

## Libero C – Instructions for use

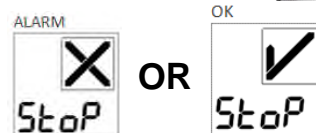
### INSTRUCTIONS TO STOP THE LIBERO:

- 1) Upon receipt, immediately place the medication kits into the storage area, retrieve the temperature monitor and press the “Start/Stop” key for **3 seconds** →

*NOTE: alternatively plug the LIBERO directly into a USB port to stop the device*



- 2) When the monitor stops, the display on screen looks as follows:



- a) If the  icon is displayed: the temperature during transport stayed in the defined range.
- b) If the  icon is displayed: a temperature excursion has occurred during the transport.

### INSTRUCTIONS FOR DOWNLOADING THE DATA:

- 1) Plug the LIBERO into the USB port of any PC. The display shows „PdF“:



- 2) Within a few seconds, a PDF evaluation report will automatically be generated and presented in the explorer. In case the auto start functionality is not activated on your PC, go to "desktop" and search for a drive named LIBERO.
- 3) Copy or “drag & drop” the file from the LIBERO drive to your local drive or network folder.
  - **Never use a PDF Editor application to save the PDF file otherwise the embedded data will be lost and no further analysis will be possible.**
  - **Do not rename the PDF report generated when copying it on your local drive/network folder**
- 4) Open and print the PDF file, file it in your Regulatory Binder/Pharmacy Binder.

### INSTRUCTIONS FOR SENDING THE FILES:

- 1) Open the PDF file, read and follow the instructions hereunder:
- 2) If the  icon is displayed: please send the PDF file by e-mail to [tmdreport@bnc-group.com](mailto:tmdreport@bnc-group.com)  
**Include the study number & B&C site number (see notification email).**
  - a. If the Libero displayed a  icon, the medication is acceptable for use.
- 3) If the  icon is displayed: please send the PDF file by e-mail to [tmdreport@bnc-group.com](mailto:tmdreport@bnc-group.com)  
**Include the study number & B&C site number (see notification email).**
  - b. If the Libero displayed a  icon, a temperature excursion has occurred.
    - ⇒ Complete IVRS (if used), indicating the temperature excursion.
    - ⇒ Quarantine these kits at the defined storage temperature until confirmation regarding their status from sponsor.
- 4) If instructed by the sponsor, please keep all devices at the clinical site until the time of the next monitoring visit.
- 5) Dispose datalogger correctly.

This product has to be disposed of according to the WEEE guidelines (Waste Electrical and Electronic Equipment, 2002/96/EC). A disused device **must not be put into the common waste bin.**