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## **PRODUCT CHANGE NOTIFICATION RESMON PRO FULL**

**HARDWARE VERSION V3**  
**SOFTWARE VERSION 21.1.1**  
*Release date: 09 August, 2021*

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## 1. Purpose

The purpose of this document is to enlist the product changes (hardware and/or software) that have been approved and released by Restech Srl for the product Resmon PRO FULL (ref. RT1100).

This document is addressed to marketing, technical and service departments of the distributors of the Resmon PRO FULL, as a support to their communication to final customers on the changes introduced to the product.


## 2. Summary of the design changes

TYPE OF DESIGN CHANGE	Software (release 21.1.1)
RELEASE DATE	09-Aug-2021
VARIANTS AFFECTED	Resmon PRO FULL v3 for ALL markets
SUMMARY OF CHANGES	This software version supports multi-language (EN, FR, ES), includes new reference equations for both FOT and SVC parameters, computes specific conductance and static lung volumes given the patient's TLC value, allows to draw a trend of a patient's results over time, allows to plot the volume instead of the flow and includes bug fixes and UX improvements.

## 3. Detailed description of changes

### New / improved features

Multilanguage support for the user interface (English, French, Spanish)
It is now possible to display charts of FOT parameters taken on different occasions (on screen and PDF)
After entering the subject's TLC, specific conductance (sGr <sub>s</sub> ) and standard static lung volumes (FRC, ERV, RV, TLC/RV) can be now computed from a slow spirometry maneuver
The upper real-time chart displayed during a measurement can be either volume or flow
New reference equations are now available for selection: GLI 2020 for SVC and equations for Indian population for FOT (De et al. 2019); the selection of reference equations for different age groups is made now more flexible
The R5-R19 parameter can now be displayed for inspiratory, expiratory or total resistance (on screen and PDF)
Improved checks on breathing activities during filter measurements and sensors zeroing
In compared SVC clinical reports, the y-scale of the two graphs is now the same
Slow spirometry measurements can be done now also with the PSRN stimulus
More information is now given to the user on the sessions to be compared: number of FOT

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measurements and number of slow spirometry maneuvers within a session
When saving a note on the clinical report note the user experience has been improved
External USB keyboards are now supported with multiple international layouts
Clinical reports now include a footnote to inform the user whenever the demographic data of a patient does not match the population of the reference equations in use
Technical backups have now a limit on their maximum size
The user experience during slow spirometry verification has been improved
More robust controls during software update or database restore to prevent fatal errors
Changing the system date and time is now separated from selecting a preference for date and time format

### Bug fixes


Patients could not be created when some special characters (. and ..) were used in the Patient ID
In some cases, the mean of the IC reported in the clinical reports could be incorrect
The value of predicted VC for non-caucasian patients was slightly incorrect
The value of predicted VC for decimal ages were slightly incorrect
The R29%pred and X19%pred values of the first session of a comparative clinical report with PSRN was not correct
Problematic characters could be entered in clinical report notes
Ventilation value did not change with the selection of different measurements in the results screen
Comparing a SVC session with a non-SVC session did not draw the SVC chart in PDF reports
Footnote G did not appear for Fres in PSRN reports
Graphical glitches in reactance charts
The recalculation of the breathing pattern parameters after the manual selection of the breaths was slightly incorrect due to wrong rounding

## 4. Evaluation of the impact of fixed bugs

The bugs fixed in this software version mainly affected software navigation or were related to rare cases where some values of a session could be reported incorrectly in the clinical report or on the device screen. The evaluation of their overall impact was estimated to be low.

## 5. What is provided as part of this notification

- **Update file:** resmonpro-fw\_21.1.1-update.tar.bz2
- **User Manual:** rev23
- **Service Manual for Resmon PRO FULL v3:** rev2
- **Manufacturer Disclosure Statement for Medical Device Security - MDS2** for the updated product

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## 6. Instructions to update the Resmon PRO FULL “v3”

- Copy the update file *resmonpro-fw\_21.1.1-update.tar.bz2* on an USB drive.
- Turn on the device
- Insert the USB drive in any of the 2 USB ports on the back of the Resmon PRO
- From the main menu select “ADMIN” then “SOFTWARE UPDATE”, let the system find the USB key and the available software updates
- Select *resmonpro-fw-21.1.1-update* and follow instructions
- Press Reboot and let the update complete