Place in Site Master File #10

Instruction for temperature logger

There will be a disposable temperature logger (TempTale4) inside the packages you receive with IMP and placebo. Inside the package you will also find a document entitled "The reading of TempTale4 temperature logger". Please read the document and follow the instructions carefully.

The reading of TempTale4 temperature logger (top half of the document)

TT4 no:	Protocol:	Site:

Follow the instructions to read the TT4 USB logger

- Stop the TempTale4 logger by pressing down the stop button for 3 seconds (The "Sun" disappears and a "Stop" appears)
- Check if the logger shows an alarm. (If a bell is visible in the display under the "Stop".

Important: If the logger shows an alarm, the study medication must be placed in QUARANTINE. Please leave the study medication in quarantine until further notice.

- If the TT4 does not show an alarm the logger device can be discarded after the result has been send to Nomeco

Send the logger data to Nomeco:
- Put the USB device in the computer and a window with two files will appear. A pdf file and a ttx file.
- In the pdf file there is a summary of the temperature curve. The ttx file can only be opened by Nomeco A/S.
- Please send both files to Nomeco A/S: **ctsm@nomeco.dk**.

IF the logger data cannot be downloaded by your computer then – and only then – fill in the bottom half of the document (shown on page 2).

Fill in the below ONLY if the logger data can not be downloaded by the computer

- If it's not possible to download the data then press down the stop button for 3 seconds and 5 successive numbers will appear. Please note the numbers in the table below.

Data results:

Digit no.1:Mean temperature (°C)	
Digit no.2:Highest temperature (°C)	
Digit no.3:Total time above high temperature limit (min)	
Digit no.4:Lowest temperature (°C)	
Digit no.5:Total time below low temperature limit (min)	

Recipient (Name, date)	

If there is an alarm and the data can't be send to Nomeco by email then send the logger to Nomeco at the following address:

Nomeco A/S
Att. CTSM
Borgmester Christiansens Gade 40
1790 Kbh. V

The TempTale4 temperature logger is disposable.

Please call CRIC at +45 35 45 71 67 for further help to handle the temperature logger.