# Coffalyser.Net™ Installation Manual

For Coffalyser.Net version 220513.1739

## INTENDED PURPOSE

Coffalyser.Net is in vitro diagnostic (IVD)[1] or research use only (RUO) software designed for the analysis of (MS-)MLPA data generated using a SALSA® MLPA® probemix[2] as described in the (MS-)MLPA General Protocol.

The results obtained with Coffalyser.Net analysis software should be interpreted by a clinical molecular geneticist or equivalent.

[1]Coffalyser.Net analysis software is registered for in vitro diagnostic use (IVD) in the countries specified at the end of this manual. In all other countries, Coffalyser.Net analysis software is for research use only (RUO).

[2]To be used in combination with a SALSA MLPA Reagent Kit, SALSA HhaI, and SD0XX as specified in the product description of the application-specific probemix.

# TABLE OF CONTENTS

# 1. INTRODUCTION

## 1.1 COMPONENTS AND SETUP POSSIBILITIES

Coffalyser.Net consists of three components that interact with each other:

1. The Coffalyser.Net Client. This is the end-user application and forms the user interface.
2. The Coffalyser.Net database. All information is stored in the database, including raw data, experiments and user accounts.
3. The Coffalyser.Net Server Service. This service connects the Coffalyser.Net Client and the Coffalyser.Net database.

By default, all components of Coffalyser.Net are installed on the same computer. This is best suited for users who do not have to share data and requires limited computer knowledge.

Coffalyser.Net supports user accounts (see this support article for more information). If sharing a single database with multiple users is desired, more advanced network installations are also possible. The components of Coffalyser.Net can be split over separate computers. These setups are intended for professional network environments and advanced users, and may require assistance from your IT department. More information on advanced setups can be found in this support article.

## 1.2 SYSTEM REQUIREMENTS

- A genuine 32/64-bit version of Windows still supported by Microsoft.
- The latest Windows updates installed.
- Microsoft.Net Framework 4.8.
- A Microsoft SQL Server still supported by Microsoft to host the Coffalyser.Net database. If no SQL database server is available, Coffalyser.Net can install a preconfigured[1] instance of Microsoft SQL Server 2014 SP3.
- 3 GB of available RAM.
- 10 GB free disk space.
- Administrative rights during installation (not required for running Coffalyser.Net).

Antivirus software and firewalls might interfere with the installation process. In case the installation of Coffalyser.Net cannot be completed, we recommend switching these off temporarily and retrying the installation of Coffalyser.Net.

---

[1]All relevant details of the preconfigured SQL server, needed for the establishment of the connection between the Coffalyser.Net Client and the SQL server, are automatically filled in during configuration.

If an existing, non-preconfigured SQL database server is used, knowledge of specific details of the SQL server (e.g. location, login credentials, authentication method) is needed to establish the connection between the Coffalyser.Net Client and the SQL server.
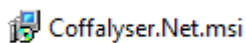
IMPORTANT NOTES:

- Coffalyser.Net is registered for in vitro diagnostic (IVD) use in the countries specified at the end of this manual. In all other countries, this product is for research use only (RUO). Please note that when Coffalyser.Net is used with RUO MLPA products, diagnostic decisions based on the results obtained with this program are the sole responsibility of the user.

- Ensure to use the latest version of Coffalyser.Net and the Coffalyser.Net Reference Manual. The latest versions are available online at www.mrcholland.com.

- For professional use only. Always consult the most recent product description AND the (MS-)MLPA General Protocol before use. These are available online at www.mrcholland.com. It is the responsibility of the user to be aware of the latest scientific knowledge of the application before drawing any conclusions from findings generated with this product. Serious incidents that have occurred in relation to the device shall be reported to MRC Holland and the competent authority of the Member State in which the user and/or the patient is established.

- The Summary of Safety and Performance will be available in the European database on medical devices (Eudamed): https://ec.europa.eu/tools/eudamed.
  - Basic UDI-DI: 872021148Coffalyser.NetVM

## 2. INSTALLATION

To analyse MLPA data with Coffalyser.Net you first need to install and configure the software according to the procedures below.

### 2.1 INSTALLATION OF COFFALYSER.NET

1. Log in to your MRC Holland account on www.mrcholland.com.

2. Navigate to *Software* in the account menu and select *Coffalyser.Net*.

3. Under the header Downloads, click on *Coffalyser.Net – application download* and save the file at the desired location.

4. Extract the zip file.

5. Start the installation by opening the Coffalyser.Net.msi file.

    Coffalyser.Net.msi

   🖥 The Coffalyser.Net installation wizard opens.

6. Maximize the Coffalyser.Net installation wizard from the task bar if this does not happen automatically.

7. If it is desired to install Coffalyser.Net at another location than the default, click **Browse**. If the default location is ok, click **Next >**.

8. Click **Next >** to start the installation.

9. If prompted, click **Yes** in the User Account Control window.

10. Ensure that the check box *Launch Coffalyser.Net* is checked and click **Close**.

### 2.2 CONFIGURATION OF A COFFALYSER.NET SERVER SERVICE

Configuration of a local Coffalyser.Net Server Service is required for the default installation with all components on the same computer. This procedure is not required if you plan to connect to a Coffalyser.Net Server Service hosted elsewhere within your network. In that case select an existing server in the Server Selection dialog.
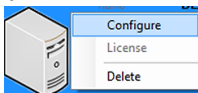
1. If Coffalyser.Net was not launched, start it via the shortcut on the desktop.

   

2. Click **I Accept** to accept the license agreement of Coffalyser.Net.

   🖥 The Coffalyser.Net Server Selection dialog opens.

3. In the Coffalyser.Net Server Selection dialog, right-click on the server with the name of your computer and select *Configure*.

4. Click Yes to enter configuration mode.

5. If prompted, click Yes to restart and elevate in order to run with administrative privileges.

6. If prompted, click Yes in the User Account Control window.

   🖵 The Coffalyser.Net – Configuration Wizard opens.

7. Click Next >.

8. Click Install to install the Coffalyser.Net Server Service and then Next >.

9. Choose one of the options below:

   • If Coffalyser.Net has not been installed before on this computer and you want to install a preconfigured SQL database server, select option 1: *I want to install a new SQL 2014 (SP3) database server on this computer (preconfigured for the Coffalyser.Net)*.

   • If you want to update Coffalyser.Net to the latest available version AND you want to use a previously installed, preconfigured SQL database server, select option 2: *I want to use a previously installed SQL database server on this computer (preconfigured for the Coffalyser.Net)*.

   • If you want to use an existing, non-preconfigured SQL database server, select the option *I want to use a previously installed SQL database server on this or a remote computer (not pre-configured)*.

10. Click Next >.

    ℹ️ FOR THE PRECONFIGURED SETUP OF A FRESH INSTALLATION, CONTINUE WITH STEP 12. FOR THE PRECONFIGURED SETUP OF AN UPDATE, CONTINUE WITH STEP 11. FOR THE NON-PRECONFIGURED SETUP, PROCEED WITH STEP 23.

11. Click Next >.

12. If prompted, start the SQL Server Installation Wizard, either by:

    • Checking the check box *start the SQL Server installation wizard* and clicking Finish (in case of a fresh new installation)

    • Clicking Yes (in case of updating to the latest version).

    When neither option is presented, continue with step 23.

    🖵 The Coffalyser.Net – SQL Server Installation Wizard opens.

13. Maximize the Coffalyser.Net - SQL Server Installation Wizard from the task bar if this does not happen automatically.

14. Click Next >.

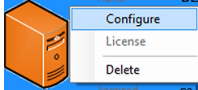15. Check the check box to either install or upgrade to SQL 2014 SP3 and click Next >.

16. Check the check boxes *try to delete the temporary folder created by this program* and *Start the Coffalyser.Net application* and click Finish .

    🖥 Coffalyser.Net opens.

17. In the Coffalyser.Net Server Selection window right click on the (orange) server with the name of your computer and select *Configure*.

    

18. Click Yes to enter configuration mode again.

19. If prompted, click Yes to restart and elevate in order to run with administrative privileges.

20. If prompted, click Yes in the User Account Control window.

    🖥 The Coffalyser.Net – Configuration Wizard opens.

21. Click Next > twice.

22. Select the option *I want to use a previously installed SQL database server on this computer (preconfigured for the Coffalyser.Net)* and click Next > .

23. Enter the details of the SQL server if these have not been filled in automatically, and click Next > .

24. Enter a name for the database. By default this is *Coffalyser*.

    Click Next > .

25. If prompted, check the check box *upgrade the database* and click Next > .

26. If prompted to create a new Coffalyser.Net database, create a name for the first organisation, a password, a secret question, and answer.

When done, click $\boxed{\textbf{Next >}}$ .

27. Do not change the server description and click $\boxed{\textbf{Finish}}$ .

28. Ensure that the check box *start the Coffalyser after the wizard is closed* is checked and click $\boxed{\textbf{Close}}$ .

29. If the server in the Coffalyser.Net Server Selection window is orange, install your license as described in the chapter **3 LICENSE** on page 9. If the server is green, you do not need to install your license.
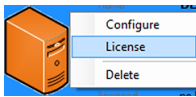
## 3. LICENSE

Before you can log in and use Coffalyser.Net, you need to activate the software by installing your free license key. This can be done by downloading the license directly from within Coffalyser.Net. When you cannot download the license (e.g. because you do not have internet access or because of network security settings), you can also import a license file.

Your license key and license file can be found in the section *Coffalyser.Net* of your MRC Holland account on www.mrcholland.com.

These procedures can also be used to renew an existing license.

### 3.1 INSTALL OR RENEW LICENSE BY DOWNLOADING FROM WITHIN COFFALYSER.NET

1. Open Coffalyser.Net.

2. In the Coffalyser.Net Server Selection dialog, right-click on the server with the name of your computer and select *License*.



🖥️ The Coffalyser.Net License dialog opens.

ℹ️ IF YOUR LICENSE KEY IS ALREADY SHOWN, PROCEED WITH STEP 6. OTHERWISE CONTINUE WITH STEP 3.

3. Log in to your MRC Holland account on www.mrcholland.com.

4. Navigate to *Software* in the account menu and select *Coffalyser.Net*.

5. Copy your Coffalyser.Net license key from the website.

6. Paste your license key in the designated field.

7. Click Download .

8. Click Always to allow Coffalyser.Net to connect to the MRC Holland server to download the license.
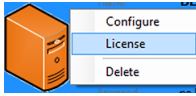
9. Click OK .

10. Click Install License .

### 3.2 INSTALL LICENSE BY IMPORTING LICENSE FILE

1. Log in to your MRC Holland account on www.mrcholland.com.

2. Navigate to *Software* in the account menu and select *Coffalyser.Net*.

3. Under the header Downloads, click on *Coffalyser.Net – license file* and save the file.

ℹ️ IF YOU DOWNLOADED THE LICENSE FILE ON ANOTHER COMPUTER THAN ON WHICH COFFALYSER.NET HAS BEEN INSTALLED, TRANSFER THE FILE TO THE COMPUTER ON WHICH COFFALYSER.NET HAS BEEN INSTALLED.

4.  Open Coffalyser.Net.

5.  In the Coffalyser.Net Server Selection dialog right click on the server with the name of your computer and select *License*.



    🖥  The Coffalyser.Net License dialog opens.

6.  Click **Import From File**.

7.  Navigate to the location of the Coffalyser.license file, select it, and click **Open**.

8.  Click **OK**.
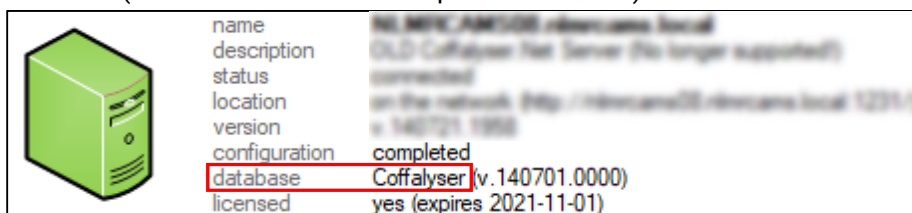
9.  Click **Install License**.

# 4. UPDATING

Based on user feedback, new insights and/or regulations, Coffalyser.Net is continuously improved.

Coffalyser.Net can easily be updated to the latest version by uninstalling the previous version , installing the latest version, and configuring the new installation to reconnect to your data.

IMPORTANT NOTES:

- **<u>Do not uninstall any version of Microsoft SQL Server.</u>** As Microsoft SQL Server hosts the database of Coffalyser.Net, uninstalling this program may lead to irreversible data loss!

- Before uninstalling the previous version of Coffalyser.Net, make note of the name of the database (the version number is not part of the name) in the Server Selection dialog:



You need the name of the database to reconnect to your data later.

- Before establishing the connection between the new version of Coffalyser.Net to the database, it is strongly recommended to make a backup of the database. Follow the instructions in chapter **5 MAKING A BACKUP OF DATABASE** to create the backup.

ADVANCED:

- If you use a centralised setup, ensure to update Coffalyser.Net on both the central server and all individual workstations (if applicable) on which Coffalyser.Net is installed.

- When you want to migrate a Coffalyser.Net database to an updated or new installation, it is recommended to upgrade the old database before migration. If the database is not upgraded before it is migrated, you can do so by starting Coffalyser.Net and following the procedure **2.2 Configuration of a Coffalyser.Net** from step 5 onwards.

**4.1 UNINSTALLING A PREVIOUS VERSION OF COFFALYSER.NET**

This procedure is based on the standard configuration of Windows 10. The location of the Control Panel and the option *Uninstall a program* may be different in other Windows versions or languages. If you are unable to find the appropriate options, consult the documentation on the operating system or contact the IT department of your institute for assistance.

> **ⓘ** TAKE THE IMPORTANT NOTES ON PAGE 11 INTO CONSIDERATION BEFORE STARTING THE UPDATE PROCEDURE AND UNINSTALLING THE PREVIOUS VERSION OF COFFALYSER.NET.

1. Open the Control Panel of Windows.

2. Click Uninstall a program in the category programs.

3. Select Coffalyser.Net from the list, right-click and select Uninstall.

   Ⲩ Coffalyser.Net

> **⚠** WARNING: DO <u>NOT</u> SELECT ANY VERSION OF MICROSOFT SQL SERVER. UNINSTALLING MAY LEAD TO IRREVERSIBLE DATA LOSS!

4. Click ⟨Yes⟩ to confirm you want to uninstall Coffalyser.Net.

5. If prompted, click ⟨Yes⟩ in the User Account Control window.

6. Close the Control Panel of Windows.

**4.2 INSTALLING AND CONFIGURING NEW VERSION OF COFFALYSER.NET**

1. Download and install the latest version of Coffalyser.Net as described in chapter **2.1 Installation of Coffalyser.Net** on page 5.

2. Make a backup of the database as described in chapter **5 MAKING A BACKUP OF DATABASE** on page 13.

> **ⓘ** IT IS STRONGLY RECOMMENDED TO MAKE A BACKUP OF THE DATABASE BEFORE ESTABLISHING THE CONNECTION BETWEEN THE NEW VERSION OF COFFALYSER.NET AND THE DATABASE.
> FOLLOW THE INSTRUCTIONS IN CHAPTER **5 MAKING A BACKUP OF DATABASE** TO CREATE THE BACKUP AND CONTINUE WITH STEP 3 BELOW.
> IF YOU DO NOT WANT TO MAKE A BACKUP, PROCEED DIRECTLY WITH STEP 3.

3. Configure Coffalyser.Net as described in chapter **2.2 Configuration of a Coffalyser.Net server service** on page 5.

## 5.  MAKING A BACKUP OF DATABASE

> **ⓘ**  IT IS ONLY POSSIBLE TO USE THE COFFALYSER.NET – SQL SERVER BACKUP WIZARD AS DESCRIBED BELOW IF COFFALYSER.NET WAS INSTALLED FOLLOWING THE DEFAULT INSTALLATION METHOD.
>
> WHEN A NOT-PRECONFIGURED SQL DATABASE SERVER IS USED TO HOST THE DATABASE OF COFFALYSER.NET, A BACKUP CAN BE MADE USING THE BACKUP FUNCTIONALITY OF YOUR SQL MANAGEMENT SOFTWARE.

1.  Open the Start menu and navigate to the program folder *Coffalyser.Net*.

2.  Start the *SQL Server Backup Wizard*.

    🖥  The Coffalyser.Net – SQL Server Backup Wizard opens.

3.  Click $\boxed{\textbf{Next >}}$.

4.  Check the check box of the database you want to back up.

5.  Click $\boxed{\textbf{Next >}}$.

6.  Uncheck the check box if you do not want to open the location of the backup.

> **ⓘ**  IT IS GOOD PRACTICE TO STORE BACKUPS IN A SECURE LOCATION ON A DIFFERENT COMPUTER TO PROTECT AGAINST HARDWARE FAILURE.

7.  Click $\boxed{\textbf{Finish}}$ to close the Coffalyser.Net – SQL Server Backup Wizard.

## 6. CONTACT INFORMATION

| | More information: **www.mrcholland.com** | |
|---|---|---|
|  | MRC Holland bv; Willem Schoutenstraat 1<br>1057 DL, Amsterdam, The Netherlands | |
| E-mail | info@mrcholland.com (information & technical questions)<br>order@mrcholland.com (orders) | |
| Phone | +31 888 657 200 | |

| IVD | EUROPE* CE<br>ISRAEL |
|---|---|
| RUO | ALL OTHER COUNTRIES |

*comprising EU (candidate) member states, members of the European Free Trade Association (EFTA), and the UK. The product is for RUO in all other European countries.