 10 central events (120 s each)**

<table>
<thead>
<tr>
<th>Time in s</th>
<th>Central apnea</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 500</td>
<td></td>
</tr>
<tr>
<td>500 - 1000</td>
<td></td>
</tr>
<tr>
<td>1000 - 1500</td>
<td></td>
</tr>
<tr>
<td>1500 - 2000</td>
<td></td>
</tr>
<tr>
<td>2000 - 2500</td>
<td></td>
</tr>
<tr>
<td>2500 - 3000</td>
<td></td>
</tr>
</tbody>
</table>

Initial phase 20 min normal respiration

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Draft test method for automatic pressure control of APAP devices.
Test 4: Simulation of changing respiration excitation (30 s each)

Initial phase 20 min normal respiration (not displayed)

- 25 % flow increase
- 75 % flow reduction

Draft test method for automatic pressure control of APAP devices.
Obstructive events are treated different according to the APAP device.
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**APAP devices: Tests 2-4**

<table>
<thead>
<tr>
<th>Pressure change</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test 2: Central hypopnoeas</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Test 3: Central events</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Test 4: Changing respiration excitation</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Example:**

![Graph showing pressure change over time](image_url)

Central events are partly treated with pressure increase.
Conclusion, suggestions and outlook: CPAP devices

**Conclusion**
- Requirements of German Health Aid List only partially fulfilled
- Aging effects are not clearly detectable
- Manufacturer dependent quality improvement
- Device depending mean pressure ➔ difficult CPAP device exchange

**Suggestions and outlook**
- Technical improvement of CPAP devices necessary
- Independent test of pressure stability before device approval
- CPAP device exchange: pressure test and adaptation

Proofed quality of CPAP devices is necessary!
Conclusion

➢ Currently no minimum requirements for automatic pressure control
➢ Test method developed and applied:
  ➢ Obstructions treated different
  ➢ Central events partly treated with pressure increase

Suggestions and outlook

➢ Introduction of minimum requirements for pressure regulation of APAP devices suggested
➢ Independent test before device approval