MilkSafe™ Desktop Reader Connect

User Manual

CHR. HANSEN
Improving food & health

Contents

Introduction

Intended Use

The MilkSafe® Desktop Reader Connect (referred to as "the Reader") is used for digital interpretation of MilkSafe® Rapid Tests for antibiotic residues and aflatoxins in milk.

Materials Included

- Reader
- Handheld scanner, USB stick and power cable
- Digital thermometer
- Test cartridge (to be used with Milksafe™ strip tests)
- Verification strips (for calibration control)
- Thermal printer paper
- Serial to USB
- Power cable
- USB stick

Warranty

The MilkSafe® Desktop Reader Connect is covered by a warranty for 12 months against defects in materials and workmanship. This period begins from the date of first delivery, and within this period readers will be repaired or replaced as decided by Chr. Hansen A/S.

The warranty does not cover defects caused by excessive wear and tear or damage due to shipping, accident, abuse, misuse, problems with electrical power, or usage not in accordance with product instructions, if other than original spare parts supplied by the manufacturer have been used or if repairs or alterations have been performed by anyone else than the manufacturer or agents approved by the manufacturer. The warranty does not cover removable parts (such as cartridges for the test strips) or consumables. The battery included is not covered by the warranty and Chr. Hansen does not carry any responsibility of use.

Main features of the app

Run Test

When selecting the **Run test** button, the user will be presented with a list of test types activated on the reader. After selecting the desired test type, the reader will guide the user through the test process. As the reader is compatible with strip and cassetted-based tests, the reade also enable the user to perform simple end-point reading or a combined flow of incubation and reading of Milksafe™ FAST tests.

Test Records

Test records allow the user to view previous test results. Each test is represented on a single line which displays the date, test type, result, sample ID, and annotation. In case of a positive test result the reader will annotate a group of test results to form a conclusive result for multiple test in a flow (Original, 1st confirmation and 2nd confirmation).

Settings

The **Settings** button in the right-hand corner will enable the user to configure language, test types, internet connection, printer setup, scanning of QR code, enable commenting on test results, sound, date & time,

screen brightness, connect to Milksafe™ Cloud, LIMS & PLC integration, incubation and calibration verficiation, and software update.

Safety Precautions

Operating location

The location of the Milksafe™ Desktop Reader Connect should be on a desk or on a stable and level surface with enough surrounding space to easily insert the test strip/test cassette or to unplug the Reader.

The results may be influenced by vibrations .e.g, if the Reader is used close a vibrating machine, or if the Reader is positioned outside the defined temperature range.

Ambient conditions

- Temperature range: 5 to 40°C / 41 to 104°F
- Humidity: Max 80%
- Protect from water (including water splashes)

Power Supply

The instrument is powered by 100V-220V AC 50Hz/60Hz 100VA. Do not connect the Reader to any power supply outside this range.

Getting started

Setting up the Reader (standard functionalities)

1. Unpack the Reader carefully and check that the following parts are present;
   - Reader
   - Handheld scanner, USB stick and power cable
   - Digital thermometer
   - Test cartridge (to be used with Milksafe™ strip tests)
   - Verification strips (for calibration control)
   - Thermal printer paper
   - Serial to USB
   - Power cable
   - USB stick

2. Place the Readeder on a level and stable surface

3. Open the printer cover, insert thermal printing paper, and close the printer cover.

4. Connect the power supply and insert the USB stick for the hand-held scanner into the USB port on the back of the Reader

5. Turn on the Reader (switch on the left backside of the Reader)

6. Please select the preferred language

7. Connect the Reader to the internet by cable or wifi to automatically access software updates and download the latest range of test types.

8. If the Reader should be connected to Milksafe™ Cloud, please login with the username and password provided by your administrator (or Chr. Hansen representative). The Reader will hereafter automatically synchronize with the account settings determined in the Milksafe™ Cloud.

9. If the Reader is supposed to operate without any internet connection, please select the test types manually during the installation flow or afterwards in Settings

10. Determine if the Reader should enable or disable printing of test results

11. Determine if the Reader should enable or disable commenting of test results

The Milksafe™ Desktop Reader Connect is now ready for use.

Handheld scanner

The scanner is powered by a lithium battery with an estimated battery time of 18 hours. With occasional use of the scanner e.g., in milk reception area, the battery time is approx. 12-15 days. The battery model/type used is INR 19/65-2000mAh with nominal voltage 3.6V. The battery cannot be removed from the scanner during recharging.

The scanner may be used to scan the QR code on the Milksafe™ FAST tests. To activate this functionality see under advanced functionalities. Furthermore, the scanner may also be used to scan QR or barcodes during the test flow to record test related information and operator identification.

How to use the scanner

1. Insert the USB stick supplied in the assesrory box in the USB plug on the back for the Reader
2. Power-on the scanner by clicking the black botton. The light on the top of the scanner will change from Green to Blue. When the color is constant Blue the scanner is connected and ready for use. If the color stays Green, the scanner has failed to connect.
3. **IMPORTANT: Place the scanner in a 45 degree angle and approx. 10-15 cm from the QR or barcode that needs to be scanned, and press the Black button. The scanner will beep one time and the Blue light flash for a successful scanning.**
4. If there is no sound the scanner has failed to scan the object.
5. To save battery the scanner goes into sleep mode after 60 seconds

Charging the scanner

1. The scanner will make a series of beep sounds when it needs recharing
2. The scanner can be charged by using the USB power cord supplied in the assecory box
3. Insert min-usb into the scanner and the USB cord into any device with a USB port e.g., the Reader or a USB 5V1A adaptor.
4. A full recharge may take up to 4 hours, and the scanner can be used while recharging. The light on the top of the scanner will constantly Red and Blue indicating “active and charge mode”
5. If the light on the top of the scanner is only Red, the scanner is in sleep mode and can be activated by clicking the button.

Setting up the Reader (advanced functionalities)

To enable the advanced functionalities, the Reader can either be connected to Milksafe™ Cloud to retrieve the relevant account settings, and/or manually managed on the Reader:

1. Access Settings on the Reader by use of password (CH123456)

2. In Settings the Reader can be setup for:
   - Test types: Manually enable new test types if the Reader is not connected to Milksafe™ Cloud.
   - QR code setup: To enable/disable the functionality of mandatory scanning of QR codes for Milksafe™ FAST tests before starting incubation
   - LIMS: To enable/disable automatic data transfer via serial cable connection
   - Milksafe™ Cloud: Login to Milksafe™ Cloud with the username and password provided
   - Verification: Define the number of tests between each verification flow

Connectivity and data transfer

The Reader supports various usage scenarios and modes of data transfer:

1. By installing the Reader without internet or cabled serial connection the Reader will function as a stand-alone device and support manual data export by USB.
    - Go to **Test Records** on the home screen
    - Insert a USB stick on the back of the reader
    - Select **Export all** and determine the preferred file type (Excel or CSV). The data will than be exported to the inserted USB stick.

2. By connecting the Reader to the internet and/or serial cabel connection. Data transfer is performed in real-time to Milksafe™ Cloud and/or local systems e.g., LIMS, PLC, SQL etc.

    - For data export via serial cable:
        - Go into **Settings** on the home screen (password "CH123456")
        - Select **LIMS** and enable data export. Everytime a new test result is performed, the reader will export the test result via serial cable
        - Connect the reader using the data cable provided by inserting into the COM port on the back of the reader and USB into a PC.
        - Setup the device management on PC by;
            - BaudR: 9600
            - DPaity: None
            - DataB: 8 bit
            - StopB: 1 bit
            - Data format: UTF8
            - Data transfer mode: One-way communication
        - The text string transmitted will start with "R" and end with "1234". Word separation will be perform by "|"
        - The data being transmitted is:
            - Date & Time
            - Reader serial no.
            - Operator ID
            - Sample ID
            - Overall result
            - Substance name(s)
            - Substance ratio(s)

    - For data export to Milksafe™ Cloud:
        - Go into **Settings** on the home screen (password "CH123456")
        - Select **Milksafe™ Cloud** and enable login with the username and password privded by the administrator or Chr. Hansen representative.
        - The test records on the Reader and any future test results will hereafter be automatically exported to the cloud from where test records can be exported.

3. The Reader is not supported by any proprietary software e.g., PC Data Manager

Updating the Reader software

It is recommend to keep the device updated with the newest software to enable new features, test types etc. The software can be found on Milksafe ™ Downloads, or downloaded automatically from Milksafe™ Cloud if the Reader is connected to the internet.

- To perform a manual software update:
  - Export the data stored on the Reader by use of USB (see section on **Connectivity and data export**)
  - From Milksafe™ Downloads obtain the necessary software package
  - Unzip the file and transfer the folder "Update" to the empty USB provided in the assesory box with the Reader.
  - Insert the USB stick on the back the reader
  - Go into **Settings** on the home screen (password "CH123456")
  - Select **Software updates** and select **USB update**
  - The reader will hereafter start the installation and restart the devices.

- To manully initiate software update from Milksafe™ Cloud.
  - Go into **Settings** on the home screen (password "CH123456")
  - Select **Software updates** and select **Net update**
  - The Reader will hereafter verify if a new software version is available on Milksafe™ Cloud. The Reader will download and install the new software and restart the device.

- OBS: If the Reader is connected to Milksafe™ Cloud a notification will display on the home screen when a new software version is available from Milksafe™ Cloud.

Reader Operation

Reading test strips (or pre-incubated cassette tests)

1. Turn on the Reader.
   The Reader will take approx. 5-7 minutes to reach the desired temperature of 50 degrees Celsius. If the Reader was heated up to 50 degrees Celsius and the specific temperature of the test required is 40 degrees Celsius, the Reader will take approx. 3 mininuttes to go down to the lower temperature.

2. Select **Run Test** on the main screen

3. Select the preferred test type (if the relevant test type does not appear, see previous section on setting up the Reader)

4. OBS!! Milksafe Afla M1 is a quantitative test, please load the required standard curve into the reader by using the supplied data chip from the test box. The curve only needs to be loaded one time per batch.

5. Fill out the operator ID and press continue (the hand-held scanner may be used for scanning any barcode or QR code in this sequence)

6. Fill out test related information and press continue (the hand-held scanner may be used for scanning any barcode or QR code in this sequence)

7. Insert the test strip into the supplied standard carridge and fully insert the cartridge into the reader housing. Press **Start Test**, or for Milksafe FAST insert the cassette in the Reader and press **Read only**

8. The reading will start automatically and show the **Result** screen after a few seconds.

9. Interpret the result: Positive and Weak Positive results are shown with a X for each antibiotic tested. Negative results are shown with a ✓. The numbers given represent the line ratio: the intensity of the test line divided by the intensity of the control line. For qualitative tests, the ratio cannot be used quantitative purposes.

Ratio <0.9:	Positive
Ratio 0.9-1.1	Weak positive
Ratio >1.1	Negative

10. The test result is automatically saved in the Reader, and if connected with Milksafe™ Cloud the test result will also be synchronized with the cloud. If commenting has been enabled on the Reader, a specific comment may be added in **Add comment**

11. If the test is a positive control, the test result can be annotated by selecting the **Mark as positive control** which help separate regular test records from positive control samples

12. The test result will be automatically printed, if this functionality has been enabled on the Reader.

13. If the test result is positive, the Reader will initiate a confirmation flow to determine the validity of the initial positive test result. Please see section performing a confirmation flow

Incubating and reading cassette tests (Milksafe™ FAST)

1. Turn on the Reader

2. Select **Run Test** on the main screen

3. Select the preferred test type (if the relevant test type does not appear, see previous section on setting up the Reader)

4. If scanning QR code has been enabled on the Reader, please scan the unique QR code on the cassette by using the hand-held scanner supplied with the Reader

5. Fill out the operator ID and press continue (the hand-held scanner may be used for scanning any barcode or QR code in this sequence)

6. Fill out test related information and press continue (the hand-held scanner may be used for scanning any barcode or QR code in this sequence)

7. Pipette the milk into the cassette and insert fully the cassette into the Reader housing. Press **Incubate and Read**

8. The incubation will start automatically and after the defined incubation time the Reader will automatically interpret the test result and show the **Result** screen after a few seconds.

9. Interpret the result: Positive and Weak Positive results are shown with a X for each antibiotic tested. Negative results are shown with a ✓. The numbers given represent the line ratio: the intensity of the test line divided by the intensity of the control line. For qualitative tests, the ratio cannot be used quantitative purposes.

Ratio <0.9:	Positive
Ratio 0.9-1.1	Weak positive
Ratio >1.1	Negative

10. The test result is automatically saved in the Reader, and if connected with Milksafe™ Cloud the test result will also be synchronized with the cloud. If commenting has been enabled on the Reader, a specific comment may be added in **Add comment**

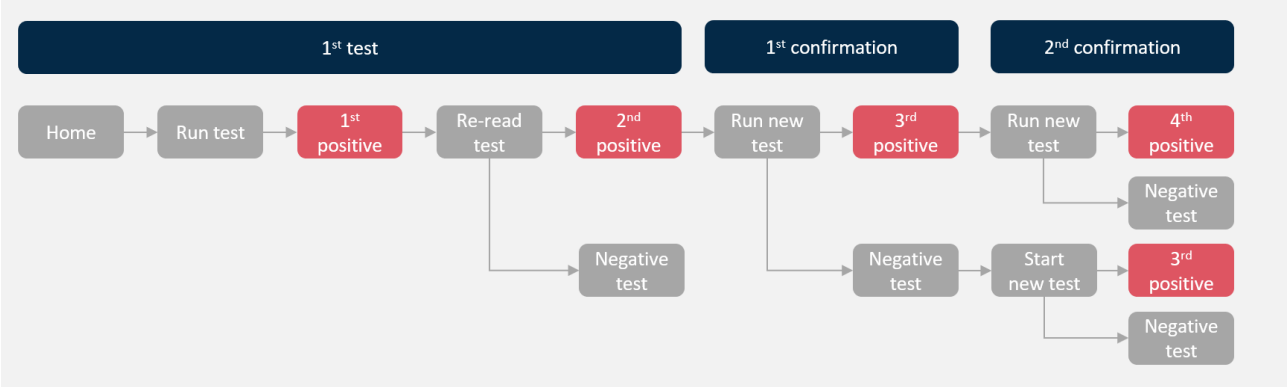
11. If the test is a positive control, the test result can be annotated by selecting the **Mark as positive control** which help separate regular test records from positive control samples

12. The test result will be automatically printed, if this functionality has been enabled on the Reader.

13. If the test result is positive, the Reader will initiate a confirmation flow to determine the validity of the initial positive test result. Please see section performing a confirmation flow.

Performing a confirmation flow

A confirmation flow will be initiated on the Reader when the test result is positive or weak-positive (ratio <1.1). Please see below flow chart for illustration:



1. The confirmation flow will be actiaved upon the 1st positive result. Please reposition the same strip/cassette into the Reader and select **Re-read test** on the result screen. This step will eliminate any false positives due to position issues of the test.

2. If the **Re-read test** result remains positive. Please initiate the confirmation flow by incubating and reading a new test. Select **Run confirmation test** on the Reader to initiate this step.

3. To complete the confirmation flow. Please run the 2nd confirmation test by incubating and reading a new test. Select **Run second confirmation test** on the Reader to complete this step.

4. The overall test result is therefore based on the flow of tests performed:

1st Test	1st test re-read	1st confirmation	2nd confirmation	Overall test result
Positive	Negative	-	-	Negative
Positive	Positive	Positive	Positive	Positive
Positive	Positive	Negative	Negative	Negative
Positive	Positive	Positive	Negative	Inconclusive
Positive	Positive	Negative	Positive	Inconclusive

5. Despite an overall flow result, the individual test results gets annotated according to their position in the flow and the annotation will be displayed in **Test records** on the Reader.

Test	Test result	Annotation
1st test	Positive	Rejected
1st test re-read	Positive	Original
	Negative	"Blank"
1st confirmation	Positive or Negative	Confirmation
2nd confirmation	Positive or Negative	Second confirmation

Test Records and Export data

- To view previous test results, select **Test Records** on the home screen of the Reader. The Reader has a storage capacity of approx. 100,000 test results.
- To navigate up and down use the **Page up** and **Page Down** buttons.
- To export the test results, select **Export all** and determine if the export should be in CSV or Excel.
- To view additional details, please select the specific test result and the complete details will display in a new window
- From the detailed view you can **Add comment** to the test result and **Print** the details

Reader verification

To verify the health of the Reader and secure accuracy in the measurements performed, it is recommended to perform a verification test of the Reader on a routine basis. A notification to perform a verification test will automatically display for each 500 tests performed on the reader.

Determing the internval between verification tests

To set a specific interval between each verification test or to manually initiate a verification test, please follow these steps:

- Go to **Settings** on the home screen (password CH123456)
- Select **Verification test**
- Type in the number of tests between each verficiation test and press **Save**
- To manually initiate a verification test, select **Start verficiation now**
- To view previous verification tests, select the **Verification history**

Verification procedure

To perform a verification test the user is required to use the supplied thermometer and standard strips accompanying the reader.

1. Initiate the verification test from the notification message on the home screen or from **Settings**
2. Make sure the temperature is stabilized on the Reader and external thermometer before entering the displayed temperature. This may take 1-2 minutes.

3. Select the standard test corresponding to the regular test performed on the reader e.g., for Milksafe FAST 3BTC, please select the standard test cassette with 5 lines and press **Start test**

4. Upon completion of the verification test, the Reader will deplay the results for temperature and reader verification on the final result screen. The verification may fail if;
   - the measured temperature with the external thermometer is >2 degrees (+/-) from the defined temperature on the Reader e.g., measured 53 degrees Celsius versus 50 degress Celsius defined for the test type.
   - The verification reading is outside the interval of ratio 0.9-1.1.

Maintenance Notes

Regular cleaning of the Reader

It is recommended to clean the Reader on a regular basis. If you use the Reader in a working area that is subject to dust or contamination, you should clean the Reader more often. Use a dry cloth to clean the Reader. If the contamination is persistent, you can also rub the surface of the Reader with a cloth that has been moisturized with pure alcohol (isopropanol or ethanol). Do not use aggressive cleaning agents such as acetone.

Cleaning of the Reader in case of milk spillage

OBS: Before cleaning the instrument turn-off the power and remove the power cord to avoid any short-circuit and electric shock hazards.

1. Prepare a 75% alcohol or ethanol cotton pad/swab. Do not use strong bleach as oxidants and solvents may damage the housing and touch screen.

2. Clean the outside of the instrument by using the prescribed resolution above. Gently wipe the surface or the instrument and try to avoid the edges of the display to prevent alcohol/ethanol from infiltrating the screen causing display faults.

3. To thoroughly clean the cassette slot, please remove the outer protection by pulling downwards. Do not pull outwards, as it will break the clamps on the upper backside.

4. After removing outer protection use a cotton swab dipped in 75% alcohol or ethanol to clean the cassette slot.
5. If milk residues are visible on the lens, gently clean the lens by use of similar cotton swab and 75% alcohol or ethanok. Then use a clean and dry cloth to wipe the lens, or wait for it to dry naturally.
6. After cleaning the cassette slot. Turn on the reader and run a verification flow to certify the reader return normal values.

OBS: If the optical module (lens) by mistake has been touched, please run a **Verification test** to check calibration of the reader.

Service and repairs

For all service or repair needed beyond the regular verification protocol, exchange of external devices e.g., hand-held scanner etc., please contact your local Chr. Hansen representative for assistance. Attempts to open or repair the Reader by non-authorized personnel will void the warranty.

Experts for the dairy industry

Chr. Hansen believes in improving the quality of food and health. We believe the best results are achieved when working closely with you.

Our experienced application and industry specialists provide you with the knowledge, inspiration, support, and customized solutions you need to be successful.

Contact your local Chr. Hansen representative to learn more about how we can work together to find the perfect solution for you.

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