Coffalyser.Net™ Installation Manual

For Coffalyser.Net version 240129.1959 and 250317.1029

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

Coffalyser.Net has the following system requirements:

- A genuine copy of Windows (64-bit, x64) that is still supported by Microsoft, with the latest updates installed[1].
- Microsoft .NET Framework 4.8.
- An account with administrative rights during installation (not required to run Coffalyser.Net).
- A system that meets the system requirements of Microsoft SQL Server 2022 if you use a preconfigured SQL Server, or an existing Microsoft SQL Server that is still supported by Microsoft (see below).

To store data, Coffalyser.Net requires a version of Microsoft SQL Server that is still supported by Microsoft. During installation and configuration you can choose to install a preconfigured SQL Server or to use an existing one. If you choose to install a preconfigured SQL Server, Coffalyser.Net will install SQL Server 2022 Express. Additional system requirements for this can be found on Microsoft's website. For system requirements of other SQL Server versions, see the relevant pages on Microsoft's website.

NOTE: Microsoft does not officially support SQL Server on Windows 11 or Windows Server 2022 in combination with a storage drive with a sector size of more than 4 KB. A workaround is available.

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.

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[1] Coffalyser.Net is compatible with 32-bit (x86) versions of Windows. However, SQL Server 2022 requires a 64-bit (x64) version of Windows. Therefore, a 64-bit (x64) version of Windows is required unless you install SQL Server on a different computer.
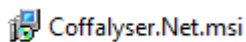
IMPORTANT NOTES:

- 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.

- The database of Coffalyser.Net is stored on a local computer or server. Data stored in the Coffalyser.Net database is not uploaded to a cloud or to MRC Holland servers. It is recommended to regularly make backups of the database. See chapter 5 for instructions.

- Users are responsible for their own data. It is recommended not to delete the raw data files after importing them into Coffalyser.Net. Instead, store the raw data files in a secure location.

- 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. Accept the license agreement and generate a license key if you haven't done so already.

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

5. Extract the zip file.

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

   🗗 Coffalyser.Net.msi

   💻 The Coffalyser.Net installation wizard opens.

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

8. If it is desired to install Coffalyser.Net at another location than the default, click $\boxed{\textbf{Browse}}$. If the default location is ok, click $\boxed{\textbf{Next >}}$.

9. Click $\boxed{\textbf{Next >}}$ to start the installation.

10. If prompted, click $\boxed{\textbf{Yes}}$ in the User Account Control window.

11. Ensure that the checkbox *Launch Coffalyser.Net* is checked and click $\boxed{\textbf{Close}}$.

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.
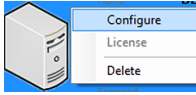
1. If Coffalyser.Net was not launched, start it via the shortcut on the desktop.

2. Click $\boxed{\textbf{I Accept}}$ 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 Server on this computer (preconfigured for 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 Server on this computer (preconfigured for 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 Server on this or a remote computer (not preconfigured)*.

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, install SQL Server 2022, either by:

    - Checking the checkbox *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 >**.

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15. Check the checkbox to either install or upgrade to SQL Server 2022 and click `Next >`.
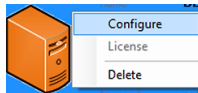
ℹ️ THE DOWNLOAD AND INSTALLATION/UPGRADE PROCEDURE STARTS. THIS MAY TAKE A WHILE.

16. Check the checkboxes *Try to delete the temporary folder(s) created by this program* and *Launch Coffalyser.Net Client* and click `Close`.

🖥️ 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 Server on this computer (preconfigured for Coffalyser.Net)* and click `Next >`.

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

ℹ️ IF AN OLDER VERSION OF SQL SERVER IS USED, YOU MAY RECEIVE THE NOTIFICATION THAT THE SPECIFIED SQL SERVER IS NO LONGER SUPPORTED. IN THAT CASE IT IS RECOMMENDED TO UPGRADE THE SQL SERVER TO SQL SERVER 2022 OR NEWER. AFTER UPGRADING, RESTART THIS PROCEDURE FROM STEP 3.

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

⚠️ WHEN UPDATING COFFALYSER.NET TO THE LATEST VERSION, ENTER THE NAME OF THE DATABASE THAT WAS LISTED IN THE SERVER SELECTION SCREEN PRIOR TO UNINSTALLING THE PREVIOUS VERSION TO RECONNECT TO THE EXISTING COFFALYSER.NET DATABASE.
IF YOU WANT TO CREATE AN EMPTY DATABASE, ENTER A NAME THAT WAS NOT USED BEFORE.

Click `Next >`.

25. If prompted, check the checkbox *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 **Next >** .

27. Do not change the server description and click **Finish** .

28. Ensure that the checkbox *start Coffalyser.Net client* is checked and click **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 10. If the server is green, you do not need to install your license.
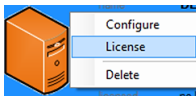
3. LICENSE

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 $\boxed{\textbf{Download}}$.

8. Click $\boxed{\textbf{Always}}$ to allow Coffalyser.Net to connect to the MRC Holland server to download the license.

9. Click $\boxed{\textbf{OK}}$.

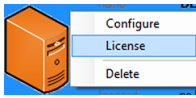10. Click $\boxed{\textbf{Install License}}$.

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**.
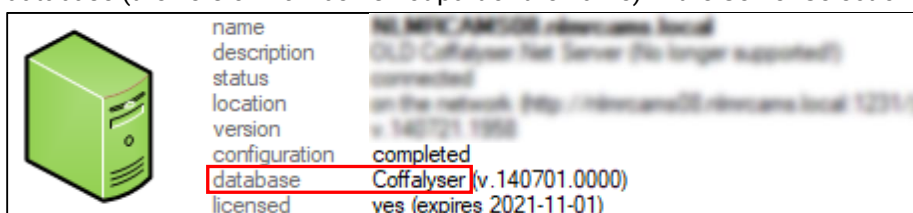
9. Click **Install License**.

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 6 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.

> **ℹ** TAKE THE IMPORTANT NOTES ON PAGE 12 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.

    Y Coffalyser.Net

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

4. Click $\boxed{\text{Yes}}$ to confirm you want to uninstall Coffalyser.Net.

5. If prompted, click $\boxed{\text{Yes}}$ 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 6.

2. Make a backup of the database as described in chapter **5 MAKING A BACKUP OF DATABASE** on page 14.

> **ℹ** 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 6.

5. MAKING A BACKUP OF DATABASE

> ℹ️ 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 Next > .

4. Check the checkbox of the database you want to back up.

5. Click Next > .

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

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

7. Click Finish to close the Coffalyser.Net – SQL Server Backup Wizard.

6. CONTACT INFORMATION

More information: **www.mrcholland.com**	
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IVD	EUROPE* C E 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.

Implemented Changes − compared to the previous version(s).	16

Version 03 − March 2025

- This manual can now also be used for Coffalyser v.250317.1029.

Version 02 − July 2024

- Sentence has been added to the section system requirements that Microsoft does not officially support SQL Server on Windows 11 or Windows Server 2022 in combination with a hard drive with a sector size of more than 4 KB.

Version 01 − January 2024

- New document