

# Instructions for Use – Cube DataReader SW

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Instructions for Use – Cube DataReader Software

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## 2 Symbols

	Attention! Important and safety-relevant information
	Manufacturer
	Please follow the instructions for use
	CE symbol

## 3 Intended Purpose

**Software accessory (PC); only to be used in combination with Cube Reader;** Allows result data export from reader to PC and control of the reader through the software via the PC.



Please also follow the instructions for use of the Cube Reader.

## 4 Scope and general information

Thank you for choosing this product.

The Cube Reader is a photometer, intended for the qualitative, semi-quantitative or quantitative measurement of the optical density of lines on test strips used in Lateral Flow Assays (LFAs) / rapid tests for in-vitro diagnostics.

The measurement results can be stored internally. In addition to its own measurement ID (identification number of the measurement), each measurement result contains the test name, lot number, the name of the test manufacturer, as well as the date and time of the measurement. The measurement results can be read out via a special USB cable using the Cube DataReader software. The device is battery operated but can also be powered via the USB cable.

For the end user the software provides a user-friendly setup wizard for installation and is easy to use.

## 5 Liability exclusion



**Results obtained from the device shall never be used as the sole basis for making a diagnosis.**

## 6 Installation

### 6.1 System requirements

Operating system:	Windows 7 (SP1), or higher
Processor:	Pentium III or higher, AMD Athlon XP or higher
Main memory:	Min. 1 GB
Hard disk:	Min. 1 GB free
Screen resolution:	Min. 1366 x 768

### 6.2 Run software without installation

The software can be run without installation for evaluation purposes. If not already installed on the PC it may be necessary to install the FTDI driver to establish a connection between reader and PC. You can find out if the driver is installed by connecting the switched-on reader with the PC via provided USB cable. If the device is recognized by the PC the driver is already installed. If the device is not recognized, please visit the following website to download the required driver according to your system characteristics: <http://www.ftdichip.com/Drivers/VCP.htm>



**Please disconnect the device from the PC for the driver installation and do not connect the device to the computer again before the installation of the driver is complete.**

After the driver installation has been successful the software can be started, and the device can now be connected to the computer.

To run the software the file **“Cube DataReader Software - XXX.exe”** must be run on the computer. The connection is only possible by using the provided USB cable. If the device is still switched off at that moment it can be switched on now.

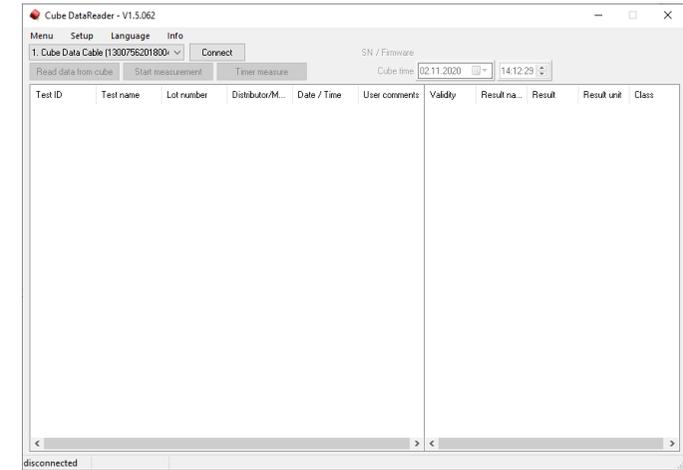
### 6.3 Software installation via setup installer

For end users, an installation setup is provided for installing the software on a PC. Double-click on the installation file **...setup.exe** to start the installation.

Follow the installation wizard step by step to complete the installation successfully. After installation, the program can be started via the Windows Start menu or the according desktop icon.

## 7 Concept

After starting the software, the following window can be seen:

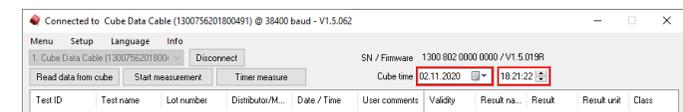


The main software consists of one tab. The major functions can be selected directly by pressing one of the four buttons. All results will be presented in the main window as well as the results done using the remote measurement function. Additionally, the top part of the software holds a menu bar and information about the reader status. The bottom left side of the software window informs about the status of the software.

## 8 Connecting the reader

To extract data from the reader memory or to perform remote measurements with the DataReader Software the reader must be connected to the software first. Switch on the reader and connect it to the PC via the provided USB cable. As soon as the reader is ready for operation the software will automatically try to connect to the reader. This automated process is preconfigured after installing the software and can be switched off later.

If the option is turned off, it is also possible to connect the reader manually. Therefore, choose a reader from the drop-down menu at the top left side and click on “Connect”.



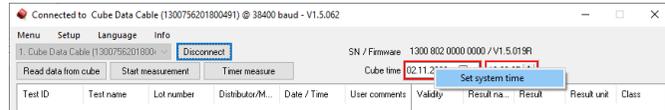
The reader is connected successfully if the serial number in the drop-down menu on the left top side fades out, the serial number and firmware version is shown on the top right side, if date and time settings are highlighted either by green or red and if the button besides the drop-down menu will show “Disconnect”.

## 9 General software settings

General software settings are placed in the top part of the software.

### 9.1 Setting date and time

After connecting the reader to the computer, the software automatically checks the internal clock of the reader and compares it to the time of the computer the reader is connected to. Incorrect clock settings are indicated by a red frame, whereas correct clock settings would be indicated by a green frame.



To set the date and time move the cursor above the time information and right click into the information. The option to set the system time is presented. This will automatically set the system time of the reader according to the time of the PC. It is also possible to set the system time manually by using the drop-down menus which can be selected by clicking the buttons integrated in the frame.

### 9.2 Menu

When clicking on "Menu" the following window will appear:



The reader needs to be connected to the software, turned on and saved measurements should have been read to have all options selectable. Options available are:

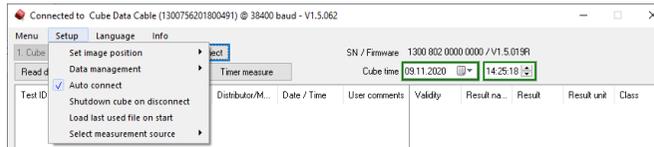
- **Delete measurement list:** By choosing this option all entries in the current list will be deleted.
- **Save data to file:** By choosing this option a window will open which allows selecting a location on the local file system to save the measurement results as a TSV file (tab separated values). Such a file can be directly opened with MS Excel; all information will be separated into different columns.
- **Load data from file:** By choosing this option a previously saved measurement list can be reloaded. The list must be a TSV file.
- **Format cube database:** By choosing this option the reader database/memory will be formatted. All data will be permanently deleted.



**Make sure to download all data before formatting the Cube database, because all data will be deleted permanently.**

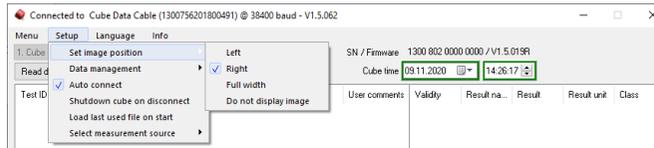
### 9.3 Setup

When clicking on "Setup" the following window will appear.:

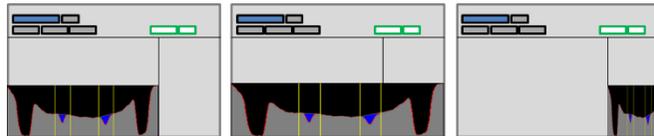


Any option can be activated by clicking on it. Activated options are indicated by check marks [ ✓ ]. Options available are:

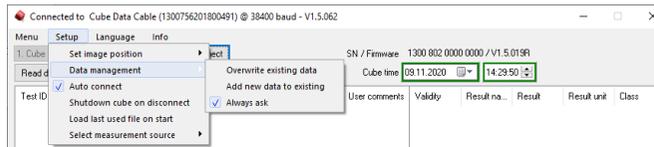
- **Set image position:** When doing a manual measurement by choosing "Start measurement" from the main window, this option determines where to place the picture of the 2D volume diagram in conjunction with the result list. Three different locations are selectable, it is also possible to deactivate this information by choosing "Do not display image".



Possible image positions are the following.



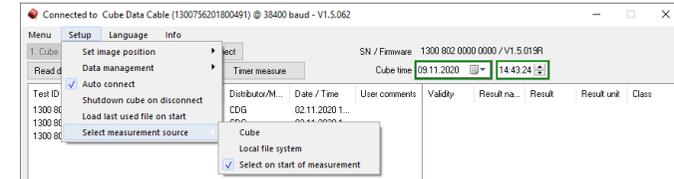
- **Data management:** This option allows choosing how the DataReader software will proceed with new data either just measured or downloaded if there is already data in the list.



The following options can be selected:

- **Overwrite existing data:** By choosing this option all entries in the list will be deleted when adding new data either by doing a remote measurement or by adding data from another Cube Reader.
- **Add new data to existing:** By choosing this option all entries in the list will remain when adding new data either by doing a remote measurement or by adding data from another Cube Reader.
- **Always ask:** The user will always be asked how to manage new data. The user can choose between adding the data and overwriting the existing data.
- **Auto connect:** By choosing this option the user can decide whether the software shall automatically connect to the reader or if the connection shall be done manually.

- **Shutdown cube on disconnect:** By choosing this option the reader gets deactivated when being disconnected from the software.
- **Load last used file on start:** By choosing this option the recently saved measurement list will be restored when restarting the software.
- **Select measurement source:** By choosing this option the source for loading the test-specific configuration for a remote measurement can be selected.

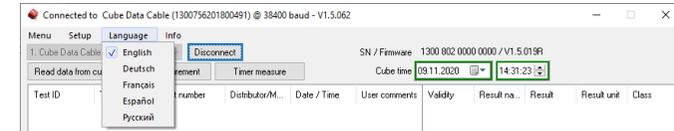


The following options can be selected:

- **Cube:** The test-specific configuration will be loaded through the reader by using an RFID card.
- **Local file system:** The configuration must be selected from the local file system.
- **Select on start of measurement:** The user will always be asked when a measurement is started which of the above option they want to choose.

### 9.4 Language

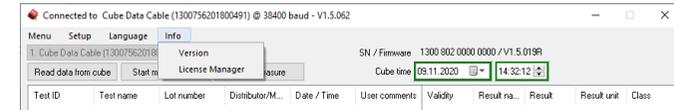
When clicking on "Language" the following window will appear:



This feature will allow changing the language of the software.

### 9.5 Info

When clicking on "Info" the following window will appear:

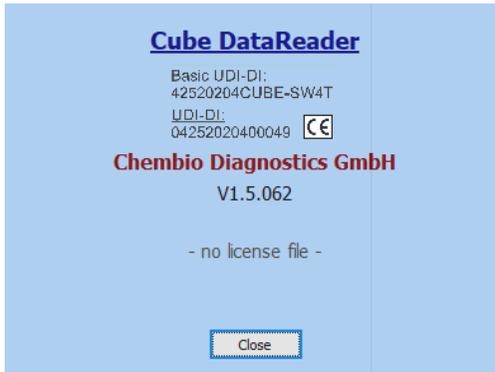


This feature holds two options: **Version** and **License Manager**.

By choosing **version**, the software shows the current version including the confirmation of validity and the information how long it will be valid. The **License Manager** informs about all installed licenses. In case one customer uses readers from other customers different license files are required.

### 9.6 Validating the software

Compared to the configuration software the DataReader is not PC dependent. Nevertheless, a license file is requested to operate the software. By clicking on **Info** and **Version** the status of validity will be shown.

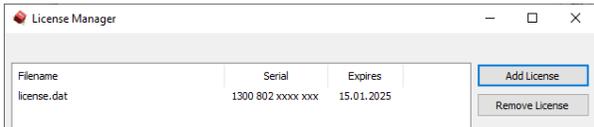


After receiving the license file, it must be implemented in the software. This can either be done by copying the license file directly into the folder where the software is located or using the License Manager.



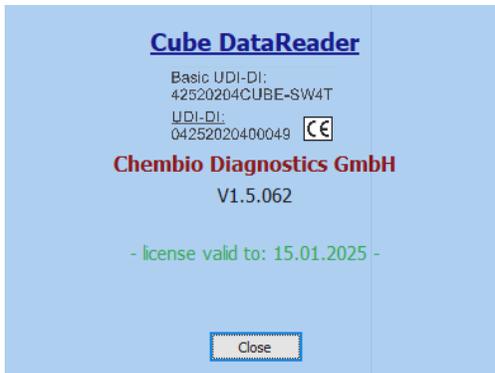
**When choosing the option of copying the license file into the program folder it is important to use exactly the name: “license.dat”. If the file is named differently the software is not able to recognize the license file automatically.**

The second and recommended option is to use the “License Manager”.



To activate a license, click on “Add License”, a window will pop up where you must state the location of the license file to upload it.

To check if the software is activated successful click on “Info/Version” again. The window will now say that the software is valid up to a certain date.



Each customer will have their own license which allows high data security since each RFID tag is encrypted using parts from the customer ID given by Chembio.

In case one customer is allowed to operate Cube Readers or RFID tags of a third-party customer, a second license file is needed which includes necessary information of the third-party customer. The second license file can be added the same way as the first one.

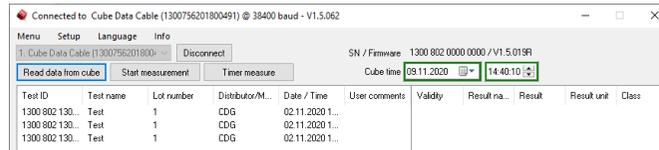
### 9.7 Information on bottom bar

The bottom bar of the software holds information about the status of the software, e.g., if it is transmitting data or measuring.



## 10 Reading data from memory

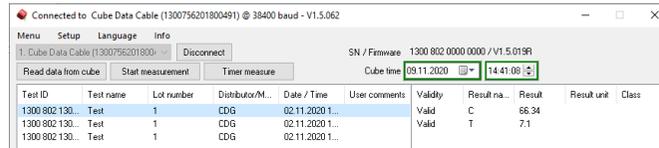
To read measurement data from the reader the device must be successfully connected to the software. By clicking the button “Read data from cube” the software will read the memory and display every saved measurement result.



The result display is separated into two parts. The first part, left window, lists all measurements using the OEM information defined in the configuration. The list contains information about the Test ID, which is a unique number added by the reader to each measurement result, Test name, Lot number, Distributor/Manufacturer and Date/Time. The sixth column is meant for “User comments” allowing adding a comment manually. This can be done with every entry listed.

It is possible to sort the entries in alphabetical or value-dependent matter. This can be done with every column.

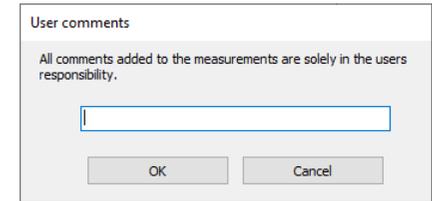
By clicking on one of the entries, the actual result values will be presented in the second list on the right side of the window. This is necessary since each measurement can include up to ten different results. The second list will show the Result name, the actual Result, the Result unit and the Class if defined in the configuration file.



It is possible to sort the entries in alphabetical or value-dependent matter. This can be done with every column.

### 10.1 Adding a user comment

To add a user comment, double-click into the measurement list on the entry intended to add a comment. A window will open where the comment can be added.



After hitting “OK” the comment will be automatically added to the list.



**All comments added to the measurements are solely in the user’s responsibility.**

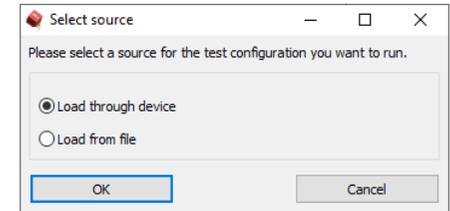
## 11 Remote measurement

The DataReader Software allows doing a remote measurement, either a manual one or a timer measurement.

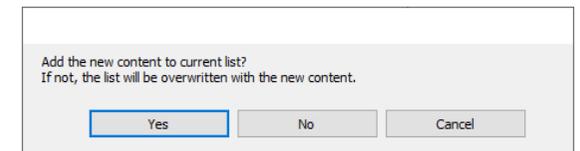
### 11.1 Manual direct measurement

To start a manual remote measurement just click on the “Start measurement” button, besides the button “Read data from Cube”.

If the option is activated to select the measurement source of the test-specific configuration on start of measurement (“Setup/Select measurement source/Select on start of measurement” v ; 9.3 Setup), the first window will ask to select the source for loading the configuration.



If the option is activated to always ask if new measurement results shall be added to the list or overwrite the list (“Setup/Data management/Always ask” v ; 9.3 Setup), the next information window presented will ask how to process the measurement result considering the list already includes data.



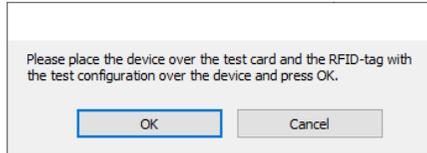
If “Load from file” or “Setup/Select measurement source/Local file system” was selected the third step will be a browser window to select the configuration for measurement from the local system. Put the test in position for measurement below the reader and select the configuration; the measurement will be started immediately after selecting the configuration.



**Be aware that if the overwriting function is activated the already listed data gets lost if not saved as soon as the new measurement starts. Make sure to have the data saved.**

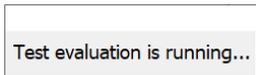
If “Load through device or “Setup / Select measurement source / Cube” was selected instead the third window will ask to put the reader above the test and to hold the RFID tag above the reader.

If the options “Always ask” and “Select on start of measurement” are disabled, this information will be the first one when selecting a manual remote measurement.

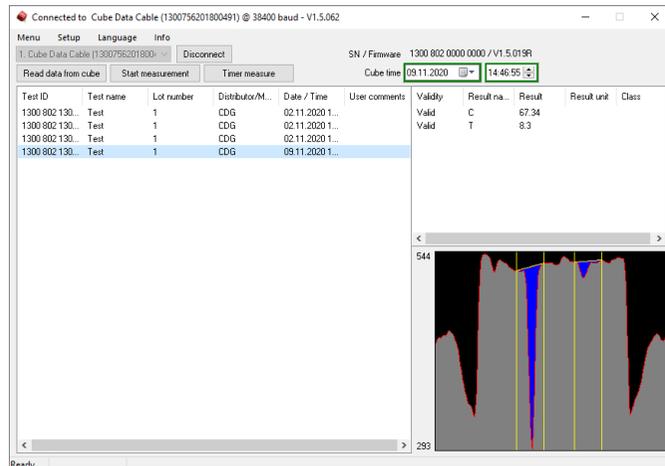


The RFID information will be loaded into the access memory of the reader. Every current condition is also shown in the display of the reader, in this case “RFID”.

After the RFID information has been loaded the reader starts the measurement. This is indicated by the following information:



When the measurement is done, the results will be added to the list and the 2D volume diagram will be presented at the position determined in 9.3 Setup.



All information concerning the demo measurement can be seen, OEM information, measurement result values and the 2D volume diagram.

The data can now be saved to a file. The file will be in TSV format and will include the information of the 2D volume diagram as intensity values per pixel. The TSV file can be opened with Excel and the data can be used to redraw the 2D volume diagram.

This feature can help to surveil lot specific changes by a superposition of multiple graphs.

### 11.2 Timer measurement

In addition to the manual remote measurement, it is possible to perform a timed remote measurement if defined in the measurement configuration. The timer measurement is meant for tests which require a specific incubation time before the test lines have fully developed.

To start a timer measurement, click on the button “Timer measure”. The procedure of measuring equals the one for the manual measurement. Please refer to 11.1 Manual direct measurement to get to know the procedure.

After the test configuration has been loaded the software opens a window to display the countdown.



After the countdown has run off the measurement starts and is indicated to the user. After the measurement is done the results will be displayed and can be processed like the ones from a manual measurement.

## 12 Manufacturer information



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**For support when using with specific tests, please contact your distributor first.**