eurisTest™

TurboReader™ Manual

Instruction For Use (IFU) manual- Version 6, April 2018

A quantitative point-of-care instrument for veterinary use.

FOR VETERINARY AND RESEARCH USE ONLY.

1 GENERAL DESCRIPTION

TurboReader™ is a point-of-care analyzer intended for veterinary hospitals and veterinary offices. It delivers reliable results, comparable with large-scale laboratory analyzers, within minutes from small sample volumes. The instrument uses two light absorption channels (525 nm and 625 nm) and two nephelometric channels (470 nm and 625 nm). It employs pre-set multi point calibration curves and self-test routines. The operation of the TurboReader™ is controlled by the color touch screen interface and an external 2D-barcode scanner. A printer DPU-414 is an optional accessory.

Dimensions (L/W/H):	195*140*110 mm
Weight:	0.7 kg
Rating:	5 V DC (3 W)
Power supply:	100-240 V AC (50-60 Hz)

2 SAFETY

Note that the reagents used with the TurboReader™ involve handling of biohazardous material and therefore, appropriate protection such as safety glasses, lab coat and latex gloves must be used at all times. If uncertain, consult expertise for help.

3 REGULATORY

All applicable EC harmonized standards (CE EN 61326-1-2-3: 2013) for radio frequency interference are met by this product. The product is fulfilling the RoHS directive 2011/65/EC.

4 PRIOR TO USE

The product must be used in the manner described in this Instruction For Use (IFU) manual in order to avoid product impairment. The TurboReader™ is designed to operate under the following conditions:

- Indoor use only
- Avoid placement under direct sunlight or strong lamps
- Well ventilated area required
- Ambient temperature range +15 °C to +35 °C

5 INSTALLATION

Connect the 2D scanner to the instrument using the connector on the backside of the instrument labeled "scanner". NEVER CONNECT or DISCONNECT THE 2D SCANNER WHILE THE INSTRUMENT IS ON! An optional printer may also be connected to the instrument by using the connector on the backside labeled "printer". Before connecting the TurboReader™ to the mains electricity supply, ensure that the AC voltage is 100-240 V and the frequency is 50-60 Hz. Keep an empty cuvette in the instrument in order to avoid dust collection in the cell holder. Turn the power switch ON (backside of instrument). "Please wait" is displayed on the touch screen while the instrument is warming up. The TurboReader™ needs 5-10 minutes to warm-up the internal cuvette holder, thereafter it is ready to be used. The instrument can be turned on in the morning and left on during the whole working day.

6 CALIBRATION

When a new lot of reagent is used, the lot specific calibration data must be transferred to the TurboReader™ prior to measurement. This is done by using the external 2D scanner and following steps 6.1-6.5 below:
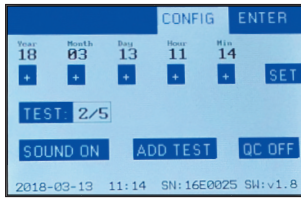
6.1   Press the SETTINGS button on the home screen.
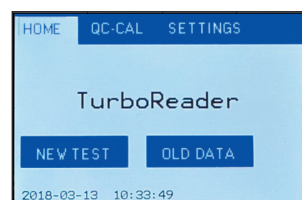
6.2   If the test (i.e. Canine CRP, Feline Haptoglobin, etc.) has been previously run on the instrument, press the TEST button until the desired test name is shown. (Example: Position 1 of 5 (1/5) is Canine CRP.)
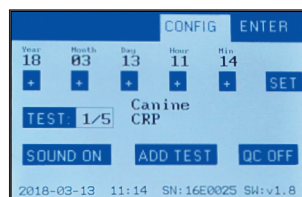

If the test is being run on the instrument for the first time, press the TEST button until a vacant position is selected (Example: position 2 of 5 (2/5) is vacant.) A maximum of 5 different tests can be installed on one instrument. **Note:** If no positions are vacant, a new test can be added to any position (old test will be replaced).
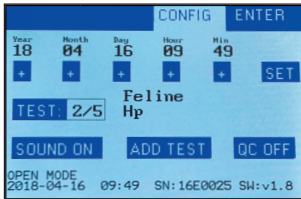
6.3 Press the ADD TEST button on the screen.

6.4 Scan the bar code on the kit instructions using the 2D scanner. After scanning, the TEST position should show the name of the test.
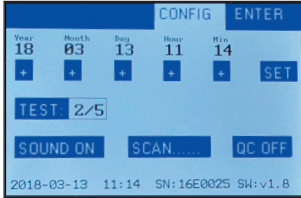
6.5 Press the ENTER button to return to the home screen.

Note: The operator can view the lot specific calibration data by pressing QC-CAL on the home screen. The QC-CAL screen shows lot specific calibration curve, instrument function, R2 zero value and reagent lot number. Refer to section 9 for more information. Press CANCEL to return to the home screen.
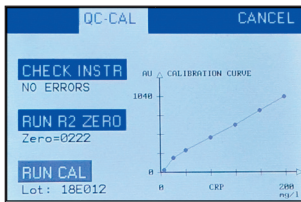

7 OPERATION: Normal Mode

After installation and calibration has been completed, measurements on patient samples can be performed according to steps 7.1-7.11 below:

7.1 If more than one test parameter is installed on the TurboReader^TM, press the SETTINGS button on the home screen. Then press the TEST button until the desired test parameter is selected. Press ENTER to return to the home screen.
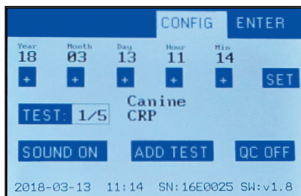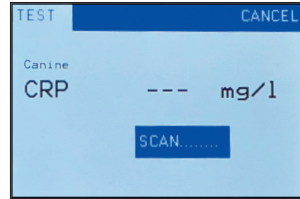

7.2 Press the NEW TEST button on the screen.
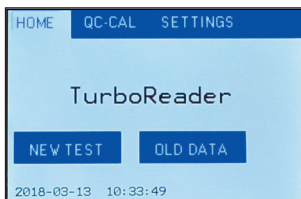
7.3 Press the TEST button on screen. **Note:** The correct test name (i.e. CRP) must be displayed. If not, press CANCEL and go back to step 7.1 and select correct test in SETTINGS menu.
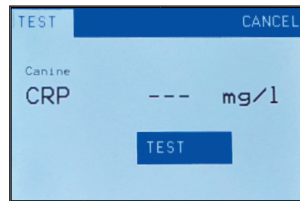
7.4 Scan the bar code on the R2 bottle using 2D scanner. The lot of reagent should match the stored calibration curve in the TurboReader^TM.


Note: If the lot of reagent does not match the stored calibration curve in the instrument, a warning message will be displayed. WARNING MESSAGES:

> 1. WARNING: LOT (lot does not match calibration)
> 2. WARNING: EXP (test kit is expired)
> 3. WARNING: LOT-EXP (the test kit is expired and the lot does not match calibration).

It is not recommended to continue with the measurement if a warning message is given. Control that the correct test kit is being used. If needed, transfer lot specific calibration data to the TurboReader^TM by following the steps under section 6 Calibration in this manual.
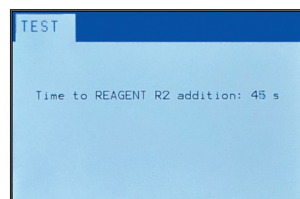
7.5 Press the RUN button on the screen.
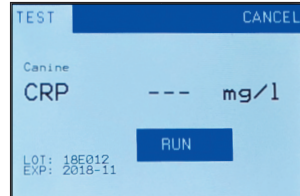
7.6 Using the sample pipette, transfer the patient sample into the cuvette and gently turn the cuvette upside down 4 times (no bubbles should be introduced). Thereafter, put the cuvette (the arrow on the cuvette wall and on instrument must align) into the instrument.
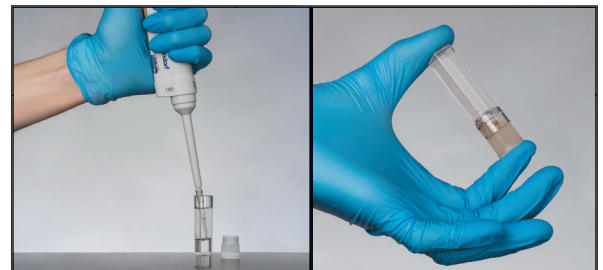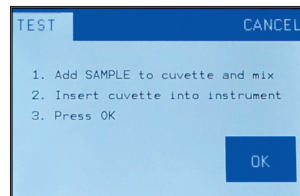

7.7 Press the OK button on the screen and wait 1 minute. The instrument automatically counts down 60 seconds before giving next instruction.


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7.8 Remove the cuvette from the instrument and using the R2 pipette, transfer R2 reagent into the cuvette. Turn the cuvette slowly upside down 4 times (no bubbles should be introduced). Place the cuvette into the TurboReader[TM] and make sure it has the correct orientation (the arrow on the cuvette wall and on instrument must align). Press OK and the operator can leave the instrument.
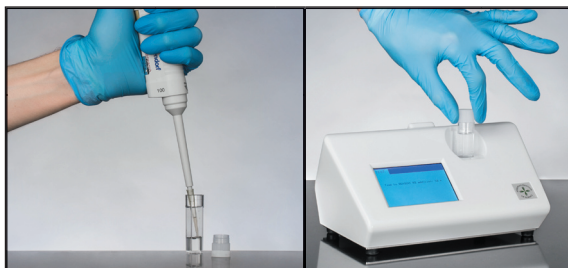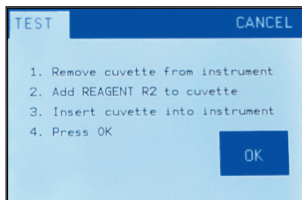
7.9 During the next 3 minutes, the instrument automatically plots the response curve over time. Every 30 seconds a new point is added to the plot on the screen. This visually represents how the measurement is proceeding in real-time.
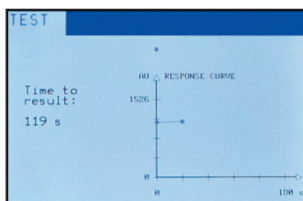
7.10 After 3 minutes the TurboReader[TM] will display the concentration of target analyte in the sample.
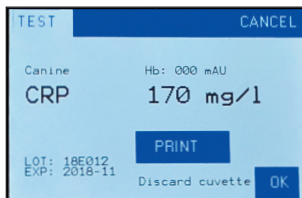

7.11 If you have a printer connected to the TurboReader[TM], results can be printed by pressing the PRINT button on the screen. When finished, discard cuvette and press the OK button to start a new test.

8 OPERATION: QC Traceability Mode

The TurboReader[TM] can be run in a special QC traceability mode which links each measurement to a specific operator, patient and reagent lot. The 2D scanner is required in this mode, as well as, bar codes for operator ID and patient ID.
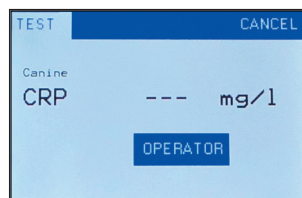
8.1 First the QC traceability mode must be activated in the settings of the instrument. From the home screen, press SETTINGS and then press QC OFF. It should now display QC ON. Control that the correct test is selected under TEST. Press ENTER to return to the home screen.
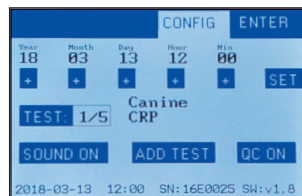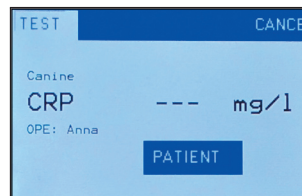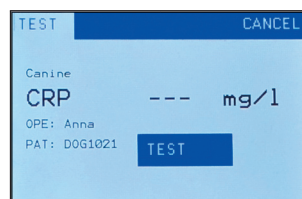

8.2 Press the NEW TEST button on the screen.
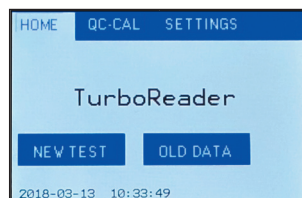
8.3 Press OPERATOR and scan the operator ID.

8.4 Operator ID (OPE) is displayed on the screen. Press PATIENT and scan the patient ID.

8.5 Operator ID (OPE) and Patient ID (PAT) are displayed on the screen. Press TEST and scan the R2 bottle.

8.6 Operator ID, patient ID and reagent lot are displayed on the screen. Press RUN and continue the measurement as outlined in steps 7.6-7.11 under heading 7 Operation: Normal Mode.

Note: If the operator prints the result after the measurement is completed, all traceability information will be given on the result report.

9 SOFTWARE SCREEN MENU

The TurboReader[TM] software menu has 3 selections: HOME, QC-CAL and SETTINGS. At any time, press CANCEL or ENTER if you want to return to the previous menu. The menu functions are described below:

**HOME**:   Main screen from which test can be initiated.
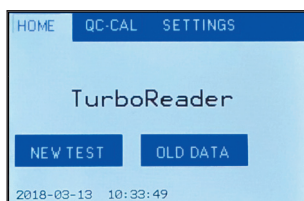
Pressing OLD DATA on home screen will display the last five measurements performed by the TurboReader[TM]. Measurements highlighted in red, indicate that the reagent lot used for that specific measurement did not match the stored calibration curve and/or reagent lot used was expired. This could provide inaccurate results. Press CANCEL to return to home screen.
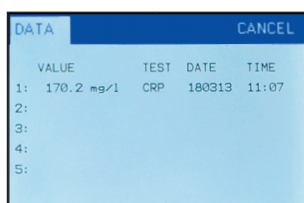
QC-CAL: This screen displays lot specific calibration curve, instrument function, R2 zero value and reagent lot. To control instrument function, place unused test cuvette with cap (Art. No. 1502-37) into the TurboReader[TM] and press CHECK INSTR. Instrument parameters are automatically checked and followed by display of "no errors". If an error warning is displayed, contact the European Institute of Science AB for technical help. If a test control does not fall within the acceptable measuring limits, it may be good to run R2 zero. To perform this, press the RUN ZERO button followed by running a test without sample. Press CANCEL to return to the home screen.
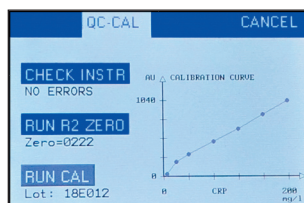
SETTINGS: This screen allows the operator to adjust TurboReader[TM] functions. The instrument date and clock can be adjusted by pressing (+) for year, month, day, hour and minutes, followed by SET to store the changes. To select a test, press TEST and any of the installed tests (1-5) in the instrument can be selected. By pressing SOUND, instrument sound can be turned on and off. By pressing ADD TEST, a new test can be installed using the 2D scanner. By pressing QC, quality control mode can be turned on and off. When QC is turned on, QC traceability mode is activated, which offers logging of time, operator, patient and reagent lot number for each measurement. Instrument serial number (SN) and installed software version (SW) are also shown on the bottom row of the screen (see picture below).
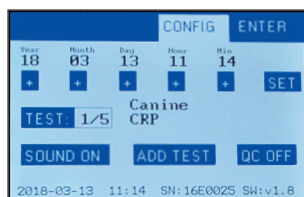
10 MAINTENANCE & SERVICING

Once every month the equipment exterior surface should be cleaned using a damp cloth. DO NOT TRY TO CLEAN THE INSIDE OF THE INSTRUMENT CUVETTE HOLDER. THIS COULD IMPAIR INSTRUMENT FUNCTION. Repairs must be undertaken by qualified personnel and only original spare parts used. Servicing should be done by the European Institute of Science AB or its agents.

11 WARRANTY

A warranty is given that this product is free from defects in material and workmanship, when used under normal laboratory conditions, for a period of one (1) year. This does not apply if damage is caused by accident, neglect, fire, fitting of non-approved parts or repair by unauthorized personnel.

Part numbers:

TurboReader[TM] instrument	2580-01
TurboReader[TM] 2D scanner	2201-02
TurboReader[TM] printer	2201-01

12 DISPOSAL

After instrument lifetime has expired, the instrument should be returned to the European Institute of Science AB or any of its agents for proper disposal.

13 SYMBOLS KEY

| Consult IFU | Manufacturer | Catalogue number | EMC-CE |

Manufactured by: European Institute of Science AB

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