

Medset Medizintechnik GmbH Curslacker Neuer Deich 66 DE-20359 Hamburg Germany

> Glamsbjerg, 2016.05.13 KI Side 1/1

## RECALL

Innovision Aps would like to recall the following devices:

Innocor Pulmonary function test device: Ref. INN00400, Serial no. SN 1543365 and 1551370.

The purpose of the recall is to replace data transmission cable (USB-cable) connecting the Innocor device with an external computer.

The replacement USB cable will provide galvanic isolation of the Innocor from the external computer via opto-couplers, as opposed to the grounding protection currently in use.

The replacement is intended to prevent risk of electric shock. No incidents have been reported and this recall is considered to be a preventive action only. As always, adverse events or quality problems experienced with use of this device should be reported to your regulatory agency as well as to Innovision.

The replacement costs will be carried by Innovision ApS.

Please acknowledge reception of this recall by contacting service manager Knud Pedersen (<a href="kp@innovision.dk">kp@innovision.dk</a>, Phone (+45) 65 95 91 00) to schedule the service activity and for answers to any inquiries you may have.

The replacement may not be done by customer; however, it may be possible to arrange for the service to be performed at your premises.

Yours Sincerely
INNOVISION ApS