

Speed Reader™

User Manual



Shaping the future of animal health

Virbac

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General information on the Speed Reader™ analyser

The Speed Reader™ analyser is a rapid immunochromatography test reader that uses laser-induced fluorescence for dosing veterinary biomarkers in biological samples.









» Principle

The sample to be analysed is tested with fluorophore nanoparticles coupled with specific antibodies of the biomarker to dose. These marked biomarker/antibody complexes are separated from other components of the sample through a migration on a nitrocellulose membrane (the immunochromatography principle) that is pre-sensitised using molecules of these complexes that have been specially refined. This migration leads to an accumulation over a specific and limited area of the membrane. Exciting the fluorophore nanoparticles by means of a laser diode leads to the emission of a specific wavelength whose intensity is correlated with the amount of biomarkers present in the sample. The emitted fluorescence is measured by a photosensitive cell, making it possible to determine the sample's concentration by comparing it to a range of calibrations and internal tests.

» Operating instructions

- Please read the manual carefully before use. Failure to follow the instructions in this manual may lead to incorrect results.
- Avoid any shock, vibration, electrical discharge or contact with chemicals that could cause a malfunction of the unit or produce incorrect results.
- The Speed Reader™ analyser can only be used for reading *in vitro* veterinary diagnostic tests of the Speed Biomarker range. The use of other tests could cause malfunctions or provide incorrect results. Bio Veto Test and its distributors disclaim all liability for any unauthorised operation.
- Before being used, the Speed Reader™ analyser must be placed on a clean, flat and stable surface, away from moisture, heat, dust, direct sunlight or any liquid.
- Do not use the device outdoors. Do not place anything on the device.
- The operating temperature is between +15°C and +35°C. For an optimal use, it is advisable to put the reader in a room having a temperature higher than 20 ° C. Recommended maximum humidity is 70%. If the unit is placed in an environment that does not meet these conditions, it is advisable to move the Speed Reader™ analyser and wait *at least* 30 minutes before using it again.
- Always operate the reader with the stylus provided
- You should always wear clean and properly maintained individual protection equipment when operating the Speed tests.
- The Speed Reader™ analyser and its reagents must only be used by the veterinary practitioner. The interpretation of the result should be carried out by the veterinarian who must always take into account the medical history and the clinical examination of the animal and any other diagnostic test result, given that no diagnostic method is 100% accurate. The final diagnosis remains the prerogative and responsibility of the veterinarian.
- Avoid applying intense pressure during the insertion of the tests in the loader or when handling the touchscreen.
- In case of a major malfunction, immediately switch off the ON/OFF button located at the rear of the unit, unplug the Speed Reader™ analyser and contact technical support.
- When necessary, you should clean your Speed Reader™ analyser with a soft and dry cloth, after disconnecting its power supply.
- After each use and before turning off the unit, check that the test loader is properly introduced in the unit. If necessary, re-insert the loader, using the button for this purpose on the main screen.
- To power off the device, strictly follow the instructions in this manual.
- You should unplug the unit when not using it for several days.
- Never disassemble the unit. This operation must only be performed by an authorised technician.
- Do not disassemble randomly.
- Since the laser module is inside the product, do not disassemble it during use.
- Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

» Symbols

	Manufacturer
	Read the instructions before use
	Only for <i>in vitro</i> diagnosis
	Warning! Read the instructions before using the device
	Separate the electric and electronic parts after use
	USB port
	Temperature limits
	Serial number

"NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense."

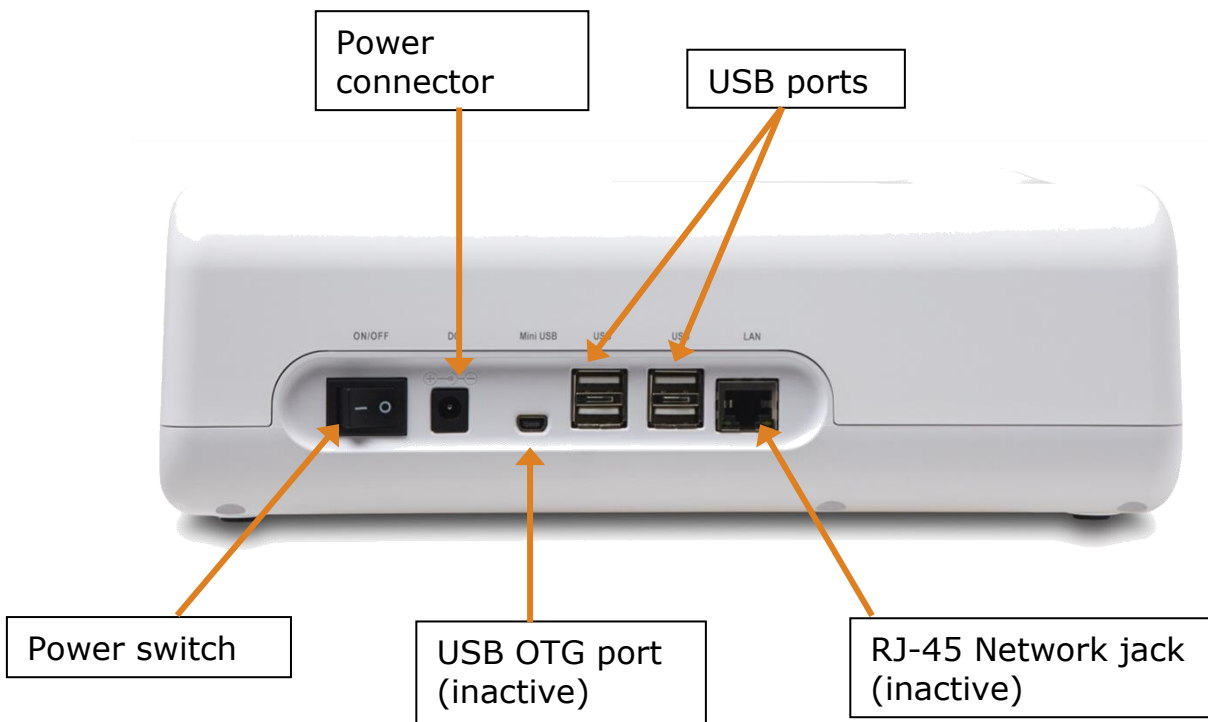
"Changes or modifications not expressly approved by Virbac could void the user's authority to operate the equipment."

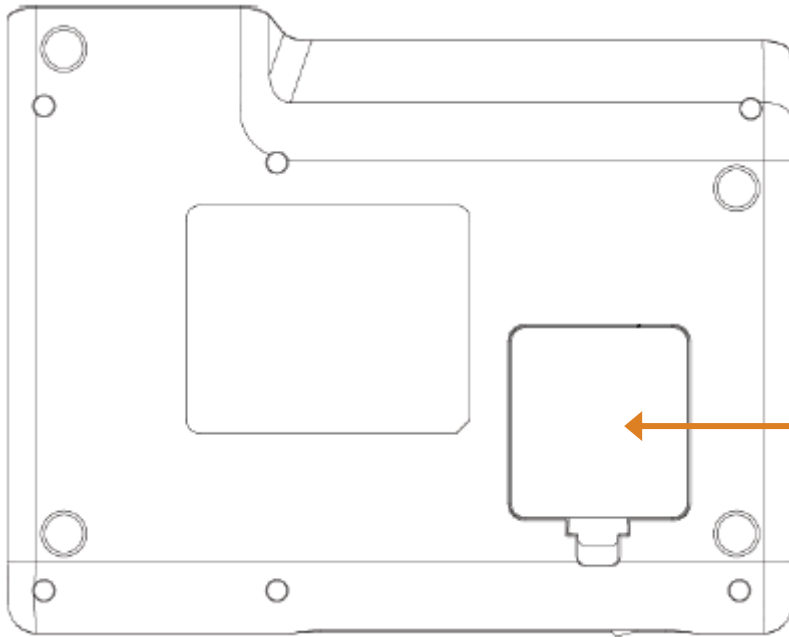
CLASS 1 LASER PRODUCT

» Contents

- 1 Speed Reader™ analyser
- 1 power supply cable in 2 parts
- 1 stylus
- 1 USB key
- 1 SD card installed in the reader
- 1 self-control kit for the reader: Speed System Check™
- 2 rolls of thermal paper
- 1 10µL pipette
- 1 50µL pipette
- 1 100µL pipette
- 1 first use guide
- 1 warranty booklet




» Presentation of the reader





Housing for
AA/LR6
batteries and
SD card

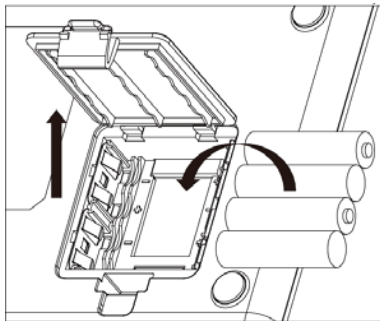
» Description of icons

Icon	Description
	Appears when the unit is plugged into the mains
	Icon is green if the temperature is between +15°C and +35°C, otherwise it's orange
	Charge level of auxiliary batteries when device is not running on the mains

Before the first use

» Installing the reader

- Place the reader on a clean, flat surface that is free from moisture
- Connect the two cables that constitute the power cord
- Connect the power cord to the rear of the reader at the level of the power supply socket and to a 100-240V earthed power supply.



The Speed Reader™ analyser can be used with batteries. This feature enables the device not to turn off in case of a power failure (power is limited to 30 minutes or about 3 tests).



Only use non-rechargeable type AA/LR6 batteries. Never use Ni-Mh rechargeable batteries or batteries of other types.

» Loading the thermal printer

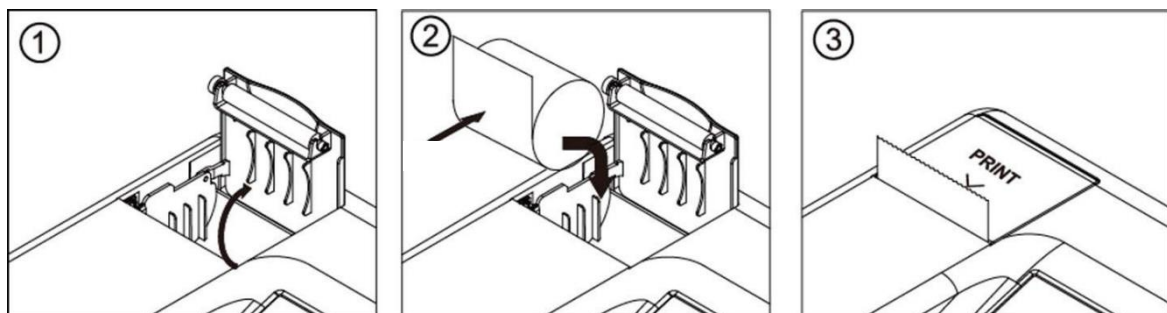
To change the paper roll, lift the printer cover, remove the old roll and replace it with the new one. Close the cover. Ensure that the printing can be performed properly by rolling out the beginning of the paper outside the printer.

This printer only works with thermal paper.

The size of the thermal paper roll is:

57 mm x 40 mm x 12 mm

(Paper width X Maximum external diameter of the roll X Internal diameter of the coil)



Each time the Speed Reader™ analyser is booted, the printer rolls out a thin band in order to verify the presence of paper

» Powering up and initialisation

- Press the "ON/OFF" button at the rear of the reader to power up the device
- When powering up, there can be a delay of about five seconds between the activation of the button and the lighting up of the screen
- After the Virbac logo appears, allow the device to initialise automatically for about one minute. A self-test procedure is performed each time it is switched on, in order to check that the reader's main components are receiving power.



» Speed Reader analyser configuration

Set the language, date, time and date format using the following screens:



- It is then recommended to carry out the first System Check immediately by pressing "Yes" then "System test".

» System Check

A Speed System Check™ control kit containing a control test cell and a control chip is provided with the unit for this purpose. The control chip is not a calibration chip, therefore it should not be saved in the reader.

- System Check notifications

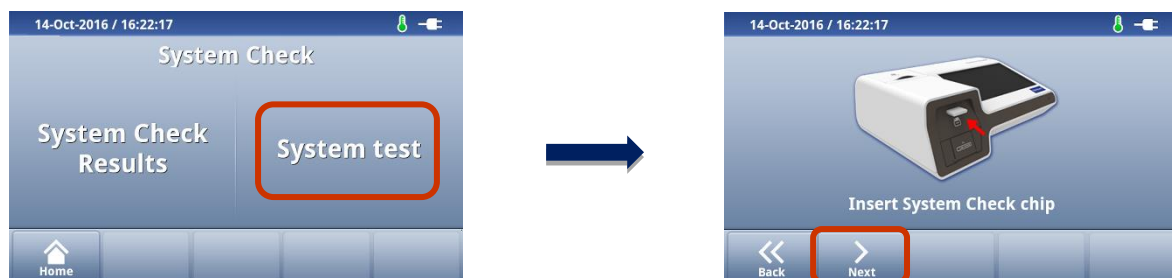
It is advisable to make a System Check before the first use of the device and then once a month (default setting). To customize the periodicity of the reminder, press the "System Check" button on the main screen and then on "Notifications", select the desired periodicity and save by pressing "Save". When a System Check needs to be done, a window appears and prompts the user to take the System Check test. However, if the user defers the test, a notification appears on the main screen and remains displayed until the System Check is performed.



When not in use, store the two control items in their bag, **away from light and with a desiccant** pack, and only take them out for the regular control operation. A validity date is written on the pack. Be sure to always use a valid control kit.

- Checking the reader

In the main menu, press "System Check".



- To perform a System Check, select "System test". Then insert the check chip supplied with the reader in the chip reader located on the front of the unit and press "Next".
- Insert the check tape supplied with the reader as far as it will go and press "Start".
- After the check has been completed, "System OK!" appears on the screen.

- Remove the tape and the check chip and store them away from light and moisture until their next use.
- Return to the main screen by pressing "End", then "Home" and close the test loader by pressing "Open/Close".

This operation should be performed when first installing the reader and then on a monthly basis. By default, a notification will appear at the start when no System Check has been done for 30 days. It is possible from the main screen to set the periodicity of the alert by pressing "System Check" and then "Notifications".

In case of malfunction, or if the check result presents an error, repeat the procedure. If the problem persists, contact technical support.

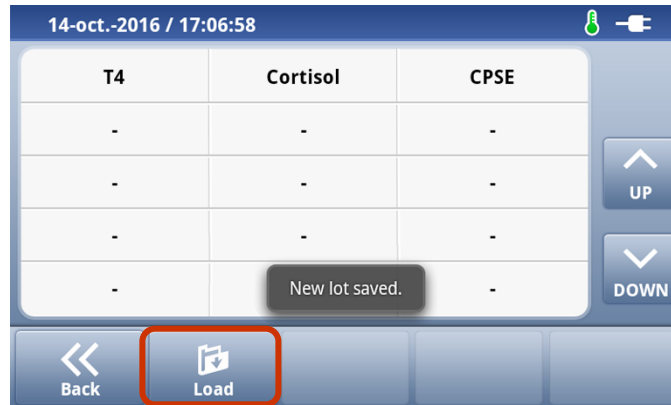
To view the results of the various checks, select "System Check", then "System Check results". It is possible to delete or to print selected results.

»» Saving a new batch of tests

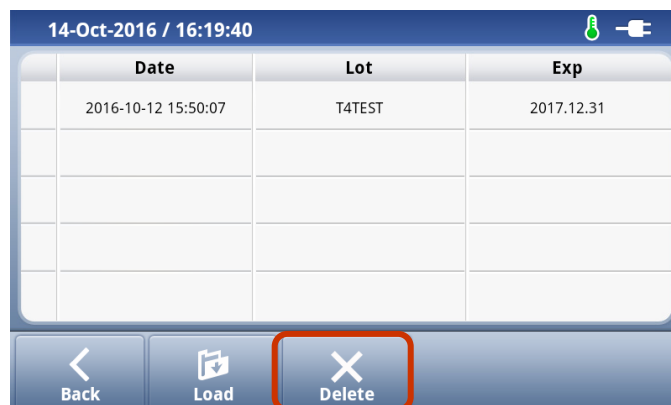
At each batch of tests, there is a specific corresponding calibration of the batch. This calibration is saved in the batch's calibration chip provided in each box of consumables.

At each reception of a new box of tests, you should save the batch's calibration chip in the Speed Reader™'s memory in order to ensure an optimal result. When running a test, if the chip of the corresponding batch is not saved, you will be prompted to do so at the beginning of the test in order to move on to Step 2.

- Saving a new batch
- Go to the home screen, then select "New Lot".
- Insert the calibration chip to be saved.
- Press "Load".
- The message "New lot saved" confirms that the chip has been properly saved.



- To check the batch number and expiration date, press the desired valency.
- To delete a valency, first select it, then press "Delete" and confirm by pressing "Yes"



The Speed Reader™ analyser can store up to 5 batch calibrations per test in its memory. When the memory is full, the Speed Reader™ analyser will erase the oldest batch calibration curve at each new saving.

Batches whose expiration date has passed appear in yellow on the reader.

You should store the calibration chip of each corresponding batch in each test box until all of the box's tests have been performed. It is possible to have several chips of the same batch. In this case, when recording, the message "New lot saved" appears even if the batch was already stored in the memory; this will not create duplicates in the unit.

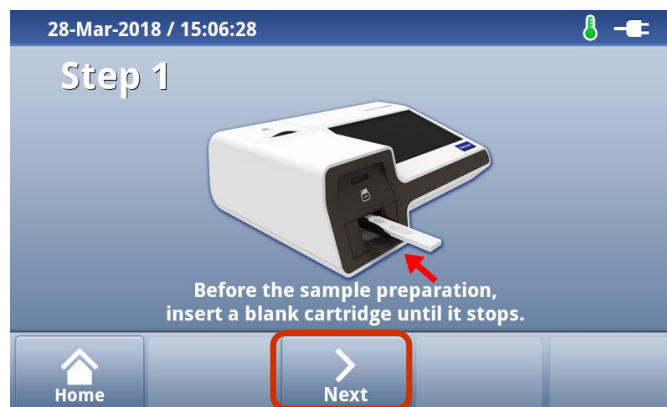
Analysing a sample

» Performing a new test

- On the main screen, select "New test".



- The following screen appears.



- **Step 1:** Introduce the blank tape of the test as far as it will go, then press "Next". The reader then checks the type of test to be performed and the presence of the calibration of the corresponding batch in the device's memory.
- If prompted, insert the calibration chip, then press "Retry". In this case, remember to remove the chip from the 2nd step and put it back in the corresponding box.

14-Oct-2016 / 16:21:27

Step 2

Owner

Animal

Animal ID

Species
 Select Species ▼

Test

Lot / Exp

Comments

Home Next

- **Step 2:** Check the test, the batch number and the expiration date. If necessary, you can add the name of the owner, the name of the animal, its identifier (chip number, tattoo...), its species and any comments (max. 25 characters).
NB: You can edit the various fields throughout the testing procedure. Once the result is being processed, it will not be possible to change these data, with the exception of the "Comments" field in the "Results" menu.
- Then press "Next".
- **Step 3:** Follow the directions on the screen for the sampling volume and the incubation time for the steps for transferring the sample. Once the mixture is complete, if an incubation time is required, press "Start" to start the Timer. A beep will indicate the end of the incubation period. Press "Next". If there is no incubation time required for the dosed valency, press "Next".

14-Oct-2016 / 16:22:17

Step 3

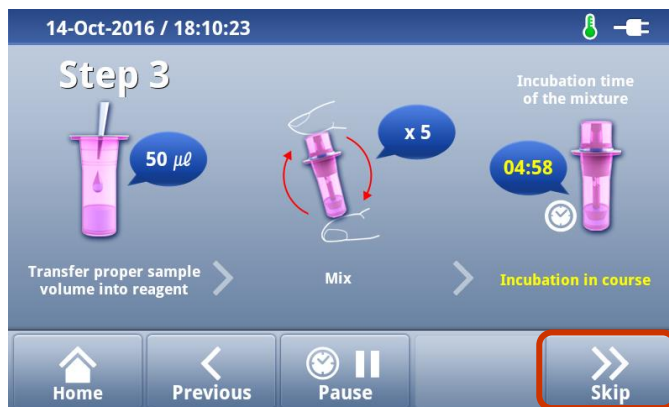
50 µl
 Transfer proper sample volume into reagent

x 5
 Mix

5 min
 Incubation time of the mixture
 Press Start to launch incubation timer

Home Previous Start

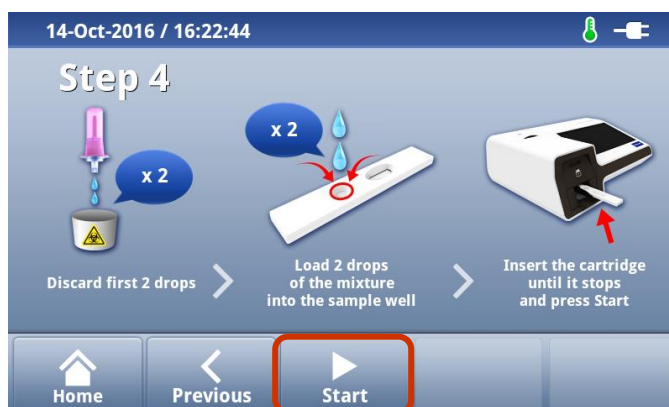
If the waiting time for the incubation has already been observed, you can skip this step by pressing "Skip" once the Timer has started. You can also stop the Timer and restart it if it is started accidentally. To do this, press "Pause", "Reset", and then "Start".



ATTENTION, when an incubation time is required, you must observe it and you cannot exceed it for more than 30 seconds in order to obtain a valid result. Always ensure you have performed this step properly before proceeding to the next step.

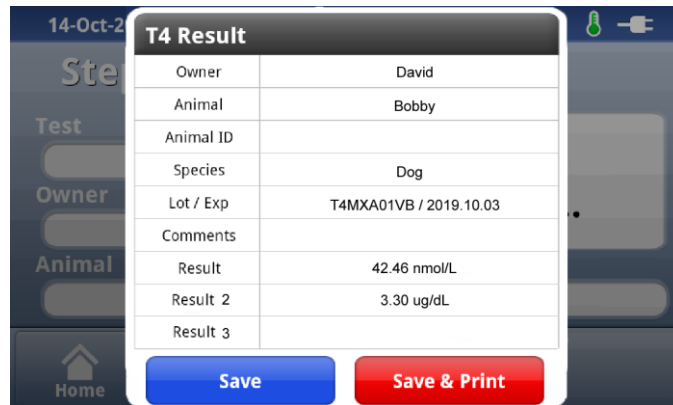
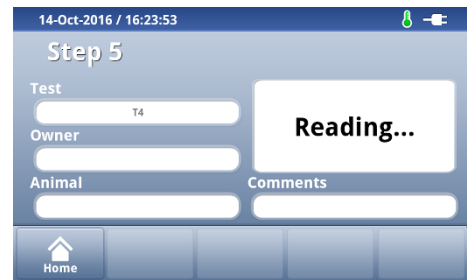
Step 4: Remove completely the blank tape from the charger and put 2 drops of the reagent-sample mixture into the sample well, first ensuring that you eliminate the first 2 drops, so as to flush out the content of the dead space of the dropper then add 2 drops of the mixture into the sample well taking care to hold the vial VERTICALLY.

- Reinsert the tape into the test loader observing the direction indicated by the arrow at the end of the tape and ensuring you keep the tape level. Once the tape has been inserted as far as it will go, **immediately press "Start"**.



Attention: be sure to insert the tape as far as it will go to ensure the correct positioning of the reading zone with respect to the fluorescence sensors. When the cassette is incorrectly positioned, the reader displays an error message inviting to insert it again. Position the cassette well and press "Retry" to restart the analysis.

- **Step 5:** The following screen will appear. The countdown ensures that enough time is given for the mixture to migrate before automatically proceeding to the reading of the result.




- At the end of the countdown, when the reaction time is finished, the result appears automatically on the screen.
- For T4, Cortisol and Progesterone tests, the result is displayed with 2 units
- Select "Save" to validate the result, save it in the device's memory and return to the main screen. Select "Save & print" to validate, save and print the result and then return to the main screen.
NB: It is possible to enable or disable an automatic printout when obtaining the result. Go to the Menu Settings/System/Printer/Auto-Print Option.
- Next, remove the test tape from the loader and dispose of it, with its reagent vial, in a suitable container.
- Close the test loader by pressing the "Open/Close" button on the main screen.

Viewing previous results

- To view previous results, select "Results" in the main screen.

	Owner	Animal	Species	Test	Result
1	David	Boby	Dog	T4 2016-10-12 15:12:40	42.46 nmol/L 3.30 ug/dL
2	Simon	Luna	Cat	T4 2016-10-12 16:22:16	34.19 nmol/L 2.66 ug/dL
3	Miller	Tom	Dog	Cortisol 2016-10-13 09:24:40	165.00 nmol/L 5.98 ug/dL
4	Martin	Rusty	Dog	CPSE 2016-10-13 11:12:24	24.07 ng/mL
5	Smith	Jazz	Dog	Progesterone 2016-10-13 14:54:05	4.80 ng/mL 15.26 nmol/L

- The screen shows all stored results (7 results per page and up to 1,000 in memory).
- For T4, Cortisol and Progesterone tests, the result is displayed with 2 units

- To select one or more results, press the number of the test in the first column on the left of the table. The icon  appears - this means the result has been selected. You can select more than one result in order to delete, print or send them.

	Owner	Animal	Species	Test	Result
1	David	Boby	Dog	T4 2016-10-12 15:12:40	42.46 nmol/L 3.30 ug/dL
2	Simon	Luna	Cat	T4 2016-10-12 16:22:16	34.19 nmol/L 2.66 ug/dL
3	Miller	Tom	Dog	Cortisol 2016-10-13 09:24:40	165.00 nmol/L 5.98 ug/dL
4	Martin	Rusty	Dog	CPSE 2016-10-13 11:12:24	24.07 ng/mL
5	Smith	Jazz	Dog	Progesterone 2016-10-13 14:54:05	4.80 ng/mL 15.26 nmol/L

- For more information, press the desired result:

28-Mar-2018 / 15:16:14

Test result			
Test	T4	Owner	-
Date	2018-03-28 15:15:43	Animal	-
Lot	T4MXA01VB	Animal ID	-
Expiry Date	2018.10.03	Species	Dog
Result	41.33 nmol/L	User ID	-
Result 2	3.21 ug/dL	Result 3	-
Comments			

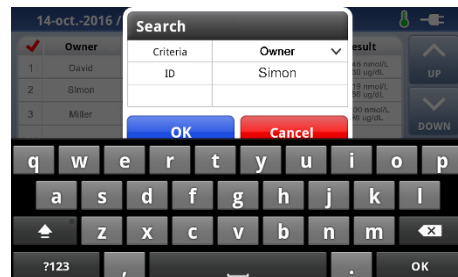
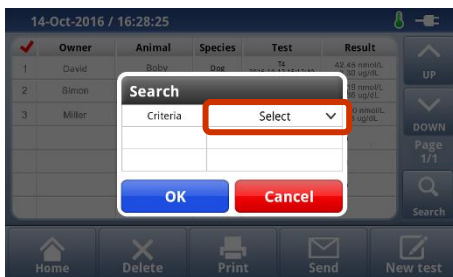
Modify Print Cancel

Home Delete Print Send New test

At this stage, you can only edit the comments field input during the analysis.

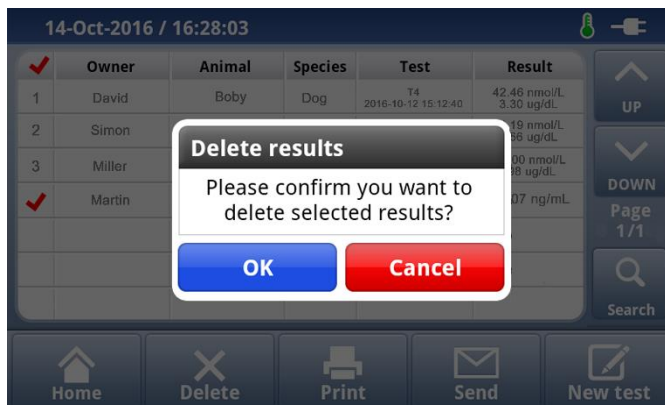
» Searching for a result

- It is possible to perform a search according to various criteria. The "Search" button lets you search for a result by test date, patient name, owner name, valency or species.



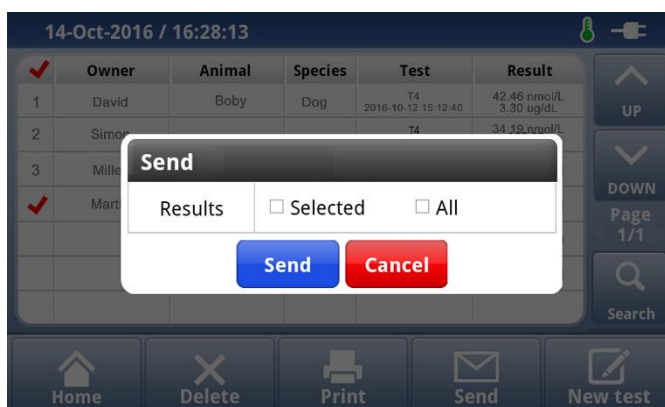
» Deleting results

- The "Delete" button lets you delete the selected results (only the administrator can delete results).



» Sending results

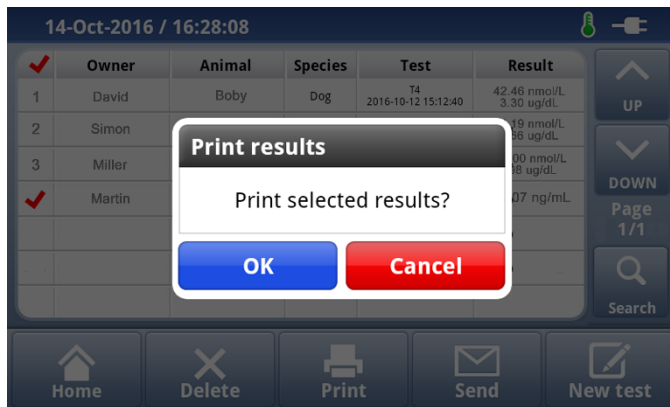
- The "Send" button lets you send all, or the selected, results to a USB key (only use the USB key provided with the reader). Results are saved in a .csv format which can be processed with an Excel type spreadsheet.



» Printing the results

The unit features a thermal printer. It is possible to print the results of the tests and the results of the System Check.

- The "Print" button prints the selected result(s).



```

-----
Speed Reader
-----
Owner : Dupont
Animal : Jack
Species : Chien
Animal ID : 1234567890
Date : 2016-11-02
Time : 10:45:06
-----
Test : T4
Lot : T4MXA01VB
Exp. : 2018.10.03


Result : 45.46 nmol/L
          3.53 ug/dL
-----
  
```

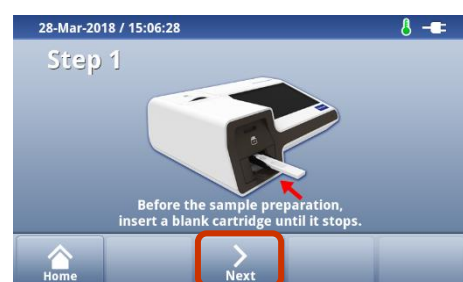
The results can be automatically printed at the end of a test (refer to ("Other settings"))

*NB: regardless of the language selected, the printing is done in English
The printing of multiple results will be sequential: one result after another.*

» Performing a new test on a previously recorded animal

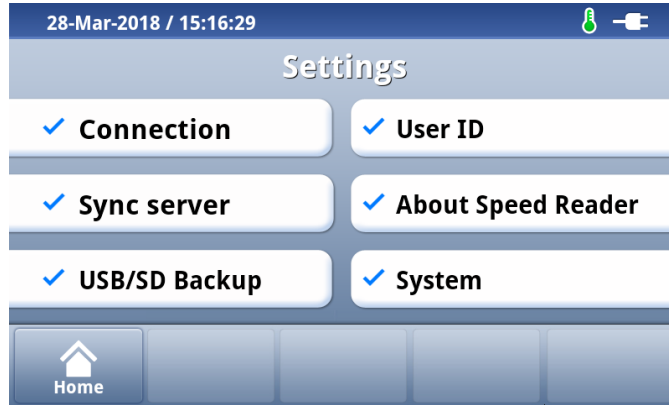
To carry out a follow-up, you can start a new test from an existing result. This allows you to keep the name of the owner and of the animal, its identifier and race without having to re-enter them during Step 2.

- Select a result line relating to the desired animal by pressing the number of the test at the left-hand side of the table
- The icon  appears
- Select "New test". A new test procedure starts



Other settings

Starting from the main screen, select "Settings". The following screen appears:



»» Connection

This menu lets you enable or disable various connection modules: WiFi and Ethernet. These features are not active at the moment. Once they are active, an update will be made available with details for connecting the device.

»» Sync server

This menu is not activated at this time. As soon as it is available, an update will be available detailing the procedure for connecting the device to a server.

»» USB/SD Backup

You can back up the data stored in the reader or restore previously saved results at any time.



- Backup

This function lets you save all the data and the results contained in the device's memory. The data can be stored on two types of media:

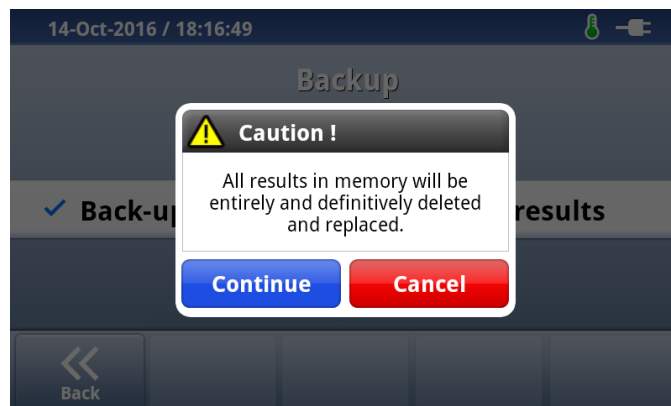
- The SD card that is in the reader.
- The USB key that came with the reader.

NB: This manual backup procedure does not let you process the data using a device other than a Speed Reader™ analyser. This procedure only lets you save data in a preventive way, in order to restore them in case the reader's memory is erased or in case the results are transferred to another device.

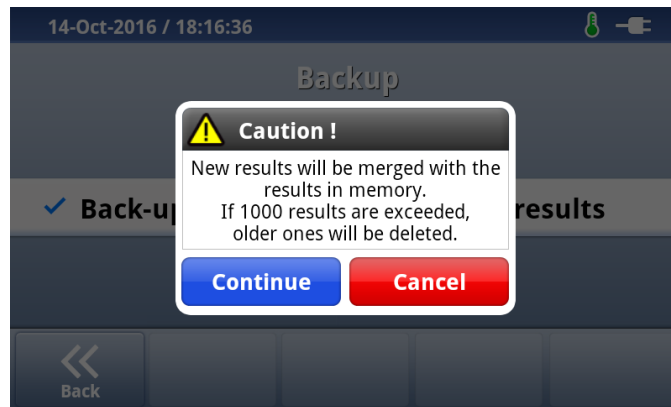
- Restoring results

The restoration of the results requires the administrator profile (User/admin). As described above, you can import results from the SD card or the USB key.

- The "Overwrite" function: If this option is chosen, the results in the Speed Reader™'s memory will be overwritten by the results that are on the external medium (the USB key or the SD card). Once the operation is completed, the old results in the Speed Reader™'s memory are overwritten in a definite manner.



- The "Merge" function: This feature lets you add results to those already stored in the reader. But you must be careful that their total does not exceed 1,000. In this case, the older results will be automatically deleted.



» User ID

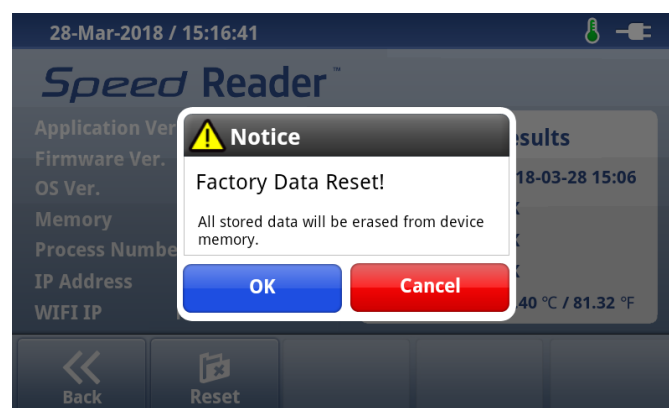
- This menu shows the user accounts stored in the unit. Each account is secured by a unique password. This feature lets you link results to an account when a user is logged in.
- To log in, press the desired user account, and then press the "Select User" button to enter the password.
- The administrator (admin) is stored by default with the password "0000". Once connected, this user is the only one that can add another user ("Add" button) or that can activate the connection function ("Login ON/OFF" button).
- The "Login ON/OFF" feature lets you specify if a user must be logged in to use the reader:
 - when it is active ("ON" mode). User identification is required before using the reader.
 - in "OFF" mode, the tests can be carried out without tracking the user who performed the operation.
- The administrator is also able to reset the reader in the *Settings/About Speed Reader* menu and to delete or restore results in the *Settings/Backup* menu.
- To disconnect a user, return to the main menu and press "Log out".

» About Speed Reader



This menu groups all the information about the software and the result of the last self-test performed. This information may be requested by technical support.

To reset to factory settings, select "Reset", then "OK". This operation permanently deletes all the settings and the results previously recorded and can only be performed by the admin user.

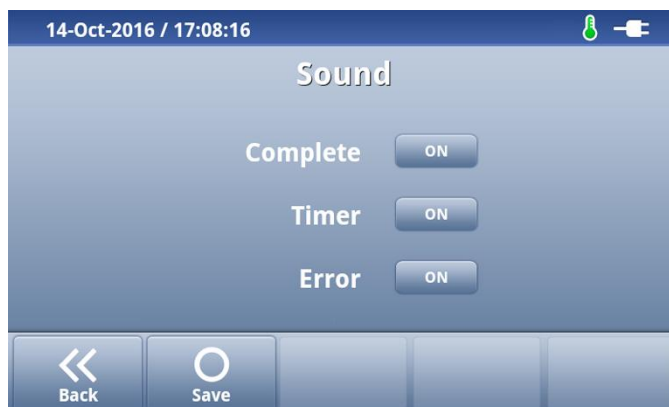


» System

○ Sound

This feature lets you turn the sound alerts on or off at different times.

- Enable or disable the various alarms with the "ON/OFF" buttons.
- Save by pressing "Save".



○ Printer

Automatic printing of the result

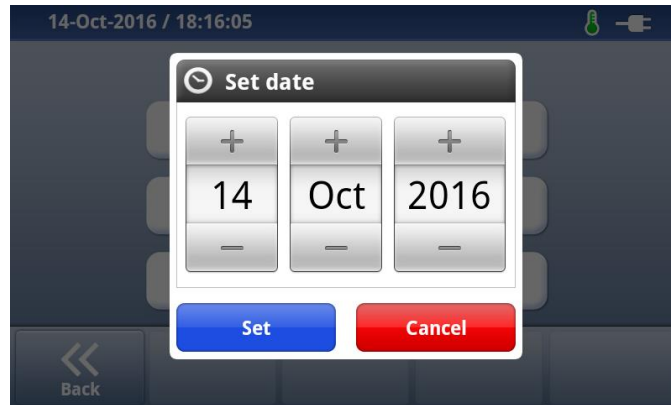
Select "ON" to enable the automatic printing of the results, "OFF" to turn off the automatic printing of the results. By default, this option is disabled.



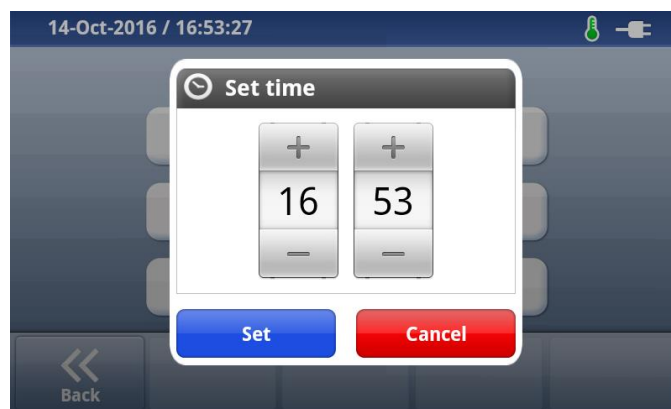
○ Date & time

This menu allows you to set the date and time. It is essential that these settings are up-to-date so that checking the expiration dates of consumables can be performed correctly.

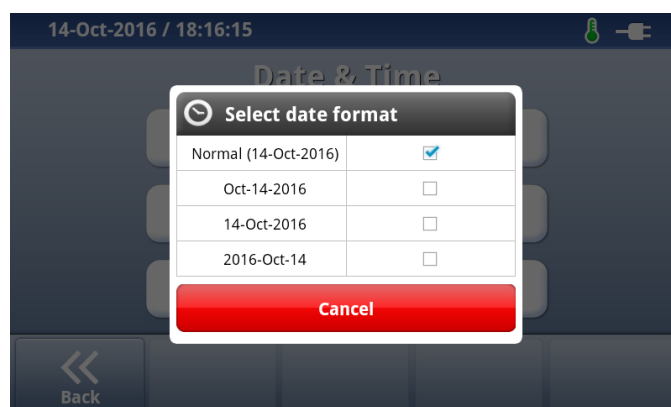
- In the menu "Settings", select "Date & time".
- Set the date using the "+" and "-" buttons.



- Save the date by pressing the "Set" button.
- Set the time using the "+" and "-" buttons.



- Save the time by pressing the "Set" button.
- Choose the date format.



- Language

Menu for selecting a language for the reader.



- Select the desired language and confirm by pressing "Yes".
 - Display
- Select the desired brightness (between 1 and 5).
- Activate or deactivate the sleep mode using the "ON" and "OFF" buttons. In sleep mode, the screen's brightness is diminished. Merely pressing the screen lets you exit this mode.
- If necessary, select the time period before putting the device to sleep (10, 20, 30, 60 or 120 minutes).



- Update

This function lets you update the application so that you can benefit from the improvements made to the reader. An update can be performed in two ways: via the USB key or via the reader's SD card.

Once the application is downloaded, save the .exe file on the USB key or the SD card. Attention: make sure you copy this file onto the root of the key/card. Do not copy this file to a folder or a sub-folder. Double-click the auto-executable .exe file.

A Speed folder is created containing the various update files. You should not change this folder.

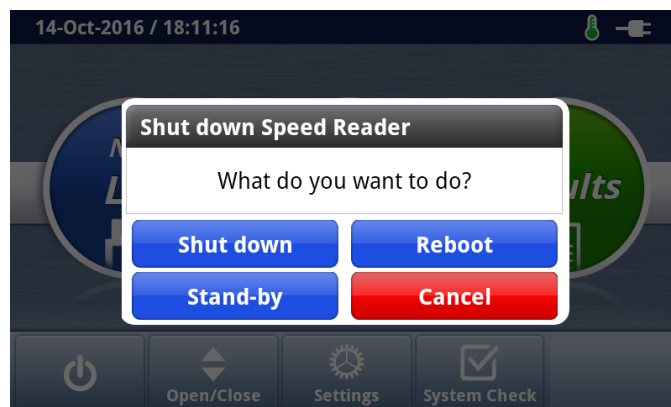
In case a Speed folder already exists on the medium prior to the activation of the .exe file, you should replace this file with a new one.

On the reader, go to *Settings/System/Update* and press "USB" or "SD card", according to the selected medium. Then follow the directions on the screen. Attention: only use the USB key or the SD card supplied with the reader. Never disconnect the key/card before the end of the update

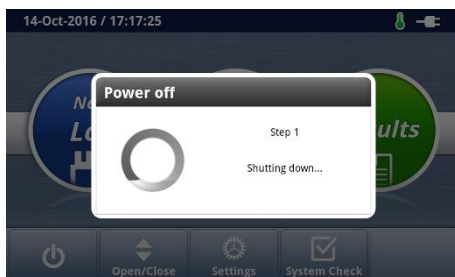
The update does not delete the data from the reader (results, settings, chips...). However, it is strongly recommended that you perform a backup on the SD card before each update (see the procedure described above).

Powering off the reader

- Return to the main screen.
- Ensure that no test tape is inserted in the loader before turning off the reader. If the loader is closed, press the "Open/Close" button on the main screen in order to perform this check.
- If necessary, make sure you close the test loader by pressing "Open/Close".
- Turn off the reader by pressing the OFF button and "Shut down".



- Next, press the "ON/OFF" button at the rear of the unit.

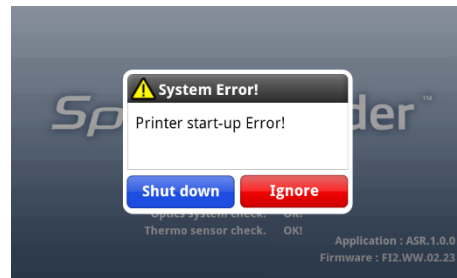
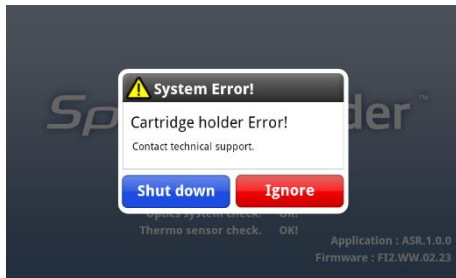


You can also restart or put the device to sleep.

You should always restart the device after an update. In the main menu, press the OFF button and then "Reboot".

You can put the device to sleep on a daily basis to avoid having to power off the device between two tests. In the main menu, press the OFF button and then "Stand-by". Sleep settings can be managed from the *Settings/Display* menu.

Error messages



Error	Cause
"Caution Error"	No check band, try again with a new tape.
"Barcode Error"	Problem in identifying the tape. Check that the barcode is not damaged or contaminated. If the problem persists, contact technical assistance.
"Mismatch Error"	The calibration chip and the test do not match.
"Can not install Lot Chip"	Try using a new calibration chip. If the problem persists, contact technical assistance.
"Optics system Error!"	Switch the unit off and restart. If the problem persists, contact technical assistance.
"Cartridge holder Error!"	
"Memory check Error!"	
"Temperature sensor Error!"	
"Printer start-up Error!"	It is not possible to print. Replace the thermal paper correctly. If the problem persists, contact technical assistance
"Temperature out of recommended range. Proceed?"	Place the unit in a room between +15°C and +35°C. If the problem persists, contact technical assistance.
"System in operation. Please wait."	The test loader is being opened or closed. Please wait.
"The expiry date of the system cartridge has passed."	Check the date and time of the device. If the expiration date has passed, the check may not work; please contact technical support.
"No record selected"	To delete, send or print data, please select at least one line.
Never disassemble the unit, even when an error occurs. If an error persists, contact technical assistance.	

Technical specifications

Name of the product	Speed Reader™
Principle	Immunological dosage through fluorescence-induced immunochromatography
Dimensions	276mmx220mmx91mm (LxDxH)
Weight	1.3 kg
Power	DC 12V/5A AC/DC Adapter Input: 100-240V ~ 50/60Hz, 1.8A Output: DC 12V/5A Batteries: non-rechargeable 1.5V x4 LR6/AA
Screen	Touchscreen, colour, LCD, 7-inch
Battery	Linear current (6V, 0.34A)
Communication ports	4 USB ports, LAN, 1 USB OTG port
Operating temperature/humidity	+15°C to +35°C 10%-70% humidity without condensation
Storage temperature/humidity	-20°C to +50°C <90% humidity without condensation
Output	LCD, printer
Results storage	1,000 test results 500 System Check
Backup of calibration chips	500 (max. 5 batches per valency)



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