Instructions for use
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1 PRODUCT DESCRIPTION

The PARI PROVOCATION TEST II (order no. 064G7300) is an apparatus that is used for conducting non-specific bronchial provocation tests in a doctor’s practice. These tests are particularly important in diagnostics and for preparing expert opinions.

The following pharmacological substances can be used:
- histamine
- methacholine
- carbachol

The individual provocation stages can be set via the bag volume and/or by varying the concentrations of the provocation solution.

The PARI PROVOCATION TEST II enables the quantity of medication or test substance inhaled to be determined and this is then quantified via the adjustable aerosol volume in the bag containing a maximum of 10 litres.

Because the droplet spectrum is so fine, the quantity of intrabronchial aerosol deposit is not significantly affected by the individual anatomy of the respiratory tract during a slow inspiratory vital capacity manoeuvre.

The quantity of the test substance deposited in the lung can be calculated directly in milligrams [mg] or micrograms [µg] according to the selected concentration and the bag volume.

Evaluation charts are available for histamine and methacholine / carbachol (order no. 041D0208 for histamine, order no. 041D0209 for methacholine/carbachol).

The act of inhaling the aerosol from the bag is controlled via a 2-way-valve by the patient's own breathing. The exhaled aerosol is trapped in a filter, thus preventing contamination of the surroundings with the provocation substance.

The apparatus is constructed in compliance with the guidelines for provocation and meets medical-scientific specifications [1].

There is no firm scientific data regarding strict contraindications. However, the relative contraindications described in section "Contraindications, page 30" are to be observed.

Additional product features
- Recommended by the German Pneumological Association (DGP) for conducting non-specific bronchial provocation tests [6]
- A timer switch makes it possible to adjust the volume precisely.
- The output of the compressor can be checked with a test nozzle and pressure gauge.
- Provocations can be conducted with only a single concentration.
- Provocation protocols are available for methacholine, carbachol and histamine (see "Provocation programmes", page 29).
- The nebuliser and all components of the respiration controller can be disinfected and sterilised chemically.
2 IMPORTANT INFORMATION

2.1 Components
Please check that the following components are contained in your package.

1 PARI PROVOCATION TEST II Compressor (14)
1 PARI PROVOCATION TEST II Nebuliser (5)
1 Stand (13)
1 Respiration controller (7-12)
1 Adhesive label “Provocation stages” (15)
1 Test pressure gauge (16)
1 Test nozzle (17)
1 Bag (2) with locking ring, connecting piece and 2 bag rails
1 Ring spanner (not shown)
1 Filter pads, pack of 30 (not shown)

If any parts are missing, please contact the PARI Service Center (see "PARI Service Center", page 35).

2.2 Intended use
The PARI PROVOCATION TEST II is an apparatus that is used for conducting non-specific bronchial provocation tests in a doctor’s practice.

2.3 Safety precautions

The following safety precautions must be followed every time before a provocation test is conducted:

The technical personnel must be familiar with treating obstructions of the respiratory tract and a doctor must always be available. If the patient is suffering from a respiratory tract infection on the day of the examination, the bronchial provocation must not be performed. The patient must not be left unattended at any time during the examination. Since the device contains small parts which can be swallowed, an increased level of care is required, especially if babies and infants are present. After the test, the patient must not leave the laboratory until the obstruction has been reversed, either spontaneously or after bronchospasmolysis (desirable FEV₁ > 90% of the initial value before provocation) [6].

<table>
<thead>
<tr>
<th>time</th>
<th>volume</th>
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<tbody>
<tr>
<td>6 sec</td>
<td>0.50l</td>
</tr>
<tr>
<td>12 sec</td>
<td>1.00l</td>
</tr>
<tr>
<td>24 sec</td>
<td>2.00l</td>
</tr>
<tr>
<td>48 sec</td>
<td>4.00l</td>
</tr>
</tbody>
</table>

1 min = 6 sec
36 sec = 0.50l
12 sec = 1.00l
24 sec = 2.00l
48 sec = 4.00l
If nebulised provocation substance should pass directly into the environment (e.g. because the exhalation filter was forgotten during assembly), it is recommended that the treatment room be aired out thoroughly.

The PARI PROVOCATION TEST II is powered by electricity. The device must not be operated in areas at risk of explosion or in damp locations, and must not be left unattended. Whenever the device is used, a thorough knowledge of the instructions for use and compliance with the same is assumed. In all cases the operator is liable for the safe operation of the appliance if it is not used according to the instructions. The appliance must only be serviced by PARI GmbH or a service center expressly authorised by PARI GmbH. If repairs are carried out by an authorised PARI GmbH service center, you must ask for a certificate giving the date, type and scope of the repair, and the company name and signature. Only original PARI accessories must be used to operate the device.

- Place the compressor on a firm, flat surface for operation
- Ensure that the rear ventilation slits are not blocked
- Check that the supply voltage complies with the data marked on the appliance.

PARI GmbH is not responsible for damage or malfunctions caused by the operator using the machine improperly or contrary to the instructions. The power plug must be disconnected from the socket to ensure that power is completely cut off.

We reserve the right to make technical changes.

2.4 Storage and transportation conditions

- Ambient temperature -40 °C to +70 °C
- Relative humidity 10% to 95% (non-condensing)
- Atmospheric pressure 500 hPa – 1060 hPa

Between applications the device must be stored in a dry, dust-free place that is protected from direct sunlight. It must also be protected against damp while it is being transported.

2.5 Conditions of use

Bronchial provocations can be conducted with the PARI PROVOCATION TEST II under the following conditions:
- Ambient temperature 15 °C to 30 °C
- Relative humidity 25% to 60%
- Atmospheric pressure 700 hPa to 1060 hPa
- The device should be at room temperature.
3 PREPARATION FOR USE

- Check the parts of your nebuliser before every application. Replace any broken, misshapen or seriously discoloured parts. Please also follow the instructions for assembly given below. Damaged components and/or an incorrectly assembled nebuliser may impair the function of the nebuliser and thus diagnosis as well.

- Before each use, as well as after long breaks in use, please follow the hygiene instructions.

3.1 Applying the adhesive provocation programme label

Three adhesive labels listing the most common provocation programmes are included with the PARI PROVOCATION TEST II for reference when setting the timer (time/volume).

<table>
<thead>
<tr>
<th>time</th>
<th>volume</th>
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<tbody>
<tr>
<td>6 sec</td>
<td>0.50 l</td>
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<tr>
<td>12 sec</td>
<td>1.00 l</td>
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<tr>
<td>24 sec</td>
<td>2.00 l</td>
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<tr>
<td>48 sec</td>
<td>4.00 l</td>
</tr>
<tr>
<td>1 min</td>
<td>8.00 l</td>
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</table>

<table>
<thead>
<tr>
<th>time</th>
<th>volume</th>
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</thead>
<tbody>
<tr>
<td>15 sec</td>
<td>1.25 l</td>
</tr>
<tr>
<td>30 sec</td>
<td>2.50 l</td>
</tr>
<tr>
<td>1 min</td>
<td>5.00 l</td>
</tr>
<tr>
<td>2 min</td>
<td>10.00 l</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>time</th>
<th>volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 sec</td>
<td>0.50 l</td>
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<tr>
<td>24 sec</td>
<td>2.00 l</td>
</tr>
<tr>
<td>1 min</td>
<td>8.00 l</td>
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</tbody>
</table>

• Please stick the selected provocation programme (G) next to the main switch (F).
3.2 Assembling the exhalation filter

- Insert a filter pad (7-2) in the upper part (7-1).

**Note:** Only use the filter pads that are designed specifically for the exhalation filter (see "Replacement parts/accessories", page 24).

- Insert the snap locks on the lower part (7-3) in the holes in the upper part. Lock the exhalation filter in place by turning the lower part clockwise as far as it will go.

- Make sure that the blue valve shim (7-4) is located in the upper part of the exhalation filter.

3.3 Assembling the stand, nebuliser and respiration controller

- Mount the stand (13) on the side of the compressor.
- Fit the ball valve (12) into the opening on the holder (c) as shown.
- Secure the ball valve with the set screw.
- Connect components (8) to (12) to the ball valve.
- Insert the fluted end of the exhalation filter into the manifold (11).

If the valve (8) is not installed by mistake and the patient is exhaling into the bag (the bag expands), the bag must be replaced before the next patient.
3.4 Fill with provocation substance

- Unscrew the nebuliser upper section (20) from the medication cup (23).
- Take the collector (22) and the gasket (21) out of the medication cup.
- Pour the provocation substance into the medication cup (min. 6 ml, max. 8 ml).

If you overfill the medication cup and the provocation substance leaks out of the nebuliser, the nebuliser must be cleaned (see "Hygienic re-use", page 15).

**Important:** When the quantity of provocation substance falls below 6 ml, fresh provocation solution must be added. As fill quantities become smaller, the test substance in the nebuliser solution becomes considerably more concentrated due to evaporation. This would increase the inhaled dose.
• Assemble the nebuliser components as shown opposite.

• Connect the nebuliser (5) to the compressor with the connection tubing (18). Twist the connector slightly as you insert it.
• Ensure that the tube connections are firmly fixed on the compressor and the nebuliser.
3.5 Assembling the aerosol bag

- Place the bag rail (1) on a table.
- Pull the magnetic strip (1.1) off the bag rail.
- Place the top strip of the aerosol bag (2) on the bag rail.
- Attach the bag so that it is clamped flat against the bag rail with the magnetic strip.

- Slide the locking ring over the opening in the aerosol bag.

- Insert the connecting piece into the air bag opening.

- Slide the locking ring over the connecting piece to create an airtight seal between the aerosol bag and the connecting piece.
• Fit the spring (6) into the middle hole on the bag rail (1).
• Hang the bag ring and the aerosol bag (2) from the stand arm using the spring (6).
• Insert the connecting piece (4) on the nebuliser (5).
• If necessary, adjust the height with the height adjuster to match the holder (c).
  **Note:** Note that the aerosol bag must not be clamped too firmly. Otherwise it may slip out of the magnetic holder during operation.
• Insert the nebuliser in the ball valve (12).

### 3.6 The control panel

(A) Air filter
(B) Air connection
(C) Timer
(D) MODE button (START / STOP)
(E) Buttons for setting the time
(F) Main switch

**Air filter**
The air filter must be replaced after about 200 operating hours, but at least once a year.
Timer
The timer can be set in a range from one second to 9 minutes and 59 seconds using the buttons (E).

Mode button
The Mode button is used to start the compressor, the timer starts automatically. As soon as the set time has elapsed, the compressor stops.
4 CONDUCTING THE PROVOCATION

4.1 If necessary, neutralise electrostatic charges
When a new bag is used, its electrostatic charge must be neutralised before the first provocation test is carried out:
• To do this, fill the aerosol bag with 10 l aerosol (0.9% NaCl solution) three times.

4.2 First measurement of lung function
• Before the provocation is begun, first a whole body plethysmography must be carried out, including an FEV₁ measurement.

4.3 First provocation stage
• Have the patient take the mouthpiece between his teeth and enclose it with his lips.
• Open the ball valve.
• Have the patient inhale the aerosol for three minutes. Make sure that the patient inhales the aerosol from the bag and only exhales through the exhalation filter. This is the only way to prevent provocation substance from escaping and contaminating the surroundings.
   The patient must inhale in a manner similar to a slow inspiratory full capacity cycle. Each inhalation cycle must last at least five seconds. If inspiratory full capacity cycles are not possible (e.g., with children), the patient may use "deeper breathing" or spontaneous breathing instead.
• Close the ball valve (12) as shown opposite.
• Switch the main switch on.
• Select the first volume according to the desired provocation programme (see "Provocation programmes", page 29).
• Set the timer to the appropriate time (see "Timer", page 12).
• Press the MODE button.
• Set the timer to the appropriate time (see "Timer", page 12).
• Press the MODE button.
• Set the timer to the appropriate time (see "Timer", page 12). The compressor will start and the bag will begin filling with aerosol.
As soon as the set time, and thus also the corresponding bag volume, is reached, the compressor will switch off and an audible signal will be emitted. The acoustic signal is switched off by pressing the MODE button and the clock will show the preset time.
• Have the patient take the mouthpiece between his teeth and enclose it with his lips.
• Open the ball valve.
• Have the patient inhale the aerosol for three minutes.

The time intervals between the individual provocation stages should be kept constant (two to five minutes). As far as possible this should be checked with a stopwatch.
4.4 Subsequent lung function measurements and provocations

- After each provocation stage, conduct an FEV₁ measurement and enter the results in the evaluation chart as required.
- Perform the next provocation stage in each case according to the chosen provocation programme (see "Provocation programmes", page 29).

4.5 Criteria for termination

The provocation test is considered positive and is terminated with a bronchospasmolysis if at least one of the following criteria is met:
- FEV₁ decrease greater than 20%
- Raw increase greater than 100% (and > 0.6 kPa/l/s)
- sRaw increase greater than 100% (and > 2.0 kPa/l/s)
5 HYGIENIC RE-USE

5.1 General
The nebuliser, the ball valve, and the components of the respiration controller are designed for multiple uses including a change of patients in hospital/medical practice:

In order to prevent a risk to health, e.g., infection due to a contaminated nebuliser, it is imperative that the following hygiene regulations are followed:

The nebuliser (5), mouthpiece (10), manifold (11), corrugated tube (9), valve (8), exhalation filter (7) and ball valve (12) must be cleaned thoroughly, disinfected and sterilised after each treatment.

- Please ensure thorough drying after each cleaning, disinfection and sterilisation. Condensation or residual moisture can encourage the growth of bacteria.
- Read section "Material resistance" on page 19.
- Please check the parts of your provocation test regularly and replace any defective (broken, misshapen, discoloured) parts.
- The aerosol bag must be replaced at least once a day.

Like all plastic parts, the PARI nebuliser is susceptible to a certain degree of wear when it is used and reprocessed frequently. Over time, this can cause a change in the aerosol, which in turn impairs the accuracy of the dosage.

In all cases, the nebuliser, connection tubing, filter insert, the sealing washer and gasket as well as the corrugated tube, the mouthpiece, and the manifold must be replaced at least every two years.

Depending on the frequency with which it is used by patients, it may be necessary to have several nebulisers and respiration controllers on hand to speed up proceedings in the practice and hospital.

The aerosol bag (2) must be replaced every day. The bag must also be replaced every time the provocation solution is changed. The used bag must be disposed of.

Proof of effective cleaning, disinfection and sterilisation of the PARI PROVOCATION TEST II components has been obtained through an independent testing laboratory using the recommended procedures described starting on page 17.
5.2 Preparations for hygienic re-use

- Unscrew the medication cup (23).
- Rinse the medication cup out with water.
- To prevent the nozzle (24) from becoming clogged, carry out the following steps immediately after the provocation test:
  - Unscrew the medication cup.
  - Fill the medication cup a quarter full with distilled water.
  - Nebulise all of the distilled water.
- Dismantle the nebuliser (5) completely (eight components).

- Dismantle the exhalation filter (7) as shown opposite.
- Dispose of the filter pad (7-2).

⚠️ The filter pad must not be used more than once.

- Use a ring spanner (SW 30) to disassemble the ball valve (12).
- For the cleaning, disinfection and sterilisation described below, turn the ball valve to the open position (see illustration opposite).
5.3 Cleaning/disinfection/sterilisation
Parts must only be cleaned, disinfected and sterilised using procedures that have been validated specifically for use on these products and devices. The validated parameters must be maintained at all times.

The cleaning and disinfection procedure used must be recognised as effective (e.g., in the list of tested and recognised disinfectants and procedures issued by the Robert Koch Institute/DGHM) and already validated in all cases.

If other procedures are used, their effectiveness must be confirmed during validation. CE-marked chemical disinfectants may also be used, as long as they meet the material resistance criteria.

Please read chapter "Material resistance", page 19 for more details.

5.3.1 Cleaning/disinfection
Clean and disinfect immediately after use. Ideally, a mechanical procedure (instrument dishwasher) is to be used.

Recommended procedure: Thermal disinfection

- Place the disassembled components of the nebuliser, the ball valve and the exhalation filter, the mouthpiece, the manifold, the corrugated tube and the valve in the instrument dishwasher.
- Select the 93 °C programme (treatment time: 10 minutes).

The effectiveness of this procedure has been confirmed using a G7836 disinfector manufactured by Miele with neodisher®medizym cleaning agent manufactured by Chemische Fabrik Dr. Weigert, Hamburg.

or

Recommended procedure: Manual cleaning/disinfection
In general, aldehydic cleaners and disinfectants are suitable for cleaning and disinfecting this nebuliser.

- Place the components in a 0.5% solution of Bodedex®forte and water at a temperature of 50 °C.
- Clean the components thoroughly for 5 minutes.
- Place the components in Korsolex®extra as a 4% disinfection solution for 15 minutes.
- Thoroughly rinse the nebuliser parts, the mouthpiece, the manifold, the corrugated tube, the valve, the exhalation filter and the ball valve under warm running water.
- Allow them to dry completely on a clean, dry and absorbent surface (for at least 4 hours).

The effectiveness of this procedure has been proven using the Bodedex®forte cleaning agent in combination with the Korsolex®extra disinfectant made by BODE CHEMIE HAMBURG.
Possible alternative: Chemical-thermal disinfection

- Place the disassembled components of the nebuliser, the ball valve and the exhalation filter, as well as the mouthpiece, the manifold, the corrugated tube and the valve in the instrument dishwasher.
- Add a suitable cleaner/disinfectant and select the 60 °C programme.

5.4 Sterilisation

- After cleaning/disinfection, pack the disassembled parts in sterilisation packaging (disposable sterilisation packaging, e.g., foil/paper sterilisation bags).

The sterilisation packaging must conform to DIN EN ISO 11607 and be suitable for steam sterilisation. Then sterilise the parts according to the following sterilisation procedure:

Recommended procedure: Steam sterilisation

This procedure has been validated according to DIN EN ISO 17665 as well as DGKH guidelines for the validation and routine monitoring of sterilisation processes using damp heat for medical devices.

Sterilisation temperature: 121 °C (to be maintained for at least 20 min.).

The product must not be autoclaved at 134 °C.

Storage

Keep the sterilised parts in a dry, dust-free place protected from contamination.

5.5 Care of the connection tubing

- After each treatment day, pull the tubing from the nebuliser and switch the appliance on.
- Leave the compressor running until any condensation in the tubing has been removed by the airflow.
- The connection tubing is to be replaced once a year or whenever it becomes contaminated (item no. 041B4591).

5.6 Cleaning the compressor

Before cleaning, turn the compressor off and remove the power plug from the socket.
- Wipe the outer surface of the compressor housing with a damp cloth.

Do not spray liquids into the ventilation slits.
Such liquid may damage the electrical equipment and other compressor parts and cause a malfunction.
5.7 Changing the filter insert on the compressor

The filter insert on the front plate must be replaced every 200 operating hours in normal operating conditions, and at least once a year.

Also check the filter insert regularly (after every 10 to 12 treatments). If the filter inside has become soiled (grey or brown colour) or blocked, replace it. The filter must also be replaced with a new filter if it has become damp.

Do not try to clean the filter insert and use it again!

Use only the original PARI filter insert (041B6400), otherwise your PARI PROVOCATION TEST II compressor may be damaged or treatment may be inadequate.

To change the filter, proceed as follows (see figure):

- Unscrew the filter insert (A) from your PARI PROVOCATION TEST II compressor with a coin of the appropriate size.
- Insert the new filter insert.
- Use the coin to tighten the filter insert again.

5.8 Material resistance

The nebuliser, manifold, corrugated tube, valve, ball valve and the exhalation filter can be sterilised up to 100 times, but then they must be replaced. The nebuliser must be replaced at least every two years in all cases.

Note the following when selecting cleaners/disinfectants:

- Essentially, the aldehydic cleaner/disinfectant group is suitable for cleaning and/or disinfecting this nebuliser.
- The use of other cleaners or disinfectants has not been tested with regard to the material resistance of this nebuliser.
6 CHECKING THE COMPRESSOR OUTPUT

Please check the output of your compressor at least once a month. To do this, carry out the following steps:

- Connect the test pressure gauge (16) to the connection tubing (18).
- Attach the test nozzle (17) to the test pressure gauge outlet.
- Switch the compressor on.
- Set a time of 30 sec. on the timer.
- Press the MODE button.
- The pointer on the test pressure gauge must be in the zone between 1.1 bar and 1.35 bar. If it is, the test can be terminated by pressing the MODE button again or by switching the compressor off.

In exceptional cases, the indicator may pass beyond this zone if the barometric pressure is high (high pressure weather conditions). Otherwise, check whether the nozzle is blocked. To do this, take the test nozzle off and flush backwards with compressed air.

If the indicator does not reach the specified zone, please contact the PARI Service Center (see "PARI Service Center", page 35), because this means that the compressor output is deficient. If the device is operated at an altitude more than 1000 m above sea level, the pressure the compressor can output will be in the lower tolerance range because of the reduced ambient pressure.
## MALFUNCTION, TROUBLESHOOTING

<table>
<thead>
<tr>
<th>Description of fault</th>
<th>Possible causes</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nozzle blocked</td>
<td>Hygienic re-use not carried out according to instructions for use.</td>
<td>Only use an original PARI nozzle cleaner!</td>
</tr>
<tr>
<td></td>
<td>A &quot;non-recommended provocation substance&quot; has been used.</td>
<td>Use the nozzle cleaner very carefully, because the small nozzle bore holes can easily be damaged irreparably.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If the nozzle becomes blocked repeatedly, replace it (order no. 019B2110).</td>
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</tbody>
</table>

If necessary, clean the nozzle as follows:

- Disassemble the nebuliser as described in section "Preparations for hygienic re-use", page 16.
- Press the nozzle (24) out of the medication cup from above.
- Pull the airflow control (f) off the nozzle.
- Take the nozzle cleaner (h) out of its disposable package (order no. 041E1101).
- Carefully poke through the nozzle holes for medication (h1, h3) and air (2) (only from below).

**Important:** After cleaning, push the air-flow control (f) back on as far as it will go!

- Reassemble the nebuliser as shown in section "Preparations for hygienic re-use", page 16.
### Description of fault | Possible causes | Remedy
--- | --- | ---
Aerosol bag (2) slips off the bag rail (magnetic strip) during filling. | Aerosol bag is under too much tension. | • Reduce the tension by adjusting the holder (c).

---

Compressor does not work. | Liquid has got into the compressor. | If liquid has got into the compressor, contact an authorised dealer or the PARI Service Center (see "PARI Service Center", page 35). Do not use your compressor except on their instructions or after a check and any necessary repairs have been performed by your authorised dealer or the technical service department of PARI GmbH.

---

Other malfunctions |  | Please contact the PARI Service Center (see "PARI Service Center", page 35).
8 MAINTENANCE

We recommend that the PARI PROVOCATION TEST II be tested once a year. The device must only be serviced by PARI GmbH or a service location expressly authorised by PARI GmbH. If repairs are carried out by an authorised PARI GmbH service center, you must ask for a certificate giving the date, type and scope of the repair, and the company name and signature. Only original PARI accessories must be used to operate the appliance, to ensure reproducibility and safety. PARI GmbH is not responsible for damage or malfunctions caused by the operator using the machine improperly or contrary to the instructions.

9 DISPOSAL

This product falls within the scope of the European Council Directive on Waste Electrical and Electronic Equipment (WEEE\(^1\)) and is included in Product Category 8: Medical Devices for the purposes thereof. Accordingly, this product must not be disposed of with domestic waste. The disposal regulations prevailing in the respective member countries must be observed (disposal by local authorities or dealers). Materials recycling helps to reduce the consumption of raw materials and protect the environment.

---

## REPLACEMENT PARTS/ACCESSORIES

<table>
<thead>
<tr>
<th>Item</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>PARI PROVOCATION TEST II (complete with accessories)</td>
<td>064G7300</td>
</tr>
<tr>
<td>Aerosol bag (12 pack)</td>
<td>064B4600</td>
</tr>
<tr>
<td>Connection tubing</td>
<td>041B4591</td>
</tr>
<tr>
<td>&quot;Provocation stages&quot; adhesive labels</td>
<td>064E1005</td>
</tr>
<tr>
<td>Bag rail</td>
<td>064B4560</td>
</tr>
<tr>
<td>Box links</td>
<td>064B2000</td>
</tr>
<tr>
<td>Exhalation filter</td>
<td>041B0519</td>
</tr>
<tr>
<td>Corrugated tube</td>
<td>064E4414</td>
</tr>
<tr>
<td>Filter insert (for compressor)</td>
<td>041B6400</td>
</tr>
<tr>
<td>Filter pads</td>
<td></td>
</tr>
<tr>
<td>30-pack</td>
<td>041B0522</td>
</tr>
<tr>
<td>100-pack</td>
<td>041B0523</td>
</tr>
<tr>
<td>1000-pack</td>
<td>041B0524</td>
</tr>
<tr>
<td>Locking ring</td>
<td>064E4108</td>
</tr>
<tr>
<td>Ball valve (incl. ring spanner)</td>
<td>064G4450</td>
</tr>
<tr>
<td>Mouthpiece</td>
<td>012E1720</td>
</tr>
<tr>
<td>PARI PROVOCATION TEST II nebuliser</td>
<td>064B4400</td>
</tr>
<tr>
<td>Test nozzle</td>
<td>041B1020</td>
</tr>
<tr>
<td>Test pressure gauge with T-member</td>
<td>041B1030</td>
</tr>
<tr>
<td>Ring spanner</td>
<td>064E1000</td>
</tr>
<tr>
<td>Expanding button</td>
<td>059B2710</td>
</tr>
<tr>
<td>Stand</td>
<td>064G7100</td>
</tr>
<tr>
<td>Valve (12-pack)</td>
<td>064B4721</td>
</tr>
<tr>
<td>Connecting piece</td>
<td>064E4415</td>
</tr>
<tr>
<td>Manifold</td>
<td>064E4444</td>
</tr>
<tr>
<td>Tension spring</td>
<td>064E4801</td>
</tr>
<tr>
<td><strong>Nebuliser components</strong></td>
<td></td>
</tr>
<tr>
<td>Gasket (10-pack)</td>
<td>070B0208</td>
</tr>
<tr>
<td>Sealing washer (10-pack)</td>
<td>070B0209</td>
</tr>
<tr>
<td>Nozzle</td>
<td>019B2110</td>
</tr>
<tr>
<td>Medication cup</td>
<td>070E0201</td>
</tr>
<tr>
<td>Collector</td>
<td>064E4401</td>
</tr>
<tr>
<td>Nebuliser upper section</td>
<td>064B4410</td>
</tr>
<tr>
<td>Nebuliser lower section</td>
<td>064E4431</td>
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<tr>
<td><strong>Accessories</strong></td>
<td></td>
</tr>
<tr>
<td>&quot;Histamine&quot; evaluation chart</td>
<td>041D0208</td>
</tr>
<tr>
<td>&quot;Methacholine, carbachol&quot; evaluation chart</td>
<td>041D0209</td>
</tr>
<tr>
<td>Nozzle cleaner (5-pack)</td>
<td>012B1011</td>
</tr>
<tr>
<td>Nose clip</td>
<td>041E3500</td>
</tr>
</tbody>
</table>

For other spare parts and accessories or more product information, please contact the PARI Service Center (see "PARI Service Center", page 35).
11 TECHNICAL DATA

General

Electrical connection: 230 V~/ 50 Hz / 0.4 A,
See type identification plate on the bottom of the compressor
Max. noise volume of the compressor: Approx. 62 dBA (acc. to: DIN EN 13544-1, section 26)
Housing dimensions (W x H x D): 34 cm x 21.5 cm x 17 cm
Weight: 4.2 kg
Pressure: 1.4 bar
Flow: 5.0 l/min

Classification according to DIN EN 60601-1:1996

Type of electric shock protection: Protection class II
Degree of protection from electric shock of the part used: Type B
Degree of protection against water penetration in accordance with IEC 529 (IP rating): No protection
Degree of protection when used in the presence of flammable mixtures of anaesthetics with air or with oxygen or nitrous oxide: No protection
Operating mode: Max. 60 min.

Information about electromagnetic compatibility

- Electrical medical equipment is subject to special precautionary measures with regard to electromagnetic compatibility (EMC). It must not be installed and operated except in accordance with the EMC instructions included in the accompanying documentation.
- Portable and mobile high-frequency (HF) communication devices can disrupt electrical medical equipment.
- Using accessories, converters and power cords other than those specified, with the exception of converters and power cords that the manufacturer of the medical electrical device sells as spare parts for internal components, can result in higher emission levels or lower the resistance to interference of the device.
- The device must not be placed directly beside or on top of other devices for operation. If the medical electrical device must be placed beside or on top of other devices to operate it, it should be monitored constantly to ensure that it is operating properly in the arrangement used.
- Technical data on electromagnetic compatibility is available in table form on request from PARI GmbH or on the Internet under "Products" at www.pari.de/en/Products on the relevant product page under "Technical data".
- The compressor must not be operated continuously for more than 60 minutes.
**Explanation of symbols**

- On/Off
- Alternating current
- Part used type B
- Protection class II device
- Caution, see instructions for use
- Warning

The medical device was distributed commercially after 13 August 2005. **This product must not be disposed of with normal domestic waste.** The symbol of the refuse bin with a cross through it indicates that it must be collected separately.

### PHYSICAL DATA

- **MMD:** 2.5 µm
- **Mass fraction *in droplets:**
  - less than 2 µm; 42%
  - less than 5 µm; 83%
- **Aerosol output:** 93 mg with full 10 l bag
- **Min. nebuliser fill volume:** 6 ml
- **Max. nebuliser fill volume:** 8 ml

*) Measurement with the Malvern MasterSizer X at 22°C and 50% relative humidity. Nebulised test solution: 0.9% NaCl.

### REFERENCE SOURCES FOR PROVOCATION SUBSTANCES

**Histamine, carbachol, methacholine**

If necessary, the solutions may be prepared by chemists in accordance with the recipe instructions of the NRF: (www.dac-nrf.de).

Methacholine is approved as a ready-to-use pharmaceutical product in the form of Provokit® manufactured by Lindopharm GmbH.
QUICK GUIDE TO PERFORMING A PROVOCATION WITH THE PARI PROVOCATION TEST II

The PARI PROVOCATION TEST II is a device that is used for conducting non-specific bronchial provocation tests with histamine, methacholine and carbachol. Provocation protocols are available for conducting non-specific provocations with these substances. They are listed in chapter 15.

Conducting:

1. Assemble the stand, the nebuliser, the respiration controller and the aerosol bag for the PARI PROVOCATION TEST II as described in 3.2 to 3.5.
   - If a new aerosol bag is being used, it must be filled with 10 l aerosol of a 0.9% NaCl solution three times in order to neutralise the electrical charges before the first provocation test.
   - If different concentrations of a provocation substance are being used, the bag does not have to be changed.
   - Change the bag once a day.

2. Fill the medication cup in the nebuliser with 8 ml of the provocation substance.
   - When this quantity falls below 6 ml, fresh provocation substance must be added. This is necessary because fill quantities become smaller due to evaporation, causing the test substance to become considerably more concentrated in the nebuliser solution. This would increase the inhaled dose.

3. Perform a first measurement of lung function (whole body plethysmography, including an FEV₁ measurement) before starting the provocation.

4. In general, when performing the provocation you must ensure that the time intervals between the individual provocation stages are constant (intervals between 2 and 5 minutes). To ensure this, it is advisable to run a clock from the beginning of the examination.

5. Close the ball valve before switching the PARI PROVOCATION TEST II on. To do this, turn the lever on the ball valve clockwise through 90°.
   - The ball valve is closed when the lever is pointing away from the nebuliser.
   - If the lever is difficult to turn, it is recommended to loosen the two parts of the ball valve gently using the ring spanner.

6. Applying the first provocation stage:
   - Switch the device on at the main switch (F) (see also the figure on page 11). A short audible signal will be emitted.
   - Select the smallest volume for the corresponding provocation programme. For example, 0.5 litre for the first provocation stage.
     (Note: Chapter 15 includes the provocation protocols for provocations using histamine, methacholine, and carbachol).
   - Set the corresponding time on the timer using the two buttons (see figure on page 11) to the left and right of the MODE button (e.g., 0.5 l = 6 sec).
- Press the MODE button on the timer. The compressor will start and the bag will begin filling with aerosol.
- When the set time has elapsed, the compressor will switch off automatically and an audible signal will be emitted. The corresponding bag volume has been reached. When the MODE button is pressed a second time, the acoustic signal is switched off and the clock will show the preset time again.
- The patient now takes the mouthpiece between his teeth and encloses it with his lips.
- Open the ball valve (the lever now points towards the nebuliser). The patient can now breathe in the aerosol stored temporarily in the bag. The patient breathes in from the aerosol bag and exhales through the exhalation filter.
- The patient should inhale in a manner similar to a slow inspiratory vital capacity manoeuvre. Each inhalation cycle must last at least 5 seconds. Exhalation may be spontaneous and forced without an exhalation pause. Please note that the patient should inhale all of the aerosol in the bag within three minutes.

7 Carry out a second lung function measurement
The first provocation stage is followed by an FEV₁ measurement in the normal way, and this is recorded and entered on the evaluation chart.

8 Applying the second provocation stage
The second provocation stage follows (e.g., 1 l = 12 sec). Close the ball valve again, and carry out the second provocation stage as described in paragraph 6.

9 Carry out a third lung function measurement
The second provocation stage is followed by another FEV₁ measurement in the normal way, and this is recorded and entered on the evaluation chart.

10 Subsequent provocation stages
The subsequent provocation stages must be adjusted according to the provocation protocol selected and carried out as described in the procedure protocol in paragraph 6.

11 Terminating the provocation
The provocation test is considered positive and is terminate with a bronchospasmolysis if one of the following criteria is met:
- FEV₁ decrease greater than 20%
- Raw increase greater than 100% (and > 0.6 kPa/l/s)
- sRaw increase greater than 100% (and > 2 kPa/l/s)

12 When the provocation has been completed, the nebuliser, the mouthpiece, the manifold, the corrugated tube, the valve, the exhalation filter and the ball valve must be cleaned to remove all medication residues, then disinfected and sterilised. The cleaning, disinfection and sterilisation processes are described fully in chapter 5. Please carry out these procedures before every patient change.
15 PROVOCATION PROGRAMMES

The following sections contain provocation programmes for conducting bronchial provocation tests with the PARI PROVOCATION TEST II

15.1 Recommendations by the Deutsche Gesellschaft für Pneumologie and the Hauptverband der Berufsgenossenschaften

15.1.1 Inhalational provocation test with histamine (as invented by Prof. Dr. D. Köhler)

<table>
<thead>
<tr>
<th>Stage</th>
<th>Aerosol volume Bag / Clock setting</th>
<th>Histamine concentration [mg/ml]</th>
<th>Nebulised aerosol-Single dose histamine* [mg]</th>
<th>Nebulised aerosol-Single dose histamine* [µg]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1 l / 12 sec</td>
<td>0.2 (≈0.02%)</td>
<td>0.0019</td>
<td>1.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>2 l / 24 sec</td>
<td>0.2</td>
<td>0.0038</td>
<td>3.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>4 l / 48 sec</td>
<td>0.2</td>
<td>0.0075</td>
<td>7.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>8 l / 1 min 36 sec</td>
<td>0.2</td>
<td>0.0150</td>
<td>15.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>1 l / 12 sec</td>
<td>3.3 (≈0.33%)</td>
<td>0.030</td>
<td>30.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>2 l / 24 sec</td>
<td>3.3</td>
<td>0.060</td>
<td>60.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>4 l / 48 sec</td>
<td>3.3</td>
<td>0.120</td>
<td>120.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>8 l / 1 min 36 sec</td>
<td>3.3</td>
<td>0.240</td>
<td>240.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
</tr>
</tbody>
</table>

Whole-body plethysmographic measurement, incl. FEV₁ at the end of the test

Tab. 1: Provocation programme for histamine

*) Methacholine or carbachol mass available at the mouthpiece (µg/mg). In order to calculate the quantity of aerosol deposited intrabronchially, the specified nebulised single or cumulative aerosol dose must be multiplied by 0.8.

Note

It must be ensured that at least 6 ml solution is always present in the medication cup. If necessary, it must be filled during the individual steps.

The possible cumulative effects of histamine have not been definitively established [2.3]. Furthermore, when conducting a provocation with histamine it must be considered that the effect of histamine is 1.5 to 2 times stronger than that of carbachol or methacholine due to its molar mass [4.5].
Contraindications
There is no firm scientific data regarding strict contraindications. Nevertheless, the following relative contraindications are to be noted:
- Severe obstruction of the respiratory tract
- Severe heart diseases; particularly bradycardiac arrhythmias when using parasympathomimetics
- Spirometry-induced obstruction
- Exacerbation of bronchial asthma
- Severe arterial hypertension
- Pregnancy
- Epilepsy requiring treatment

Safety precautions
- Resuscitation equipment or emergency drug kit must be at hand.
- It must be possible to contact the physician at all times.
- A fast-acting bronchospasmolytic such as salbutamol or fenoterol must be readily available. Alternatively, inhalation of pediamol, 5-10 drops (adults) in 3 ml NaCl 0.9%

The induced obstruction typically subsides spontaneously within 15 minutes. Even so, bronchospasmolytic treatment is still beneficial for obstructions.

Important: Each provocation step (inhalation plus measurement) should not last longer than 5 minutes, so that the total time taken to obtain the maximum dose does not exceed 20 minutes.

After the provocation test, it is important to empty the solution out of the container. If it is left to stand for long periods, the liquid evaporates and the concentration increases.

The following items are required
- PARI PROVOCATION TEST II
- Histamine solution 0.02% and histamine solution 0.33%
- Spirometer (FEV₁ measurement)
- Emergency equipment

Criteria for termination
- FEV₁ decrease greater than 20%
- Raw increase greater than 100% (and > 0.6 kPa/l/s)
- sRaw increase greater than 100% (and > 2.0 kPa*s)

Evaluation (acc. to Prof. Dr. D. Köhler)
The following division is recommended for the test procedure for graduating bronchial hypersensitivity:

Positive result:
- Up to 30 µg: High-grade bronchial hypersensitivity
- Between 30 - 120 µg: Medium-grade bronchial hypersensitivity
- Between 120 - 240 µg: Low-grade bronchial hypersensitivity
- Limit range: 240 - 480 µg
15.1.2 Inhalational provocation test with methacholine (MCH) or carbachol (CBCH)

<table>
<thead>
<tr>
<th>Stage</th>
<th>Aerosol volume</th>
<th>Methacholine-carbachol concentration</th>
<th>Nebulised aerosol single dose*</th>
<th>Cumulative aerosol dose*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bag / Clock setting (%) (0.3 mg/ml)</td>
<td>[µg]</td>
<td>[mg]</td>
<td>[µg]</td>
</tr>
<tr>
<td>1</td>
<td>0.5 l / 6 s</td>
<td>0.33</td>
<td>15.2</td>
<td>0.0152</td>
</tr>
<tr>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1 l / 12 s</td>
<td>0.33</td>
<td>30.4</td>
<td>0.0304</td>
</tr>
<tr>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>2 l / 24 s</td>
<td>0.33</td>
<td>60.7</td>
<td>0.0607</td>
</tr>
<tr>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>4 l / 48 s</td>
<td>0.33</td>
<td>121.4</td>
<td>0.1214</td>
</tr>
<tr>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>8 l / 1 min36 s</td>
<td>0.33</td>
<td>242.9</td>
<td>0.2429</td>
</tr>
<tr>
<td></td>
<td>Whole-body plethysmographic measurement, incl. FEV₁ at the end of the test</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Tab. 2: Provocation programme for methacholine or carbachol [6]
*) Methacholine or carbachol mass available at the mouthpiece (µg/mg). In order to calculate the quantity of aerosol deposited intrabronchially, the specified nebulised single or cumulative aerosol dose must be multiplied by 0.8.

**Note**
At least 6 ml solution must always be present in the medication cup. It may be necessary to add more solution during the individual steps.

**Contraindications**
There is no firm scientific data regarding strict contraindications. Nevertheless, the following relative contraindications are to be noted:
- Severe obstruction of the respiratory tract
- Severe heart diseases; particularly bradycardiac arrhythmias when using parasympathomimetics
- Spirometry-induced obstruction
- Exacerbation of bronchial asthma
- Severe arterial hypertension
- Pregnancy
- Epilepsy requiring treatment
Safety precautions

- Resuscitation equipment or emergency drug kit must be at hand.
- It must be possible to contact the physician at all times.
- A fast-acting bronchospasmytic such as salbutamol or fenoterol must be readily available. Alternatively, inhalation of pediamol inhalation solution, 5-10 drops (adults) in 3 ml NaCl 0.9%
- The induced obstruction typically subsides spontaneously within 15 minutes. Even so, bronchospasmolytic treatment is still beneficial for obstructions.

**Important:** Each provocation step (inhalation plus measurement) should not last longer than 5 minutes, so that the total time taken to obtain the maximum dose does not exceed 20 minutes.

After the provocation test, it is important to empty the solution out of the container. If it is left to stand for long periods, the liquid evaporates and the concentration increases.

The following items are required
- PARI PROVOCATION TEST II
- Methacholine and carbachol solution 0.33%
- Spirometer (FEV₁ measurement)
- Emergency equipment

Criteria for termination
- FEV₁ decrease greater than 20%
- Raw increase greater than 100% (and > 0.6 kPa/l/s)
- sRaw increase greater than 100% (and > 2.0 kPa*s)

Evaluation (see also [1])
The results are to be analysed as a dose-effect relationship. A positive result must normally be indicated in the form of the provocation dose (PD) or as a provocation concentration (PC) that has yielded the positive result (e.g. PD₂₀, FEV₁, PD₁₀₀, sRaw etc.). Evaluation charts with a semi-logarithmic scale are useful for this (see attachment).
## Bronchial provocation tests according to the recommendations of the American Thoracic Society (ATS)

### Bronchial provocations according to ATS guidelines using the recommended methacholine concentration solutions

<table>
<thead>
<tr>
<th>Stage</th>
<th>ATS methacholine concentration</th>
<th>Aerosol volume Bag / Clock setting</th>
<th>Nebulised aerosol single dose methacholine*</th>
<th>Cumulative aerosol dose*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(µg) [mg]</td>
<td>[µg]</td>
<td>[mg]</td>
</tr>
<tr>
<td>Whole-body plethysmographic measurement, incl. FEV&lt;sub&gt;1&lt;/sub&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0.03 mg/ml</td>
<td>10 l / 2 s</td>
<td>2.7</td>
<td>0.0027</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2.7</td>
<td>0.0027</td>
</tr>
<tr>
<td>2</td>
<td>0.06 mg/ml</td>
<td>10 l / 2 s</td>
<td>5.4</td>
<td>0.0054</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>8.1</td>
<td>0.0081</td>
</tr>
<tr>
<td>3</td>
<td>0.125 mg/ml</td>
<td>10 l / 2 s</td>
<td>11</td>
<td>0.011</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>19.1</td>
<td>0.0191</td>
</tr>
<tr>
<td>4</td>
<td>0.25 mg/ml</td>
<td>10 l / 2 s</td>
<td>22</td>
<td>0.022</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>41.1</td>
<td>0.0411</td>
</tr>
<tr>
<td>5</td>
<td>0.5 mg/ml</td>
<td>10 l / 2 s</td>
<td>44</td>
<td>0.044</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>85.1</td>
<td>0.0851</td>
</tr>
<tr>
<td>6</td>
<td>1 mg/ml</td>
<td>10 l / 2 s</td>
<td>89</td>
<td>0.089</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>174.1</td>
<td>0.1741</td>
</tr>
<tr>
<td>7</td>
<td>2 mg/ml</td>
<td>10 l / 2 s</td>
<td>178</td>
<td>0.178</td>
</tr>
<tr>
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<td></td>
<td></td>
<td>352.1</td>
<td>0.3521</td>
</tr>
<tr>
<td>8</td>
<td>4 mg/ml</td>
<td>10 l / 2 s</td>
<td>356</td>
<td>0.356</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>708.1</td>
<td>0.7081</td>
</tr>
<tr>
<td>9</td>
<td>8 mg/ml</td>
<td>10 l / 2 s</td>
<td>712</td>
<td>0.712</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1420.1</td>
<td>1.4201</td>
</tr>
<tr>
<td>10</td>
<td>16 mg/ml</td>
<td>10 l / 2 s</td>
<td>1424</td>
<td>1.424</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>2844.1</td>
<td>2.8441</td>
</tr>
</tbody>
</table>

| Whole-body plethysmographic measurement, incl. FEV<sub>1</sub> at the end of the test |

**Tab. 3: Provocation protocol for methacholine using the methacholine concentration solutions recommended in the ATS guidelines**

The table indicates the associated settings on the PARI PROVOCATION TEST II for each of the methacholine concentrations recommended by the ATS.

*) Methacholine or carbachol mass available at the mouthpiece (µg/mg). In order to calculate the quantity of aerosol deposited intrabronchially, the specified nebulised single or cumulative aerosol dose must be multiplied by 0.8.
15.2.2 Bronchial provocations according to ATS guidelines using only three methacholine concentration solutions.*

*) A special adaptation of the reservoir method of the PARI PROVOCATION TEST II.

<table>
<thead>
<tr>
<th>Stage</th>
<th>ATS methacholine concentration</th>
<th>Aerosol volume Bag / Clock setting</th>
<th>Nebulised aerosol single dose methacholine*)</th>
<th>Cumulative aerosol dose*)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[µg] [mg]</td>
<td>[µg] [mg]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1 mg/ml</td>
<td>0.3 l / 4 sec</td>
<td>2.7</td>
<td>2.7</td>
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<tr>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1 mg/ml</td>
<td>0.6 l / 7 sec</td>
<td>5.4</td>
<td>8.1</td>
</tr>
<tr>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>4 mg/ml</td>
<td>0.3 l / 4 sec</td>
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<td>Measurement: FEV₁</td>
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</tr>
<tr>
<td>4</td>
<td>4 mg/ml</td>
<td>0.6 l / 7 sec</td>
<td>22</td>
<td>41.1</td>
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<td></td>
<td>Measurement: FEV₁</td>
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</tr>
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<td>4 mg/ml</td>
<td>1.2 l / 14 sec</td>
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<tr>
<td>6</td>
<td>4 mg/ml</td>
<td>2.4 l / 29 sec</td>
<td>89</td>
<td>174.1</td>
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<tr>
<td></td>
<td>Measurement: FEV₁</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>4 mg/ml</td>
<td>4.8 l / 58 sec</td>
<td>178</td>
<td>352.1</td>
</tr>
<tr>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>4 mg/ml</td>
<td>9.7 l / 1 min 56 sec</td>
<td>356</td>
<td>708.1</td>
</tr>
<tr>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>16 mg/ml</td>
<td>4.8 l / 58 sec</td>
<td>712</td>
<td>1420.1</td>
</tr>
<tr>
<td></td>
<td>Measurement: FEV₁</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>16 mg/ml</td>
<td>9.6 l / 1 min 56 sec</td>
<td>1424</td>
<td>2844.1</td>
</tr>
</tbody>
</table>

Table 4: Provocation protocol for methacholine according to ATS guidelines using only three dilution levels of methacholine

The ATS recommendations specify the use of solutions with 10 different methacholine concentration solutions. Since the PARI PROVOCATION TEST II uses the reservoir method, the protocol can be adapted so that a provocation test can be conducted using just three methacholine concentration solutions.

*) Methacholine or carbachol mass available at the mouthpiece (µg/mg). In order to calculate the quantity of aerosol deposited intrabronchially, the specified nebulised single or cumulative aerosol dose must be multiplied by 0.8.
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E-Mail: info@pari.de

Information as of: September 2010
REFERENCES


Guarantee certificate for PARI PROVOCATION TEST II

We guarantee this device for 2 years. The warranty period shall commence on the date of purchase. Within the warranty period we or an authorised customer service center will repair, free of charge, any defects in the appliance resulting from faults in material or workmanship. Damage arising from improper use of the appliance is not covered by this warranty. The warranty shall become void if repairs are carried out on the device by unauthorised persons. The owner shall not be entitled to cancel the sale or demand a partial or full refund of the purchase price. No liability shall be accepted for direct or consequential damages. Wearing parts are excluded from the warranty. In the event of a claim under this warranty, please bring the complete device to your dealer or send it to us in sturdy packaging and with postage paid, together with this warranty certificate.

PARI GmbH
Technical Service
Holzhofstr. 10 b
82362 Weilheim, Germany

Proof of purchase: The appliance with the above appliance number was sold by us in its original packaging.

Purchase date Stamp and signature of the dealer