



RHINO-SYS

4-component complete system for
functional diagnostics of nasal breathing

otopront®



RHINO-SYS



4-COMPONENT COMPLETE SYSTEM FOR FUNCTIONAL DIAGNOSTICS OF NASAL BREATHING

The RHINO-SYS measuring system is a complete system for the diagnosis of nasal obstruction.

It consists of rhinomanometry, rhinoresistometry, acoustic rhinometry, long-time rhinometry and the nasal provocation test. The combination of rhinoresistometry and acoustic rhinometry not only objectifies the extent of nasal obstruction, it also differentiates its causes (constriction due to swelling or skeletal deformation, pathological inspiratory nostril collapse and pathological turbulence). For special questions, long-term rhinometry over 24 hours allows an

insight into the nasal breathing under everyday conditions of a patient. The nasal provocation test provides information about changes in the nasal respiratory flow due to swelling of the mucous membrane as an allergic reaction after administration of an allergen. Due to the improved diagnostic significance compared to classical rhinomanometry, RHINO-SYS enables well-founded surgical planning for nasal breathing disorders as well as objective postoperative quality control, taking into account the patient's medical history and clinical findings.

RHINO-SYS

- + Rhinomanometry and rhinoresistometry
- + Acoustic rhinometry
- + Long-term rhinoflowmetry
- + Nasal provocation test

Hardware

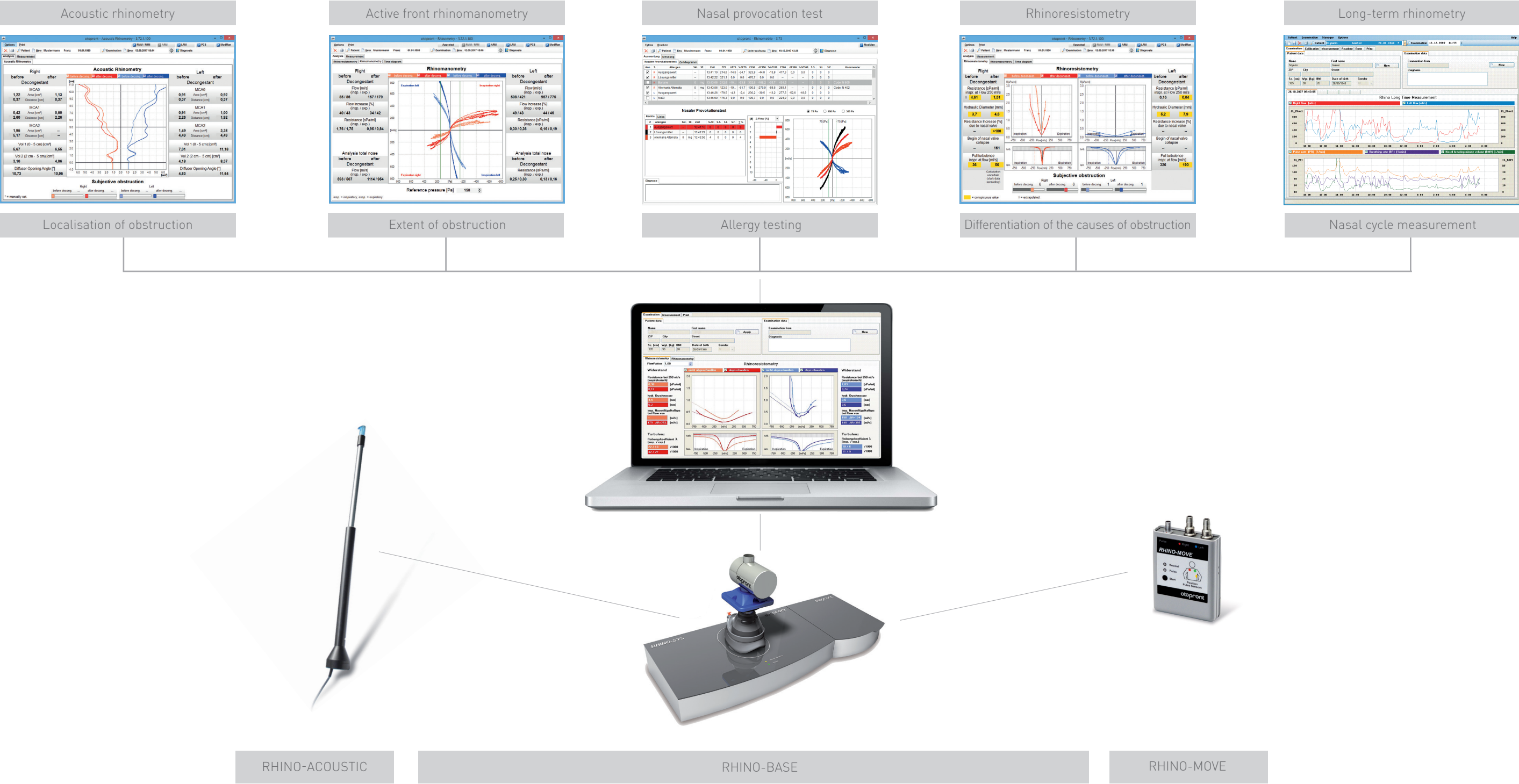
The RHINO-SYS measuring system consists of the RHINO-BASE central station including a laptop for performing rhinomanometry and rhinoresistometry, the RHINO-ACOUSTIC for displaying the cross-

sectional profile of the nasal cavities and the RHINO-MOVE mobile device for 24-hour recording of nasal breathing.

Software

The software guides you comfortably through the examination and offers a clear presentation of the measurement results for a reliable diagnosis. The

measurement results and the recorded patient data are automatically stored in the internal database and can be retrieved quickly if required.



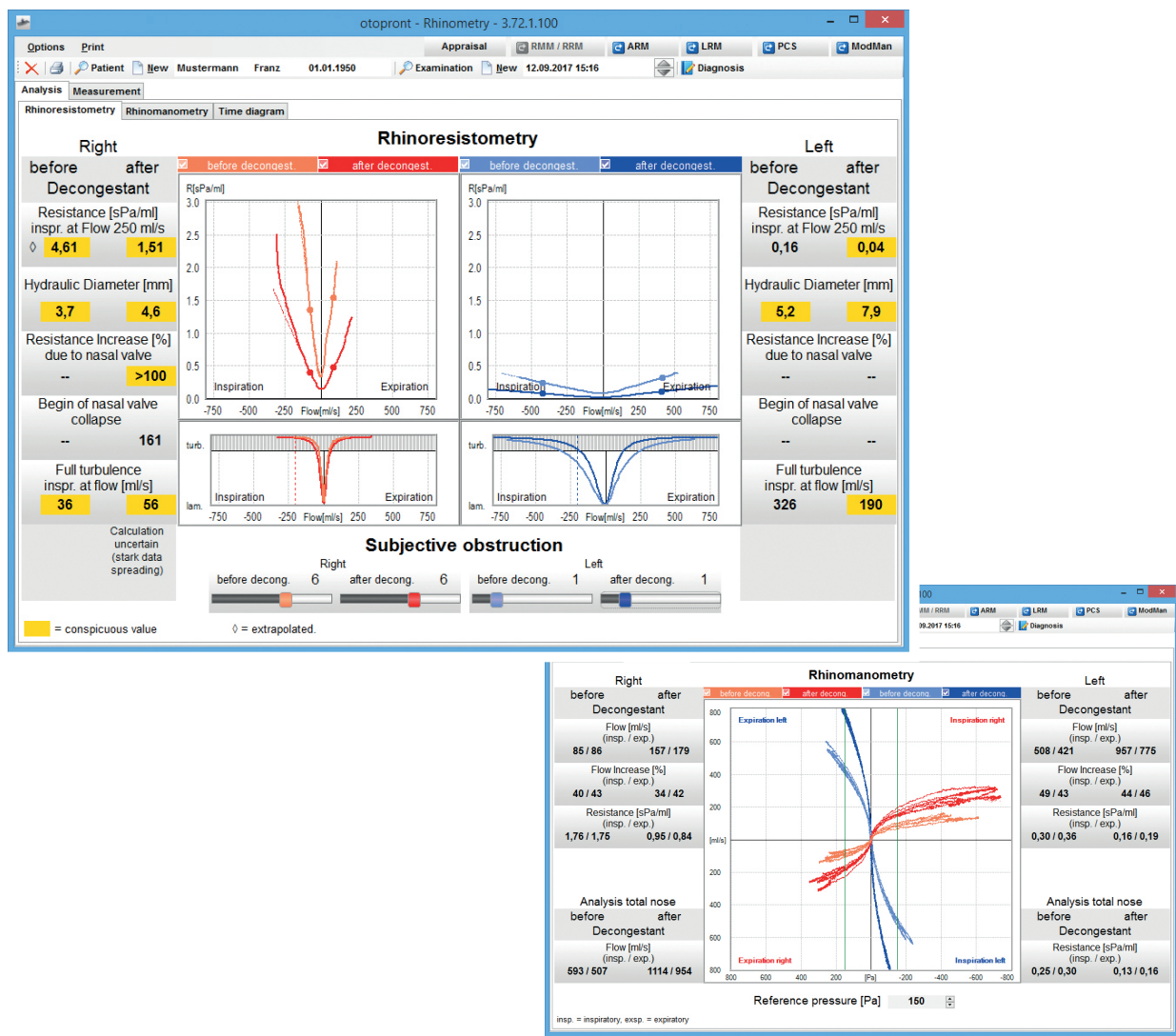
RHINOMANOMETRY AND
RHINOESISTOMETRY

The central element of the RHINO-SYS diagnostic system is rhinoresistometry, a further development of active anterior rhinomanometry. The measurement of the nasal flow rate takes place via a breathing mask with a special, high-sensitive measurement nozzle.

An exchangeable filter ensures maximum hygiene. The choanal pressure is measured via an adhesive nose adapter.

Another advantage is that the micropressure sensors are directly attached to the breathing mask. This avoids the measurement inaccuracies inherent in other methods. With the highly complex evaluation software developed and improved over the years by Prof. G. Mlynski (University of Greifswald, Germany),

the nasal flow resistance can be objectified in a reproducible manner and the possible causes of nasal obstruction (constriction, inspiratory nasal collapse, pathological turbulence) can be differentiated and recorded diagnostically.



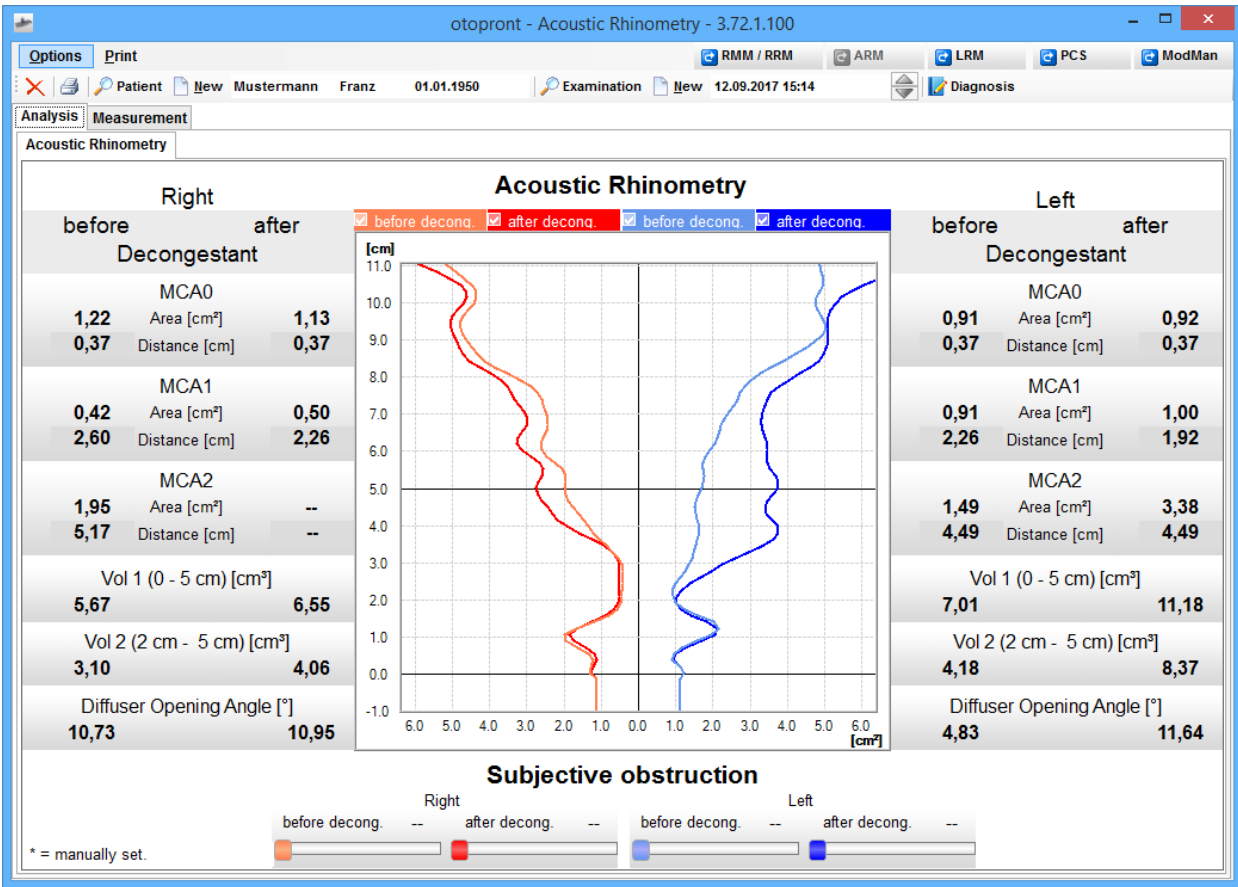
RHINO-SYS measuring nozzle with exchangeable filter and face mask for rhinomanometry and rhinoresistometry

ACOUSTIC RHINOMANOMETRY

The RHINO-ACOUSTIC system is the ideal instrument for visualising the cross-sectional profile of the nasal cavity. Acoustic rhinometry is based on the computerassisted analysis of reflections generated by a nasally applied sound signal and specifically altered by the geometry of the nasal cavity.

This results in the two-dimensional representation of the flow channel of the nose. Acoustic rhinometry is easy to use, reliable, non-invasive and accepted by the patient.

The examination of children is feasible without any problems. Acoustic rhinometry makes it possible to objectify constrictions as the cause of increased nasal resistance as well as deformations of the nasal diffuser as the cause of pathological turbulence.



Software Acoustic Rhinometry

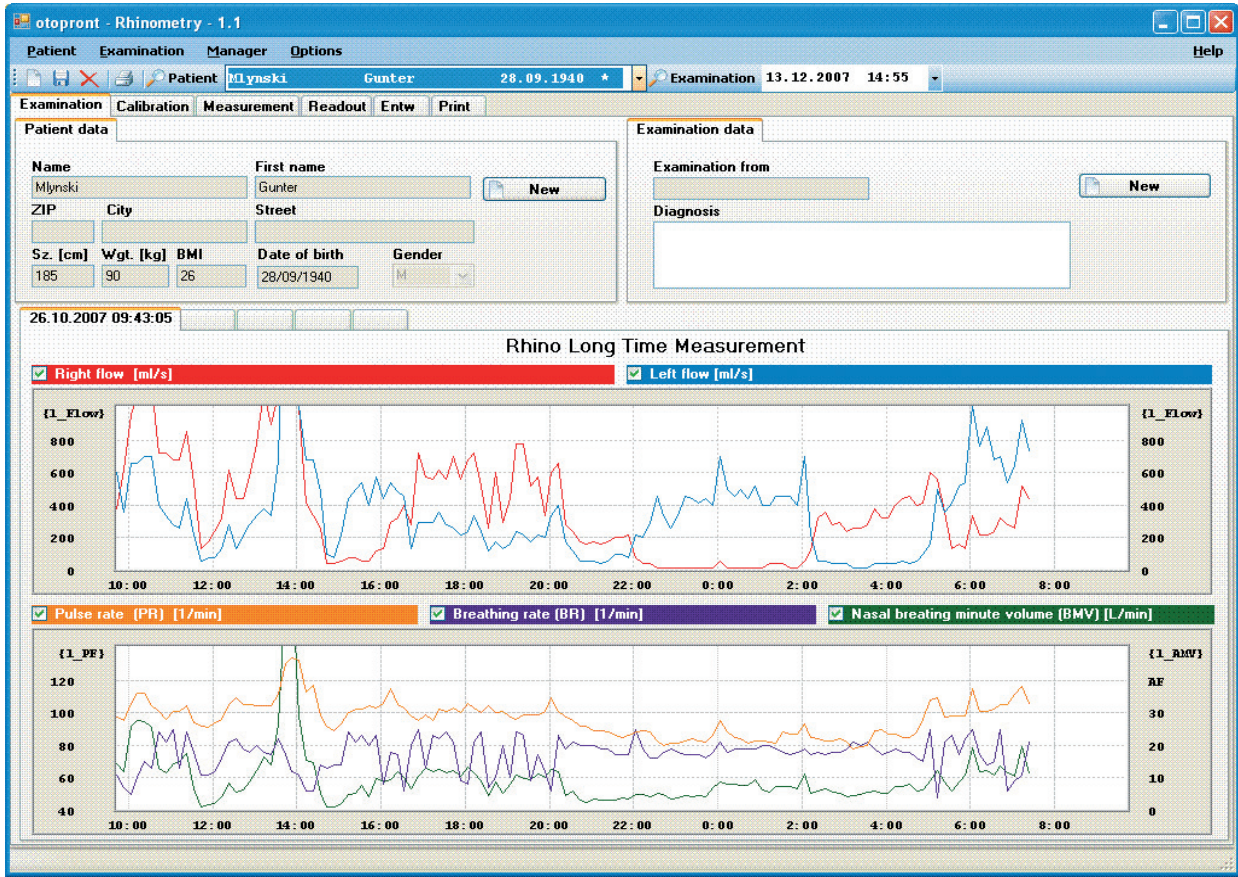
RHINO-ACOUSTIC measuring tube with distal nose adapter for acoustic rhinometry

LONG-TERM RHINOFLOWMETRY

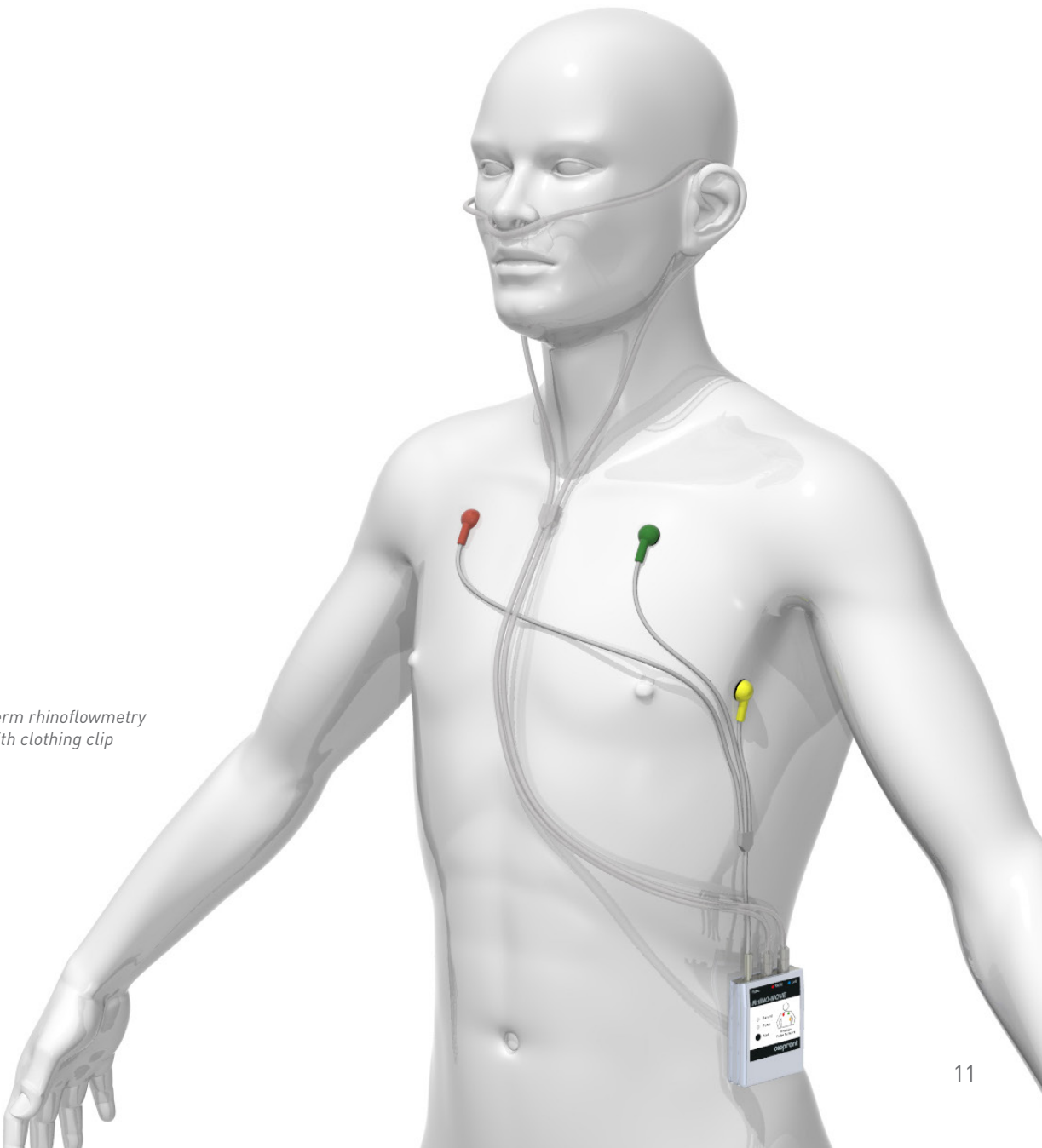
Rhinomanometry, rhinoresitometry and rhino-acoustics allow an objectification of the momentary situation within the nasal cross-sections at the time of measurement (swollen, not swollen). For many patients, however, it is also important to gain an insight into possible functional disturbances during the course of the day or night.

Long-term rhinoflowmetry was developed for this purpose. RHINO-MOVE is a portable measuring system that enables 24-hour recording of breathing, separately for both sides of the nose. The synchronous registration of the heart rate allows an assessment of the physical strain.

After the measurement, the stored data is transferred to a laptop and analysed with the RHINO-SYS software. This makes it possible for the first time to record the nasal cycles and its disturbances under the physiological everyday conditions of the patient.



Software long-term rhinoflowmetry



RHINO-MOVE long-term rhinoflowmetry measuring system with clothing clip

ALLERGY SOFTWARE

The optional software package RHINO-ALLERGY for nasal provocation tests (NPT) is available for the clarification of allergens and allergic reactions. The evaluation of the rhinomanometry measurement series provides information about the change in the nasal respiratory flow due to mucosal swelling as an allergic reaction after administration of an allergen. In addition, parameters such as secretion, irritation and distant symptoms are included in the evaluation with the help of a point system. The software offers a large selection of allergens, which in turn are clearly arranged in allergen groups, for an optimal examination procedure and for recording.

Allergens as well as allergen groups can be easily adapted to the individual circumstances by the respective user. The intuitive software supports the recording of all relevant parameters for the nasal provocation test. The timer function helps to keep the necessary time intervals. Any clinical symptoms (e.g. secretion, irritation) are automatically recorded. During the rhinomanometric measurement, the RHINO-SYS indicates as soon as the respiration is in the sufficient range and the measurement can be started. After the required number of breathing cycles has been reached, the measurement stops automatically. The evaluation can then be started.



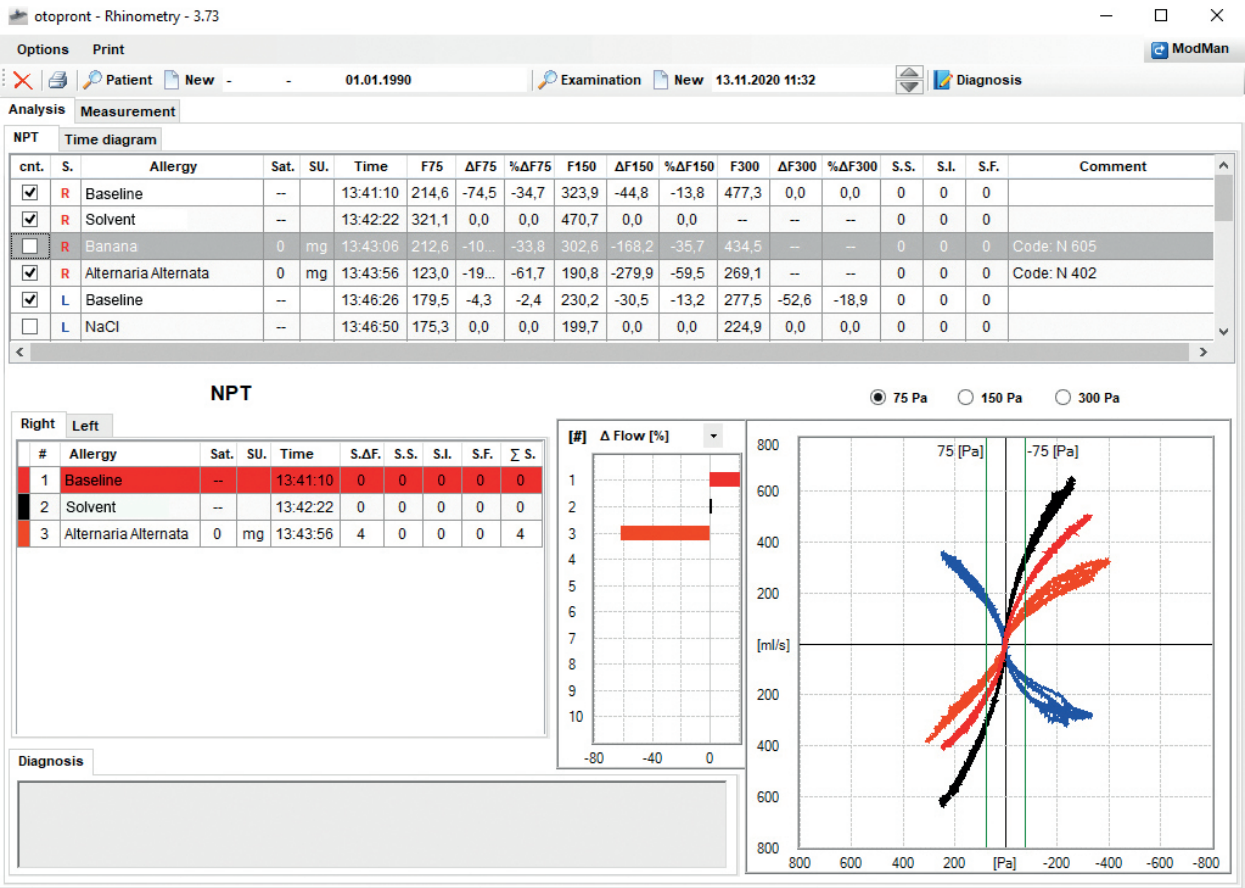
Nasal provocation test (NPT)
The rhinomanometer is used to objectify the swelling of the mucous membrane after local allergen application

Nasal provocation test - 3 measurement types

- + First, the initial measurement (type 1) is carried out without application
- + The reference measurement (type 2) is carried out with the application of liquid (water or NaCl)
- + After repeated measurement, an allergen (type 3) is applied for the final measurement

Values after renewed measurement provide information about a possible change in the nasal respiratory flow.

For type 2 and type 3 measurements, clinical symptoms such as sneezing are also assessed by scoring in addition to rhinomanometry. This is naturally omitted in the initial measurement. If the flow reduction at 150 Pa is > 40 % or the score > 3, the reaction is positive and the test is finished. If this is not the case, a new measurement is carried out after a 10-minute waiting period, possibly with an increased dosage of the allergen.



NPT with application of allergen "Alternaria alternata"

PREPARATION, ASEPSIS AND HYGIENIC PREVENTIVE MEASURES

The RHINO-SYS offers all the prerequisites for diagnostics at a high hygienic level. This effectively prevents the risk of cross-contamination during regular device operation. To ensure patient and user safety with regard to viruses in general, but also with regard to the Covid-19 situation and the resulting recommendations of the DGHNO-KHC and the BVHNO for ENT selective/non-emergency treatment to Corona, the RHINO-SYS rhinometry system consists on the one hand of a series of disposable items that are to be replaced after each measurement run and on the other hand of reusable components that can be prepared as follows:

- + In accordance with the recommended course of action, all parts that come into direct contact with the patient are designed as disposable items (nasal pressure tube, connection sleeve for nasal pressure tube, nasal adapter, nasal cannula, bacterial-viral filter)

- + The face masks are available both as disposable and reusable items. The multi-use face mask can be reprocessed with all standard manual and mechanical hospital procedures (incl. cleaning and disinfection device 95° C and autoclave 134° C)



Reusable face-mask



Disposable face-mask

- + The bacteria-virus filter has a high retention rate (>99.999%) for viruses (incl. SARS-CoV-2) and bacteria
- + The surface of the unit can be reprocessed with all VAH-listed wipe disinfectants. The nozzle unit and the acoustic tube can also be sterilised using the gas sterilisation method and STERIS V-Pro



RHINO-SYS measuring nozzle with exchangeable filter and disposable face mask for hygienic practice

ACCESSORIES

Accessories box

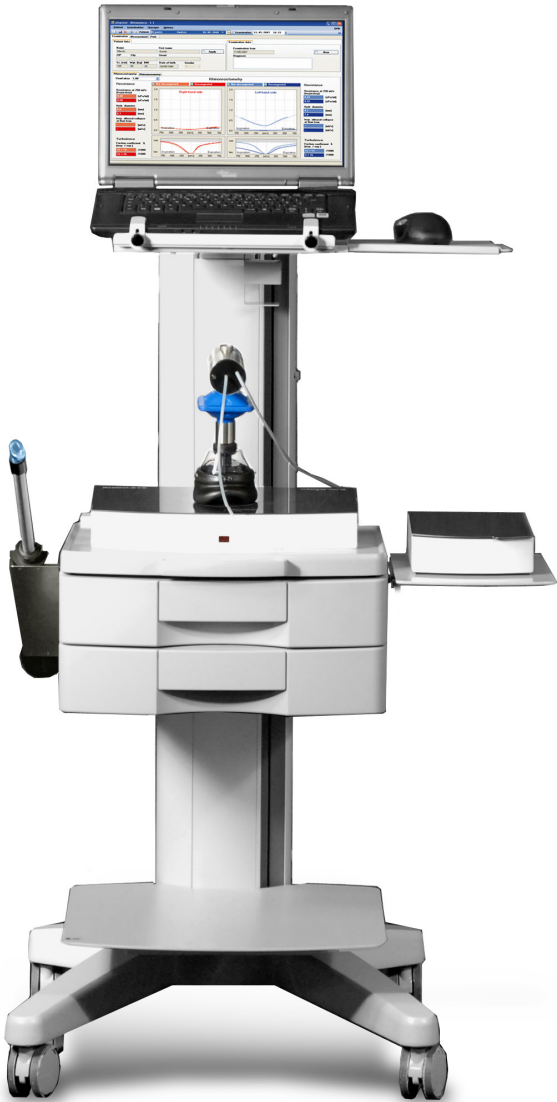
The functional RHINO-BASE accessory box contains all the necessary materials for performing rhinomanometry or rhinoresistometry and acoustic rhinometry in an easily accessible manner. The accessory box is part of the RHINO-BASE central station.



Accessories box

RHINO-CART

The optional RHINO-CART is the ideal complement to the RHINO-SYS. It contains a laptop holder with mouse pad pull-out, a mouse holder, shelves for the RHINO-BASE central station with accessories box, a large drawer for filters, face masks and tubes, a holder for the RHINO-ACOUSTIC measuring system, a shelf for printers and an integrated cable duct including power supply.



RHINO-CART

TECHNICAL DATA

Mains voltage	100-240 V~, 50/60 Hz
Power consumption	15 VA
Unit dimensions	70 x 370 x 200 mm (H x W x D)
Weight	4 kg
Measuring method	Rhinomanometry, rhinoresistometry, nasal volume flow and transnasal pressure, pneumotachograph, Fleisch nozzle
Measuring nozzle	heated, temperature compensated
Sensors	automatic flow and pressure detection
Long-term rhinoflowmetry	nasal respiratory minute volume, volume flow per side, respiratory rate, heart rate
Acoustic rhinometry	Reflex measurement, filtered /digitally evaluated, broadband pulse
Acoustic tube	Signal handle ergonomically shaped, acoustically decoupled

Classification

Electrical protection class	I
IP classification	IPX0
Medical device class	Ila
Applied parts	Type BF
Interfaces	galvanically decoupled acc. EN 60601-1
Environmental conditions	Ambient temperature +10°C to +40°C Relative humidity 20 % bis 80 % Air pressure 700 hPa to 1060 hPa
CE marking	in accordance with Directive 93/42/EEC