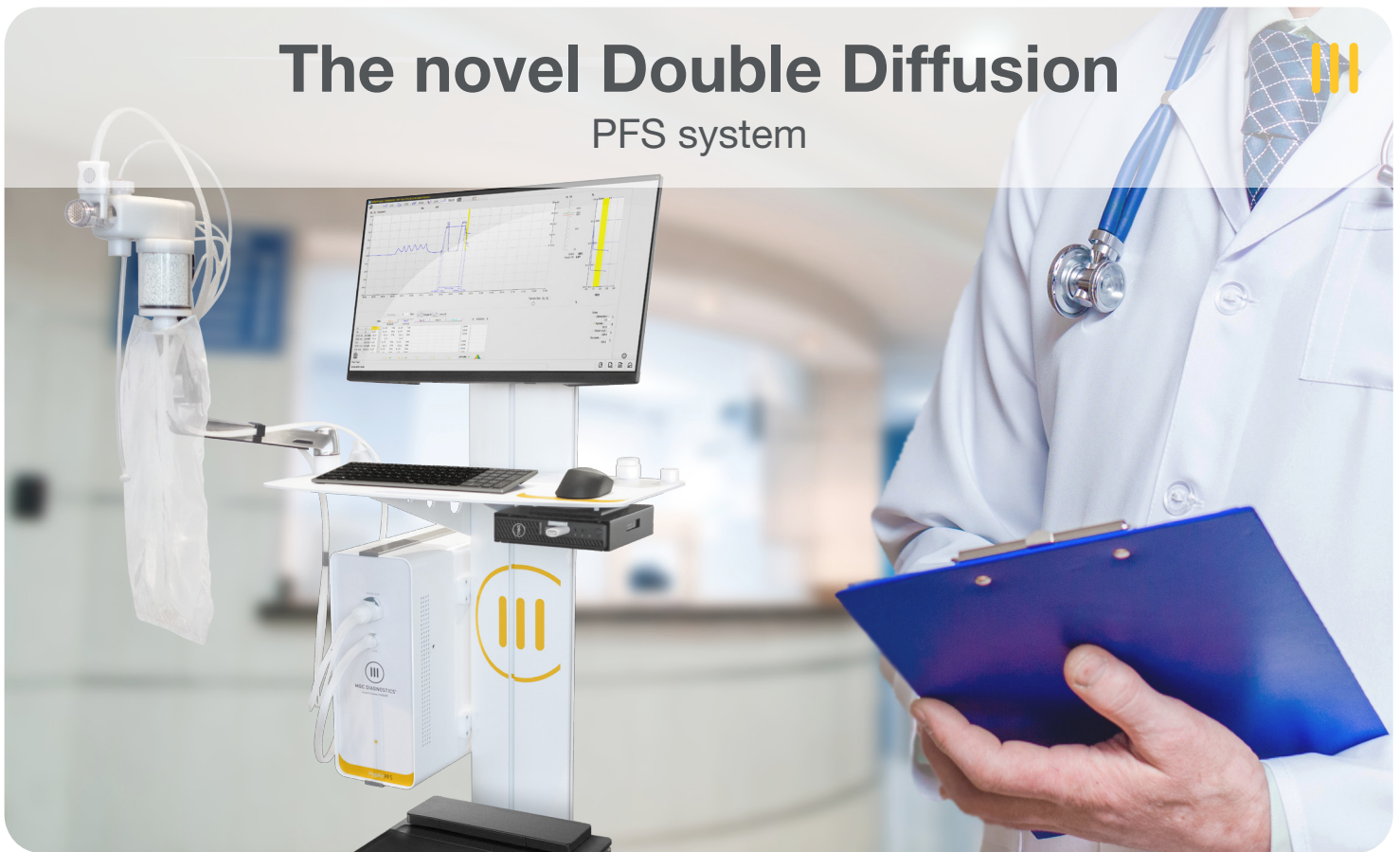


The novel Double Diffusion

PFS system



FEATURING THE CLINICALLY VALIDATED DLNO TEST... AND MORE

MGC Diagnostics is pleased to feature the Double Diffusion PFS special diagnostic system configuration.

An **all-inclusive**, ready to go station, with PC, printer, and trolley with wheels for easy mobility in the hospital, department or at the bedside. Includes the complete analyzer module, arm assembly with valves and bags for an all-automated easy and practical measurement.

Features the innovative and validated **DLNO** or **Pulmonary diffusing capacity for nitric oxide**, which is widely used and now even more utilized for Post-COVID patients. All this in one system, along with the traditional DLCO measurement and with a simple **6 second breath-hold time**.

A unique system: compact and complete configuration that allows fast testing of traditional spirometry, well proven He dilution FRC and the special DOUBLE DIFFUSION test.

With this simple diagnostic maneuver, among other important parameters, the user will get the **DLCO**, **DLNO**, **DLNO/DLCO ratio**, **Dm** (Membrane diffusion) and **Vc** (Pulmonary Capillary Volume) that, along with the measured **VA** (Alveolar Volume) will give the FULL picture of the patient pulmonary status. This is especially important during testing in Covid Pandemic situations and for post-Covid patient evaluations as now recommended by many scientists.



FEATURING PREVENT® FLOW SENSOR TECHNOLOGY

The small, durable and lightweight preVent® flow sensor is used on all systems.

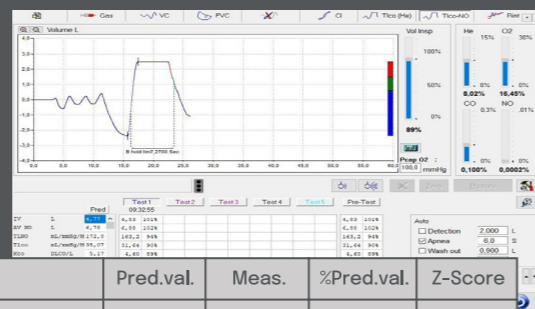
- Saves time between patients with no warm-up or recalibration needed between changes and provides maximum infection control
- No moving parts or electronics



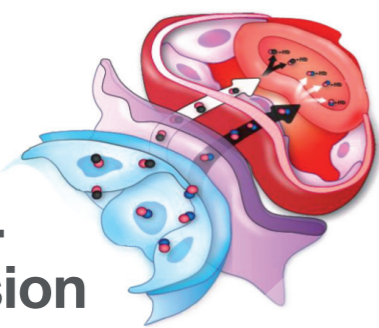
EXPAIR II SOFTWARE

The driving force of the system is **Expair II**, a powerfully intuitive, user-friendly and complete software package. Available for all devices.

- Advanced, powerful database function and electronic storage, full networking, HL7 and MySQL options
- Trend Reporting of any parameter
- New interpretation algorithm based on LLN, ULN, Z-Score and percentile
- Comments and Offline data input such as arterial blood gases
- Online data transfer
- Report designer
- Predicted value editor
- Choice of languages and units of measurement
- Bronchial challenge testing software
- Measurement sequencing configuration
- Full calculation function: display of calculation points with manual correction capability
- Quality control automated software, diagnostic functions and full program control



The SPECIAL Double diffusion DLNO configuration: robust science behind it.



DLCO is a well-established technique from the 1920s, used routinely all over the world.

We offer 6 different methods of DLCO in the Hypair system; however, since 1987, we have also developed and helped international research centers to develop and fine tune the simultaneous **DOUBLE DIFFUSION** test of DLCO single-breath with the DLNO measurement and implemented it into this system. The system was initially used for research and is now a well-recognized, needed clinical test and technique used in dozens of articles, publications and presentations.

DLNO has become a validated, clinical reproducible test (even more than traditional DLCO) and reveals the underlying reasons for DLCO reduction. Since 2017, Pulmonary diffusing capacity for nitric oxide with its' reference values is standardized by a panel of experts for use around the world, published on the ERJ and now well documented in its clinical advantages.

The DLNO measurement, will provide important information on **the capillary and alveolar membrane, interstitial tissue, capillary blood volume status.**

The **preVent® flow sensor (PFS)** is based on an **exclusive design** which is small, durable and lightweight. The **preVent® flow sensor** has been validated to meet or exceed the ATS/ERS specifications. It is used worldwide in thousands of labs on MGCD devices and provides accurate testing results with safety and infection control in mind.

- No warm-up or recalibration needed between patients, can be verified with 3L cal syringe at any time to comply to standards.
- Practical Snap-in setup, no moving parts or electronics.

We give you three options for infection control, you make the choice that is right for you!

- 1. Change:** simply change the filter and keep the same preVent® flow sensor.
- 2. Re-Use:** change the flow sensor between patients and replace with disinfected components.
- 3. Dispose:** dispose of the flow sensor after each patient.

DLNO, DLCO, DLNO/DLCO, VC, DM HAVE SHOWN TO BE CLINICALLY USEFUL IN:

- Lung surface damage assessment and therapy monitoring over time
- Pulmonary capillary impairment due to disease, i.e. Covid-19
- COPD, Lung fibrosis, emphysema, parenchymal diseases, interstitial pneumonia, prescription of Oxygen therapy
- Pre-post thoracic surgery evaluation
- Diffused Interstitial Lung Disease (ILD)
- Pulmonary Arterial Hypertension
- Pulmonary vascular diseases
- Cystic fibrosis

But also:

- Chronic heart failure, severity assessment and therapy selection
- Interstitial edema
- Assessment of severe LVAD patients (Left Ventricular Assist Device)
- An easier test in physiological research studies on morphological/physiological changes under different conditions
- Exercise (physical effort)
- High altitude



OPTIONS: recommended devices to complete the Double Diffusion measurement.

For true, pulmonary volumes, to confirm hyperinflation conditions, TLC, RV, the gold standard of **Body Plethysmography**, Hypair combined with **Body Box PFS Plethysmograph**.



Complete the diagnostic picture with the **Resmon Pro Full V3** for accurate pulmonary resistance measurements.

The **Resmon Pro Full V3** is a revolutionary and validated **Forced Oscillation Technique (Oscillometry)** stand-alone device. Get the full picture of asthma, COPD and Post-Covid patients. Testing includes fast (10 breath tidal breathing) assessment of sensitive small airways and lung recruitment.



Resmon Pro Full V3 is a product from Restech srl



Technical and Physical Specifications:

Power requirement: 230 VAC 50 Hz or 115 VAC 60 Hz

Power consumption: \pm 100 VA (module)

Warmup time: 20 min.

Meets all electrical safety requirements: IEC60601-1

Classification: IIa

CE MARK: CE 1434

MDD: 93/42/EC and harmonized standards

Computer interfacing: Windows 10™ Pro

Serial interface RS232 / USB 2.0 / 3.0

Ambient conditions for use:

Temperature: 10 - 35°C

Relative humidity: 25 to 85 % (non condensed)

Barometric pressure: No restriction

Technical specifications: 1119H – Y - EN

Physical Dimensions Module Trolley:

(H x W x D) cm 13,7 x 40 x 34 Standing - 140 x 73 x 55

Seated - 120 x 73 x 55

Weight with trolley \pm 35 Kg

Gas requirements: one mixture and one Nitric Oxide gas tanks, please check with your local distributor or sales rep for details.

OTHER OPTIONS:

Double Diffusion PFS system, is the most modular in the world. By adding modules you can perform many more pulmonary diagnostic measurements and integrate them in its' data base for combined reporting, with more tests such as:

Choice of extra alveolar capillary diffusion methods:

- DLCO Single Breath with Helium tracer gas (He) and sample bag
 - Rapid gas analysis diffusion RTD test, Single Breath using Helium tracer gas (He) or Methane trace gas (CH₄)
 - Intra-Breath no breath hold, diffusion with Cardiac Output (Qc).
 - Steady State real time diffusion TLCO ss.
-
- FRC by Nitrogen Washout method
 - Automated, software controlled dosimeter module for bronchial challenge testing
 - Cardiopulmonary Exercise Testing module (CPET)
 - Respiratory Mechanics such as MIP/MEP, SNIP, lung compliance, P.01 (respiratory drive), Negative Expiratory Pressure (NEP)
 - Exhaled Nitric Oxide (FeNO) as a stationary system or portable for asthma diagnostics.

References and suggested reading:

- B. Cooper et al – Lung Function Testing in the Covid-19 endemic Lancet (2020)
- PG Agostoni et al - Variability in pulmonary diffusing capacity in heart failure - Resp. Phys & Neurob. (2020)
- Hughes JMB et al - Standardization and application of the single-breath determination of nitric oxide uptake in the lung - Eur Respir J (2017)
- Thamrin C et al - Double diffusion method for evaluating DLCO and DLNO in health and COPD – Respiration (2019), Supplement: TSANZSRS 2019, AO 005
- JB Martinot et al - Nitrogen monoxide and carbon monoxide transfer interpretation: state of the art - Clin Physiol Funct Imaging (2015)
- JMB Hughes et al – The TL,NO/TL,CO ratio in pulmonary function test interpretation - Eur Resp J (2013)
- JMM van den Bosch - Diffusing Capacity for Nitric Oxide and Carbon Monoxide in Patients With Diffuse Parenchymal Lung Disease and Pulmonary Arterial Hypertension - Chest (2006)
- M. Guazzi et al - Alveolar–capillary membrane gas conductance: a novel prognostic indicator in chronic heart failure - European Heart Journal (2002)