



Leiden, December 22, 2015

Our ref. : 15M0006

Re. : ADVISORY NOTICE: Important notification to users of Medis' Qlvus® 2.0, 2.1, 2.2 and 3.0

Dear Customer,

Medis is dedicated to improving the quality of its products and to providing adequate services to its customers. Recently, we found that there is a lack of clarity with respect to the use of some of the Qlvus modules in clinical practice. We therefore would like to re-inform all users of the Qlvus versions 2.0, 2.1, 2.2, and 3.0 of the limitations of Qlvus.

The statement about the limitations of "research use only" modules in Qlvus (iMap module, VH module, TVC module and OCT module) in the User Manual might be confusing. None of these modules are cleared for clinical purposes anywhere in the world. They are intended for research purposes only, exact wording should read:

"The iMap™, V , TVC Chemogram™ and OCT modules of Qlvus are intended for research use only and are not to be used for clinical purposes".

We would kindly like to ask you to confirm that the information above has been received and communicated to the staff working with Qlvus. Further, we appreciate feedback on the current **purposes of use of Qlvus in your facility.**

If you have any questions with respect to this notification, you can contact the Medis support desk by mail (support@medis.nl) or by telephone (North America and South America: +1 919 278 7888, other countries: +31 (0)71 52 32 44).

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