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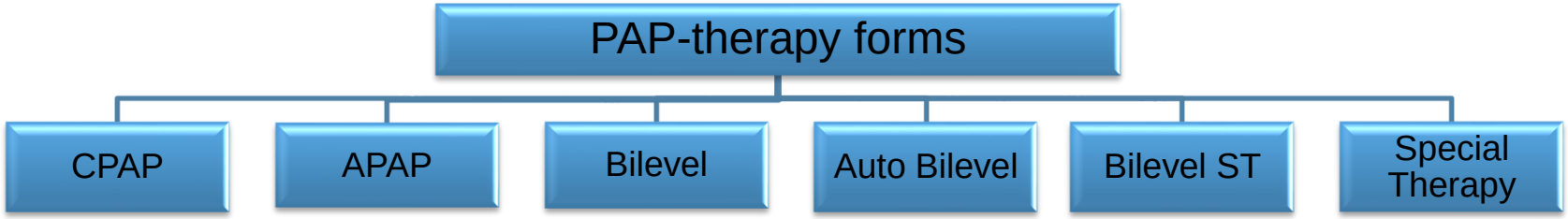
Requirements for the admission of CPAP devices

Contents

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

Performance

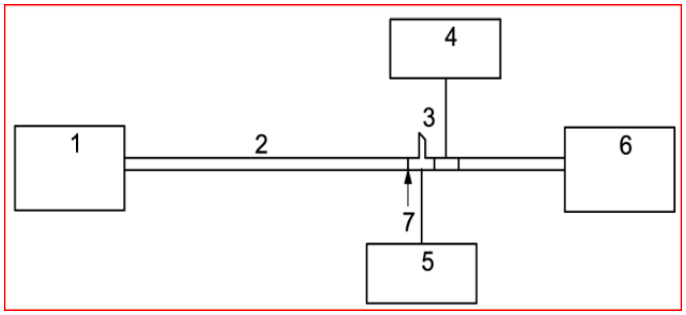
CPAP device in German Health Aid List

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

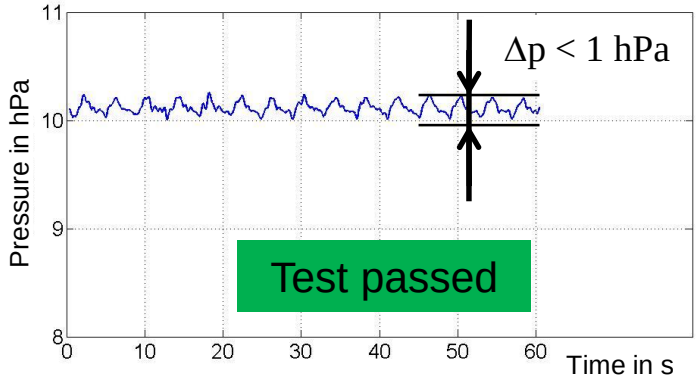
- CE marking
- Operating voltage
- Pressure adaptable by physician in 0,5 hPa steps
- Display actual pressure, service and therapy hours
- Adaptable insp./exsp. support and ramp functions
- Instruction manual + identification plate
- Delivery of tube system and connectable humidifier
- Declaration service live, maintenance freedom re-use

Pressure stability is the key KPI in PAP-therapy. DIN EN ISO 17510-1

CPAP devices: Test methods

Name	Short-term accuracy (pressure stability)
Description	Stability of dynamic airway pressure accuracy
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 settings*: - E/I = 1 - Tidal volume: 500 ml - sinusoidal flow - breaths/min: 10, 15, 20 - set pressure: (⅓, ⅔, 1) of $p_{max,device}$, 10 hPa
Result	$\Delta p = p_{max} - p_{min}$
Set value**	**$\Delta p \leq 0{,}5$ hPa** (set pressure < 10 hPa) **$\Delta p < 1$ hPa** (set pressure ≥ 10 hPa)

Example



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

** Minimum requirement in German Health Aid List

Perfomance 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 exspiration support deactivated

Test

Short-term accuracy (screening) with

Set pressure: 10 hPa

Respiration frequency: 15 breaths /min

Tested devices

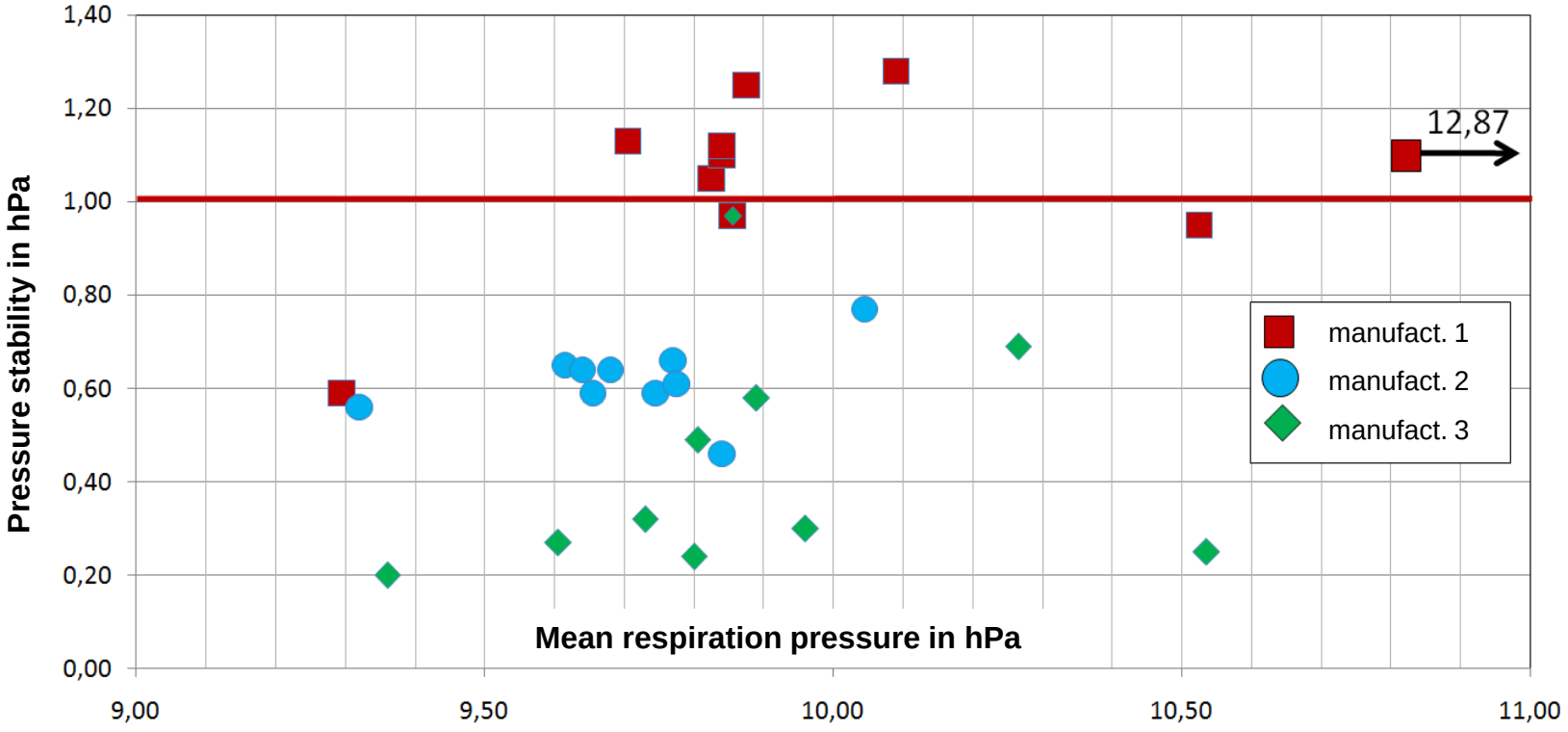
- 3 different marketable CPAP-devices (brands)
- Each brand 10 identical devices

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

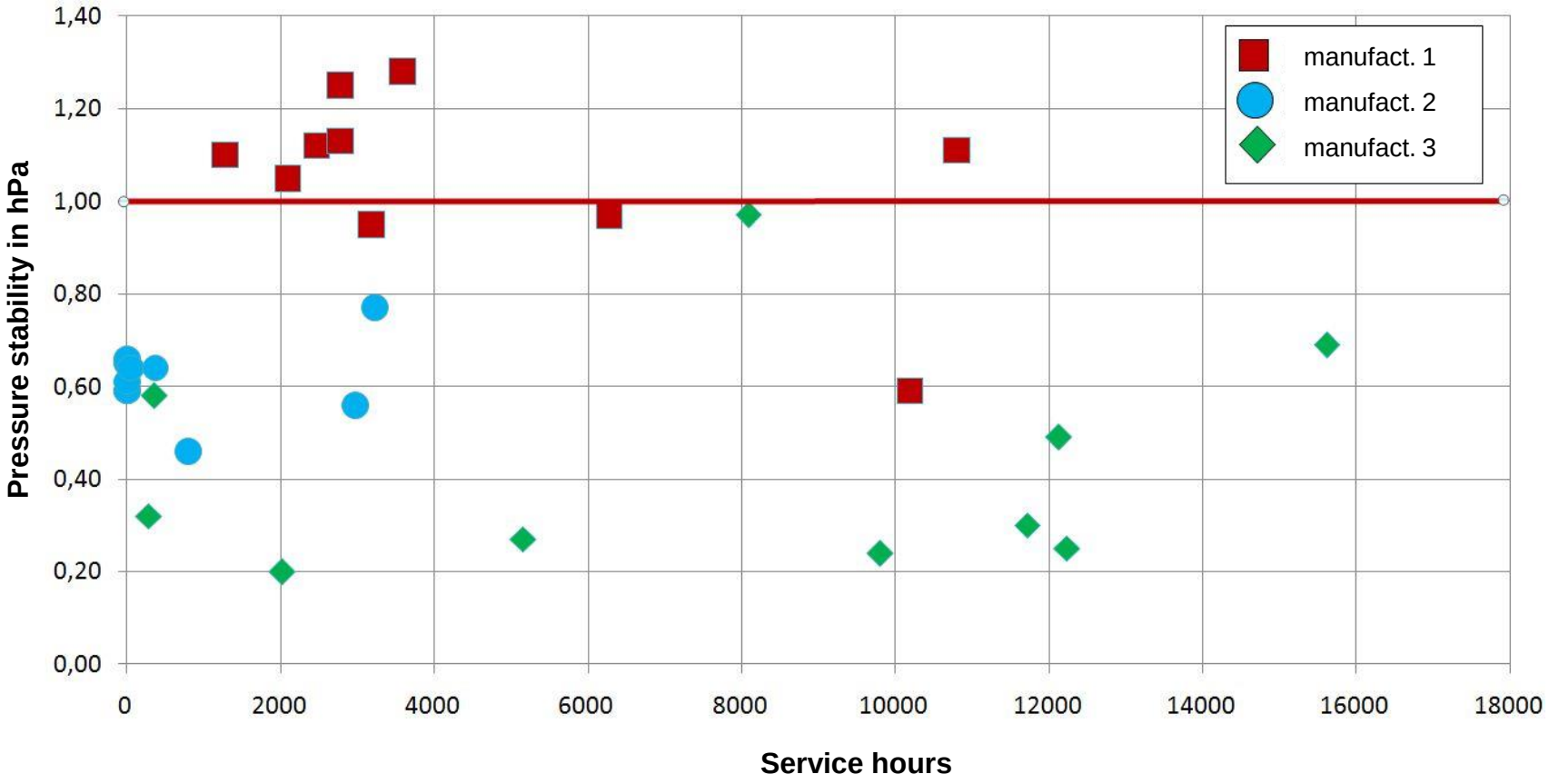


Device	■	●	◆
Pressure stability Test passed	30 %	100 %*	100%
Mean set pressure in hPa	9,3 - 12,9	9,3 - 10,1	9,4 - 10,6

* Partly spikes

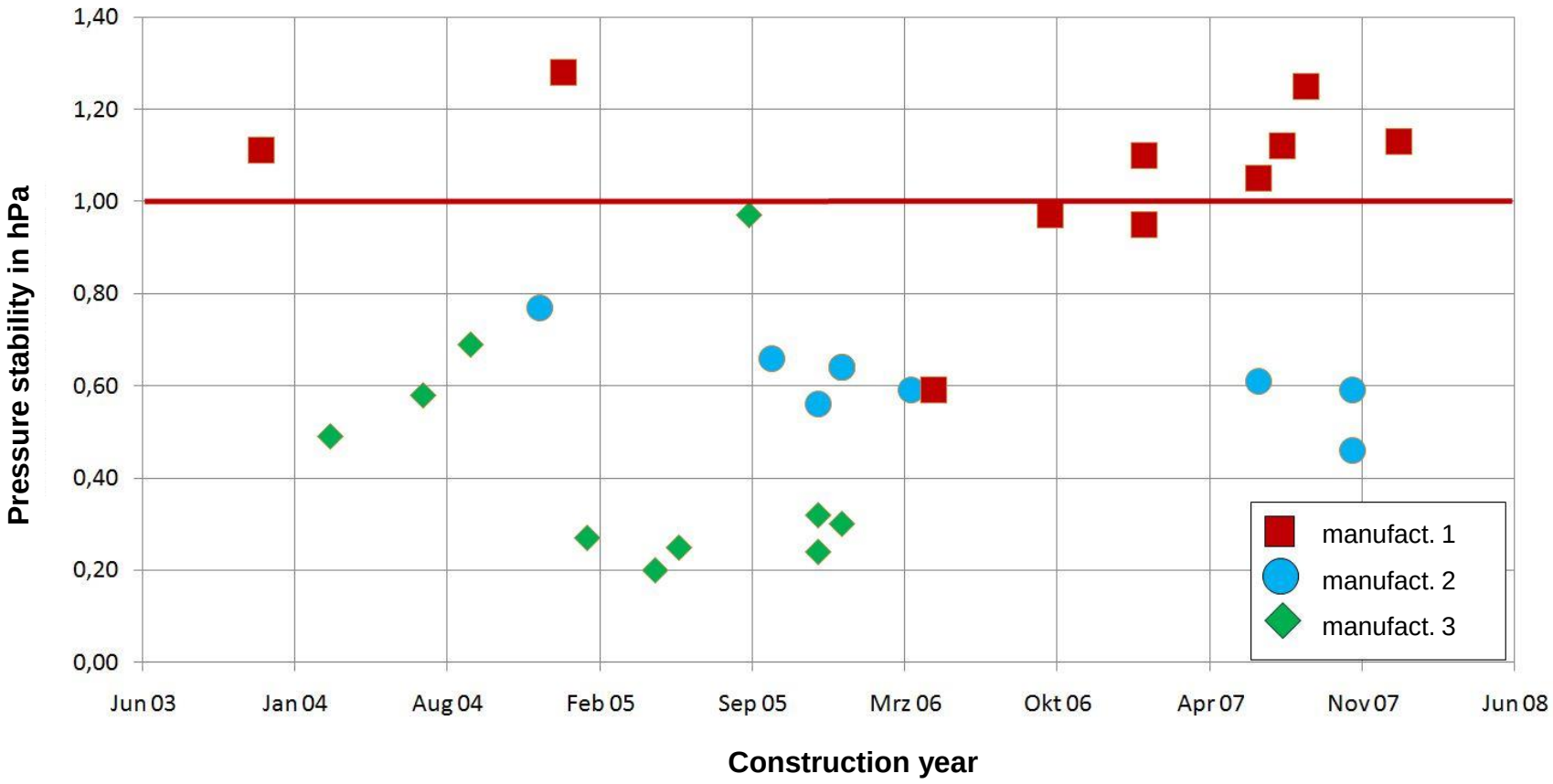
Manufacturer-dependent quality differences.

CPAP devices: Pressure stability, service hours



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

CPAP-device in German Health Aid List

- CE marking
- Operating voltage
- Pressure adaptable by physician in 0,5 hPa steps
- Display actual pressure, service and therapy hours
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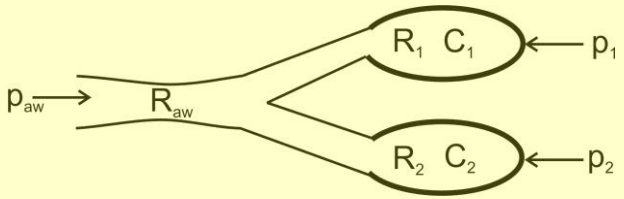
Automatic pressure control has no minimum requirement.

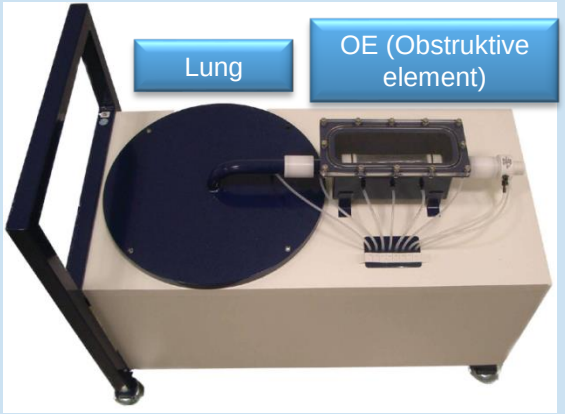
APAP devices: Test methods

1. Simulation of human lung with computer



2. Connection with real Simulator

3. Simulation of respiration with obstructions



4. Connection of Auto CPAP device

Parameters:

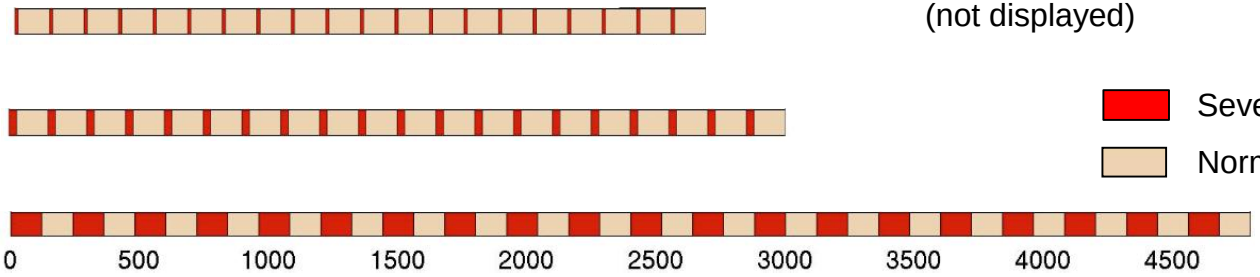
- Exspiration/inspiration: 1,5
- Respiration frequency: 14 breaths/min
- Tidal volume: 500 ml

Technical test of APAP-devices.

APAP devices: Test methods

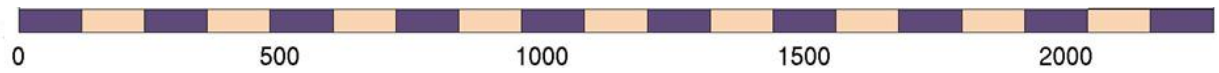
Test 1: Simulation 20 obstruktive events* (15s, 30s, 120s)

Initial phase 20 min normal respiration (not displayed)



* Obstructions fully opened with 10 hPa pressure

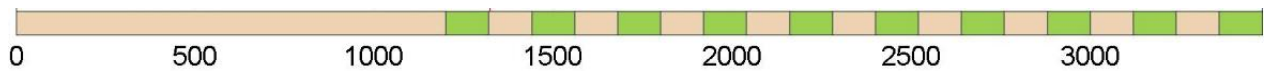
Test 2: Simulation 10 central hypopnoeas with 70 % flow reduction (2 min each)



Initial phase 20 min normal respiration (not displayed)

Central hypopnoea

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



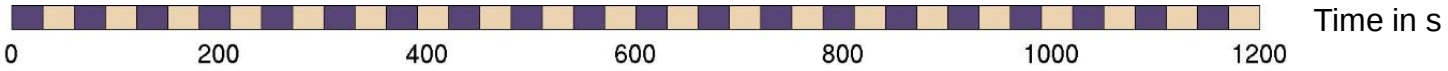
Initial phase 20 min normal respiration

Central apnea

Draft test method for automatic pressure control of APAP devices.

APAP devices: Test methods

<u>Test 4</u>: Simulation of changing respiration excitation (30 s each)



Initial phase 20 min normal respiration (not displayed)

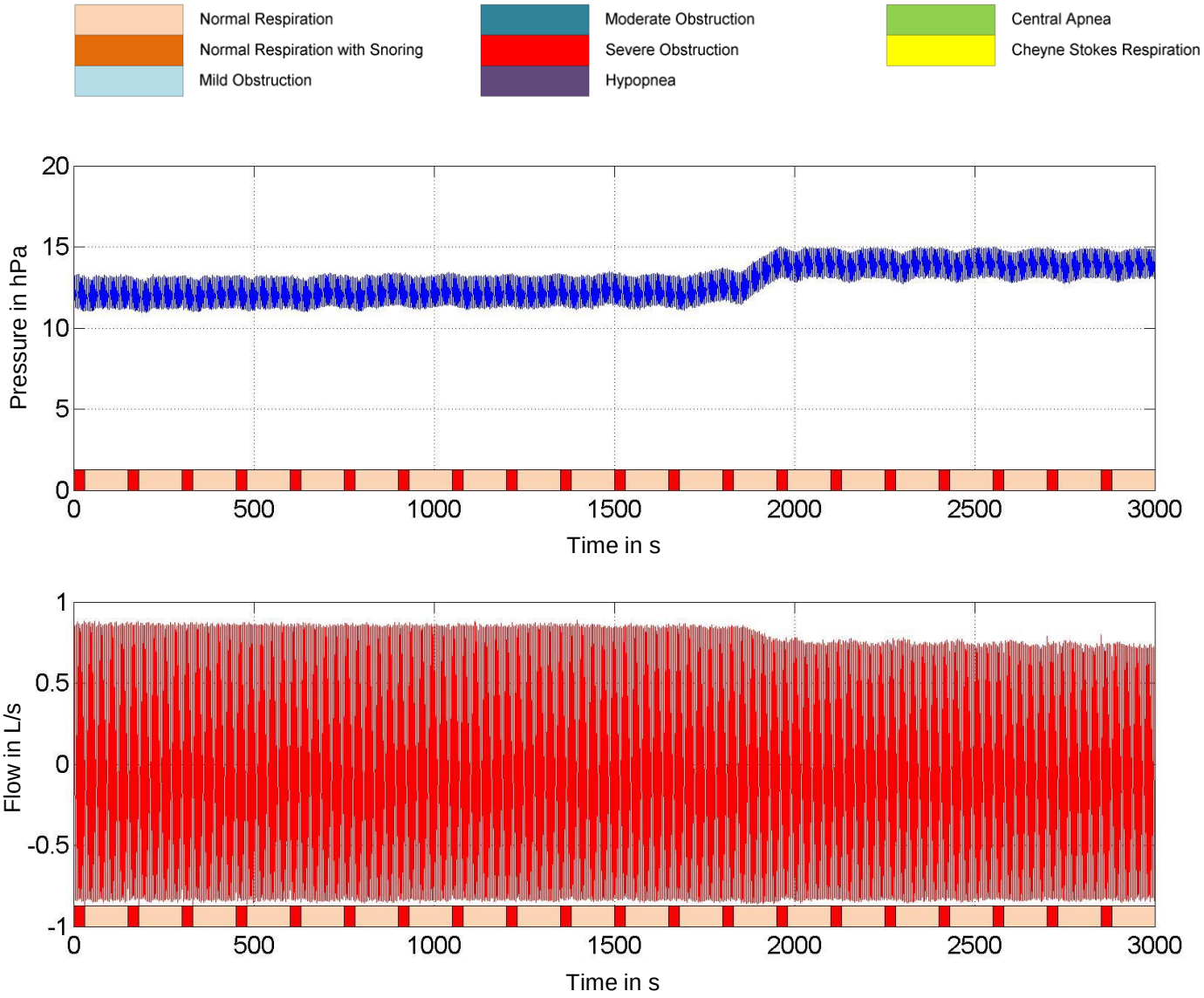
25 % flow increase

75 % flow reduction

Draft test method for automatic pressure control of APAP devices.

APAP devices: Test 1: Severe obstruction 30s

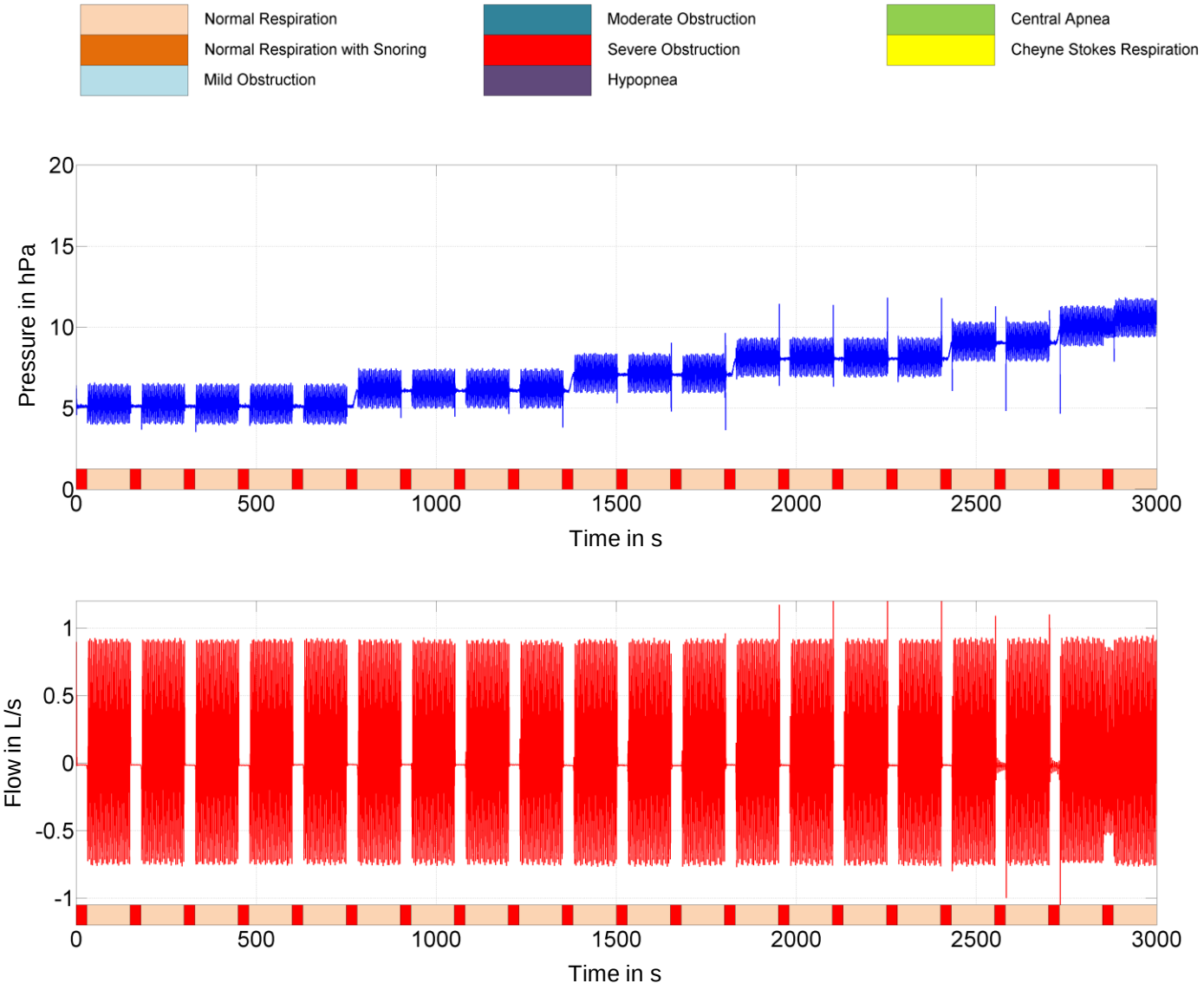
Device 1



Obstructive events are treated different according to the APAP device.

APAP devices: Test 1: Severe obstruction 30s

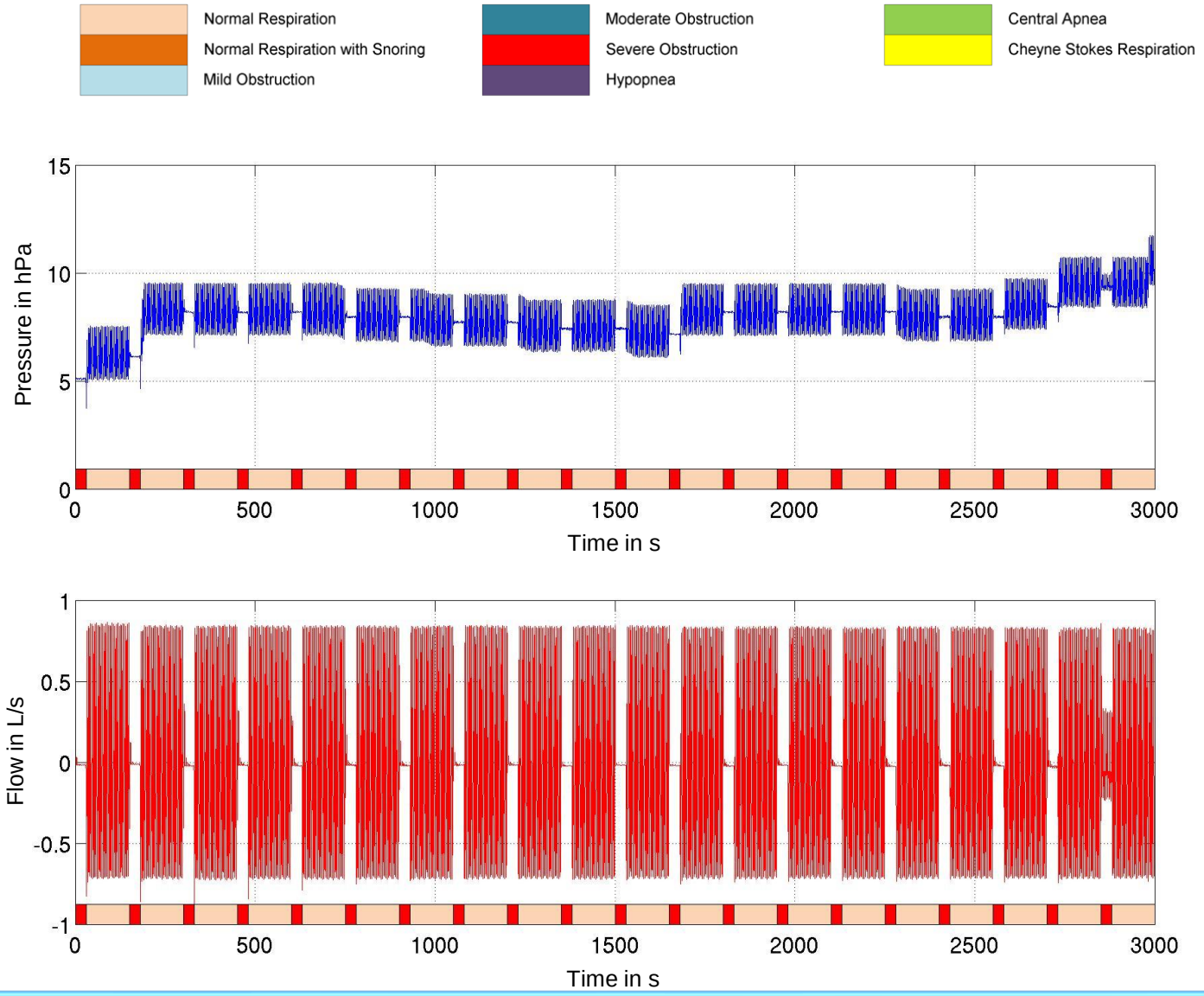
Device 2



Obstructive events are treated different according to the APAP device.

APAP devices: Test 1: Severe obstruction 30s

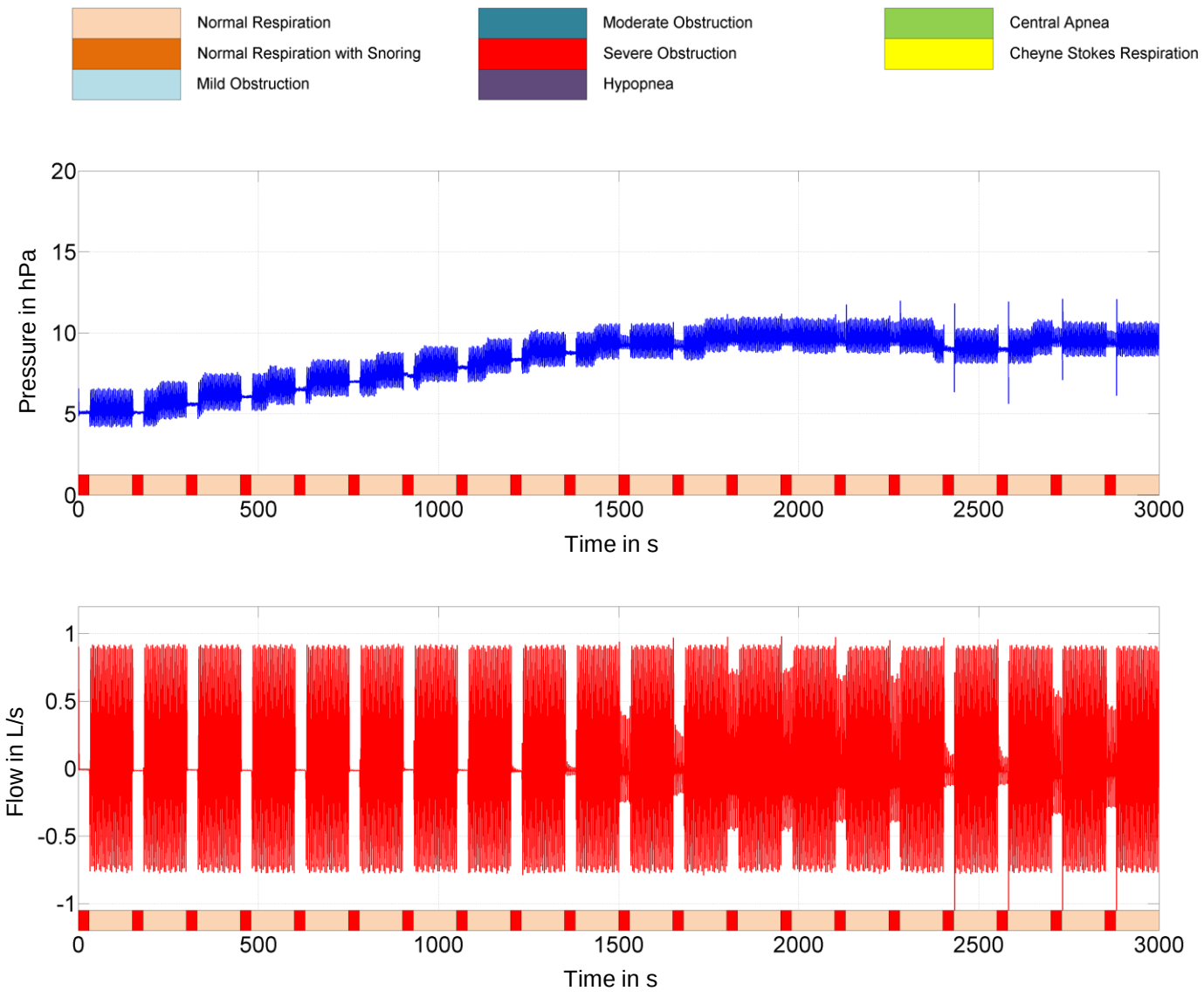
Device 3



Obstructive events are treated different according to the APAP device.

APAP devices: Test 1: Severe obstruction 30s

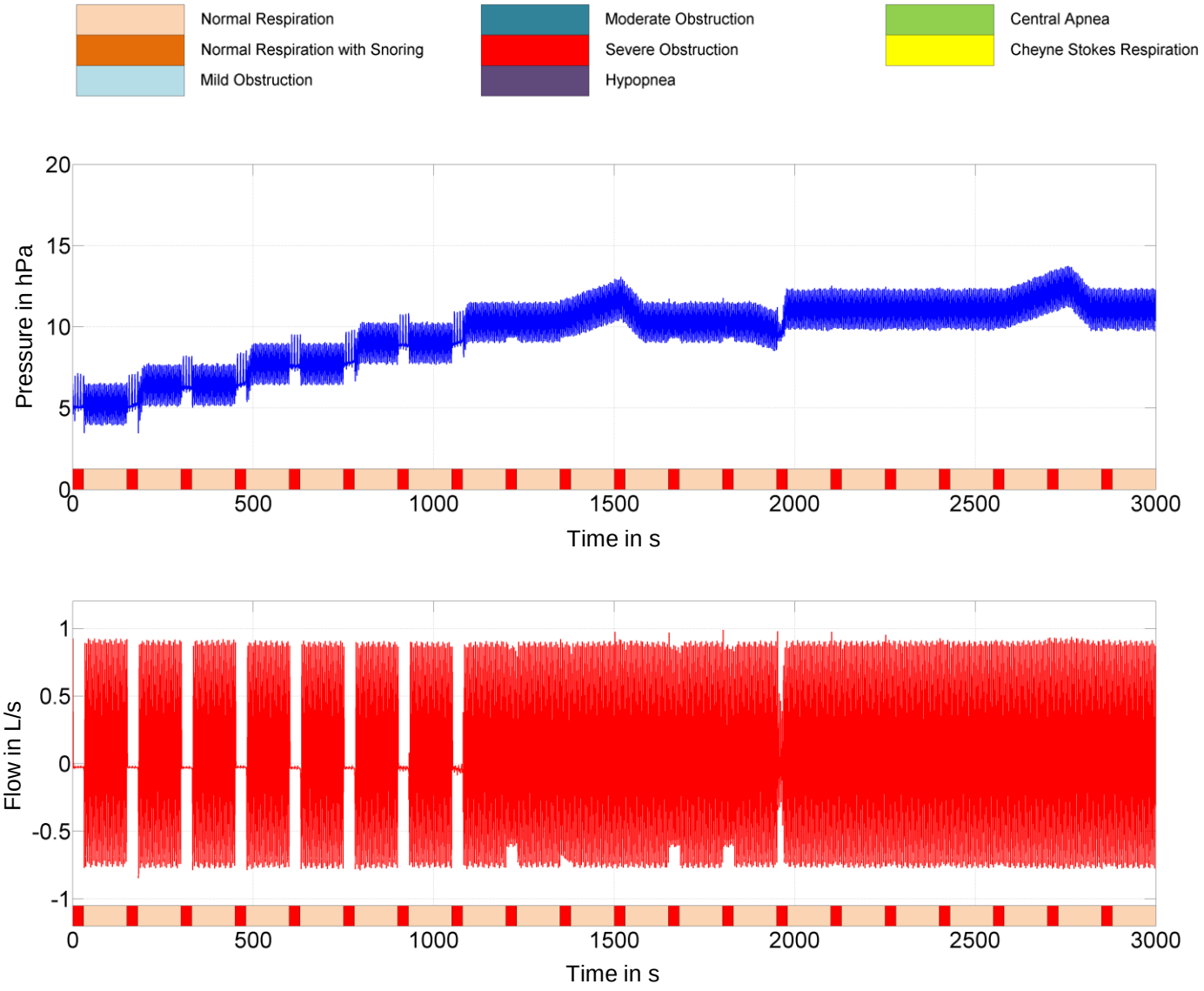
Device 4



Obstructive events are treated different according to the APAP device.

APAP devices: Test 1: Severe obstruction 30s

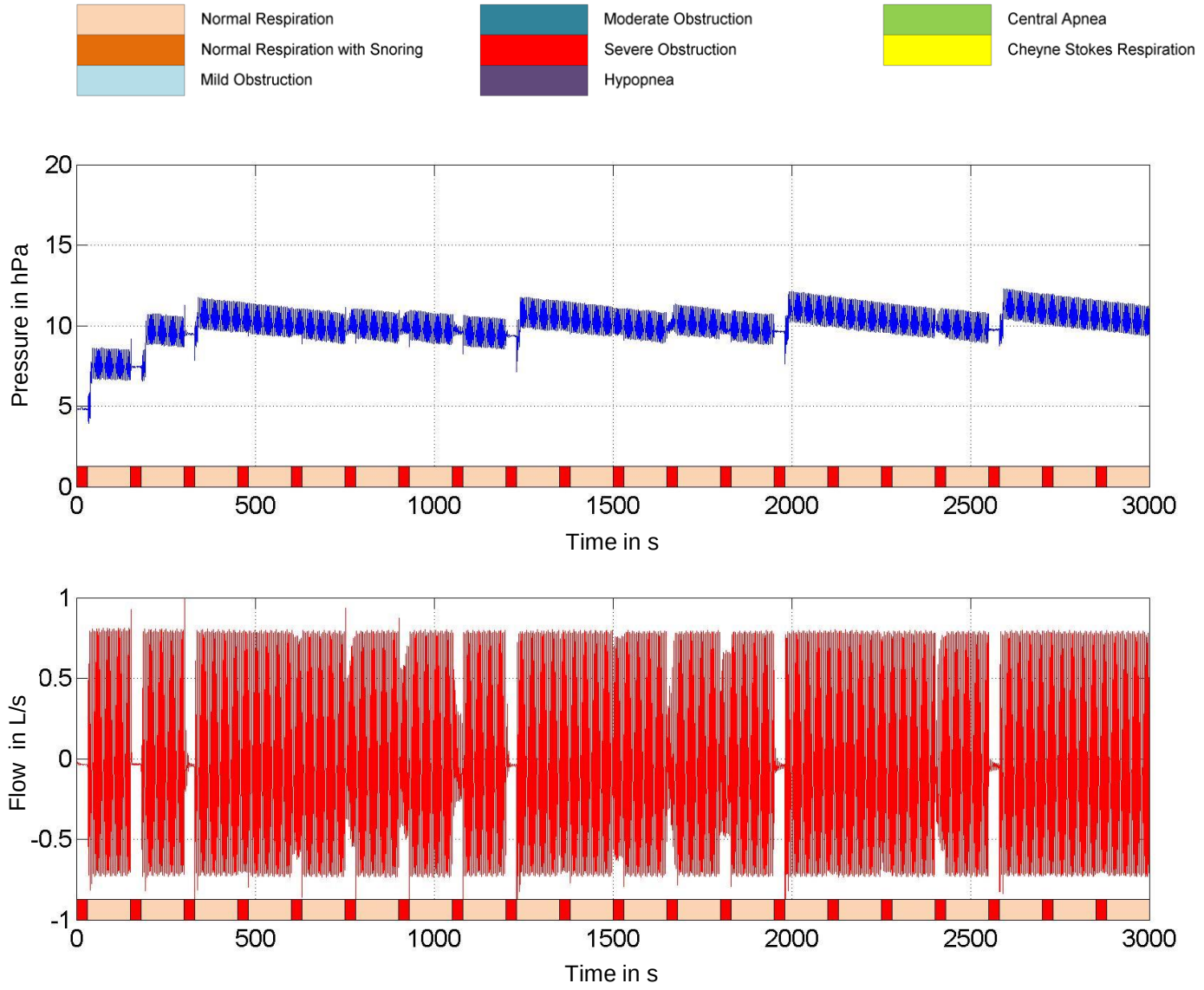
Device 5



Obstructive events are treated different according to the APAP device.

APAP devices: Test 1: Severe obstruction 30s

Device 6

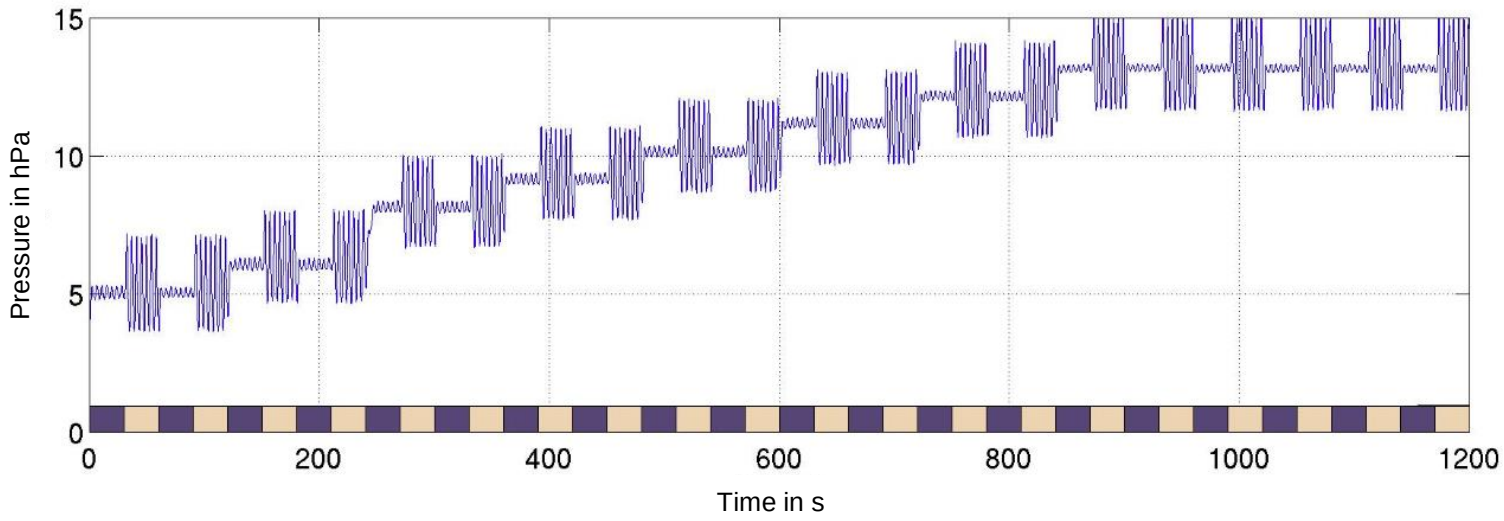


Obstructive events are treated different according to the APAP device.

APAP devices: Tests 2-4

	APAP device					
Pressure change	1	2	3	4	5	6
Test 2: Central hypopnoeas	Yes	Yes	Yes	No	No	Yes
Test 3: Central events	Yes	No	No	Yes	Yes	No
Test 4: Changing respiration excitation	Yes	Yes	Yes	Yes	Yes	Yes

Example:



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, suggestions and outlook: **APAP devices**

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

Minimum requirements for pressure regulation of APAP devices suggested.