



Global LUNGS INITIATIVE
ERS Task Force (TF-2009-03) to establish improved
Lung Function Reference Values

Chairs: J Stocks, X. Baur, G. Hall, B. Culver
www.lungfunction.org



To the reader:

July 20, 2011

We regularly receive questions whether manufacturers have implemented the Stanojevic 2009 prediction equations for spirometry into their software. Since implementation of the ERS Global Lungs (ethnic specific) reference equations will use an identical format, any company that has already implemented the Stanojevic equations will be in an excellent position to rapidly upgrade once the ERS equations are published, which will hopefully be later this year. We have therefore conducted a limited survey with the following questions:

Have you implemented the Stanojevic 2009 equations?

a. If so, when was this done?

b. If not, is implementation planned, and if so when will new software be available?

Will implementation be limited to certain devices or software releases? (*e.g.* only available in those developed most recently?)

a. If so please give details

Will updates be available for free?

a. If not, how much would you charge for the update?

Below is a brief summary of the information received so far, and some contact details. The information is provided 'as is'.

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We are collaborating closely with Medisoft as we are keen to implement All-Age Equations ASAP. Implementation of the Stanojevic 2009 equations could begin in Medisoft software as soon as May 2011. We have no immediate plans to implement these equations with our ECO MEDICS or Bedfont products as yet.

It is not clear whether updates will be available free of charge in Australasia. Of course, this decision will be aligned with what our suppliers choose to charge us. What I can tell you is the main society with which we associate, the ANZSRS, would expect not to pay for such updates. These members feel such updates are part of the basic fabric of PFT software and should be included as standard. However, I also respect the need for manufacturers to be reimbursed for their intellectual property (*i.e.* software). Who is right? Perception is reality, ...but 'The Customer is always right'!

CareFusion

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Implementation

i. For JLAB V 5.x

- We are using not the exact implementation, but a mathematical approximation of the tables used by Stanojevic 2009 into formulas. In most cases, these values (rounded to 2 decimals) are identical to the Stanojevic calculations; the mean difference found was (absolute) < 0.01 and never > 0.03 L (relative never > 0.8%)

- This has the advantage, that these formulas can be implemented into JLAB version 5x .

- If needed, also z-score will be available with the following approximation: $z\text{-score} = 1.645 * (\text{observed} - \text{predicted}) / (\text{predicted} - \text{LLN})$

- JLAB V 4.5, V 4.6 and V 5.x handles AGE as integer. which may introduce some additional errors, this will be rectified in Sentry Suite

ii. For Sentry Suite the exact Stanojevic 2009 equations will be available from versions V 2.5 or higher.

CareFusion (Micromedical)

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Implementation is planned for April 2012.

Available on the MK8 MicroLab and MicroLoop and Spirometry PC software (SPCS)

i. MicroLab and MicroLoop V1.xx

ii. SPCS V1.xx.

Updates will be available free of charge for the MicroLab, MicroLoop and SPCS (Spirometry PC software) from the website using the Upgrade utility and by checking for updates in the SPCS software.

COSMED ltd

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We have not implemented the Stanojevic 2009 equations yet, but we are planning to do this with the next release of our new SW which will occur within 2011.

New predicted values will be implemented on all devices.

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We have implemented Stanojevic 2009 during March and are planning to make the new software available for Spirare users in April 2011.

The Spirare computer program is being developed and upgraded continuously. All Spirare users receive upgrades at least one time per year, or more often upon request.

Our customers pay a yearly license fee that includes support and software upgrades. Stanojevic 2009 will be available for all of our customers without any added costs.

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We consider implementing for our Exhalyzer D by the end of the year.

We could update all our Exhalyzer D (VMax26) units delivered since 11.10.1999.

We never charge for upgrading software except if a new application is added (Implementing "predicted values" will be an update - free of charge).

ECO PHYSICS, INC.

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Ganshorn is developing a complete new Software platform. New formulas will be implemented before ERS 2011.

No limits, general implementation in all equipment.
No additional charges apply for this upgrade

Jones Medical Instrument Company

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Not implemented, but possibly at a future date.
Unknown at this time whether implementation will be limited to certain devices.
Updates will probably be available for free.

Medical Graphics Corporation

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The Stanojevic Equations are already in our software. We included them nearly a year ago. There is no charge to customers

Medikro Oy

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Implementation not planned yet. We will wait for the official Global Lungs publication.

Implementation planned for presently sold and coming hardware versions together with coming software version. Implementation of reference values require update of the software.

Updates will not be available for free.

Medisoft

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Medisoft have included the new predicted format to the Expair software suite, this is rolling out on new products , however due to the work necessary under CE manufacturing to document and perform risk analysis to existing users, this is not presented as an upgrade yet for the existing customers. It is also necessary to ensure the existing computing hardware is able to run the later software to all users and this will be a task for all distribution channels to check and advise customers as is necessary.. Implementation in various devices to be confirmed at later date.

Costs: it is likely that whilst the provision of the new software will be covered by our existing service agreements on "free software upgrades" to contract customer with a token charge to other users where support is necessary to install the upgrade.

Midmark Corporation

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MIR srl

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At the moment the Stanojevic 2009 equations are not in our implementation planning. But we are interested in comparing the Stanojevic 2009 equations to the principal Authors for further implementations.

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Very recently we have worked with Daniel Weiner (Children's Hospital Pittsburgh) on the implementation, making it possible to utilize the tables and provide a practical way for customers to update them when they are augmented.

In our CompAS software suite, all customers and devices will be able to utilize the equations.

In the USA all of our customers pay a modest annual license fee for CompAS which provides all updates, remote support via TeamViewer, telephone support and updated HTML Help.

ndd Medical Technologies

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We have implemented the Stanojevic 2009 equations as of January 2011.

Stanojevic 2009 predicted values are available in the following devices:

1. EasyOne: All EasyOne produced after October 2009 (Ser.Nr. $\geq 80'000$) can be upgraded by the user. EasyOne devices produced before that date cannot be updated since the memory within the unit is too small.
2. Easy on-PC, EasyOne Pro: Installation of the newest software makes the Stanojevic 2009 predicted available.

All updates are available for free (software update can be downloaded from the ndd Web site).

Pharmaxis Ltd

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We have not yet implemented the Stanjovic 2009 equations as of yet, but anticipate release in 2012. Once implemented, these equations, both in PC software and instrument firmware will be made available upon request for all SDI Astra 200 and 300 spirometers currently in use, provided that the user updates the spirometer software/firmware to the latest version. Any spirometers manufactured prior to the Astra series (before 2007) will not be eligible for update.

We will not charge for the update.

Sensormedics Italia srl

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To be Implemented in the next Vmax Encore version 21-3 (scheduled for Fall 2011).

Vmax Encore - will be available on all hardware devices.

Vmax Encore - implementation of look-up tables.

Vmax Spectra/Legacy - no implementation.

The next Vmax version is scheduled to be released on Windows 7 operating system and costs will apply

VacuMed

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We have not implemented the Stanojevic equations.

We plan to implement them at a future date in certain devices.

Such upgrades would be free.

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The Stanojevic 2009 implementation was released in 2010.

Implementation will be limited to our PC based spirometry software called Spirotrac.

All updates are free in Vitalograph software with current support licences. (A software support licence is free for the first year and costs £50 annually thereafter)