STUDIO Software

MedRx

Studio Software Installation Manual

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EC REP

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MedRx's Archived manuals are available at www.medrx-diagnostics.com/support/manuals-studio-software/archive

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Computer Requirements

MedRx Minimum Computer Specs:

Windows® - PC compatible computer
Intel™ i5 2.0 GHz or better
4 GB RAM
20 GB free hard drive space
Available 2.0 USB port
Windows 10 or 11 Professional
Compatible with 3.0 USB

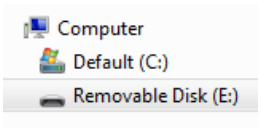
MedRx Recommended Computer Specs:

Windows® - PC computer
Intel™ i5 Quad Core or better
8 GB RAM or more
Available USB 3.0
Graphics adapter with 2GB dedicated video memory
50 GB or more free hard drive space
High speed internet connection
Windows 10 or 11 Professional
Compatible with 3.0 USB

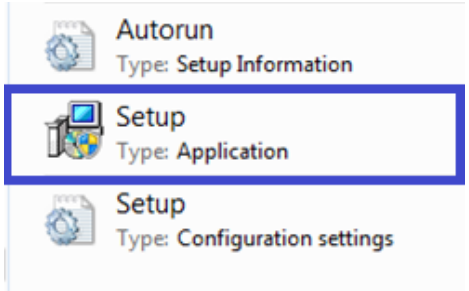
Software Installation



1. Insert the MedRx USB Flash Drive into a USB port:
   - Launch **My Computer**
   - Locate USB Drive



(E:) may vary depending on the USB port selected.
Consult your computer's documentation.

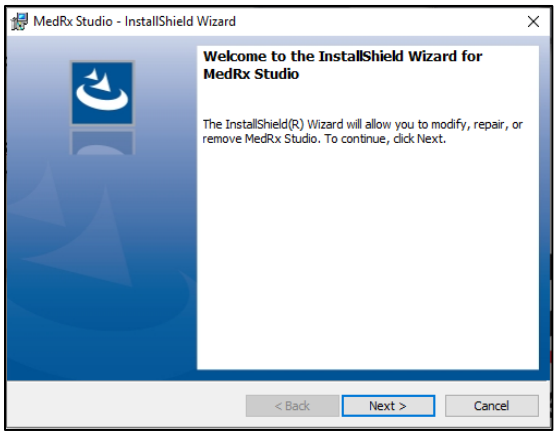


2. Double click on **Setup** to launch:

   NOTE: If requested, *Accept Permission to Install Software*.

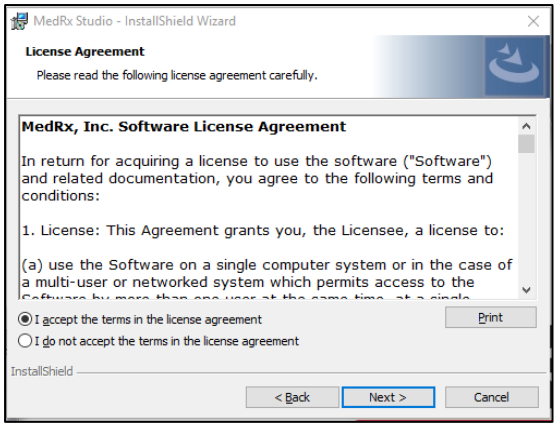


3. On the Setup screen, choose **Install MedRx Studio**.

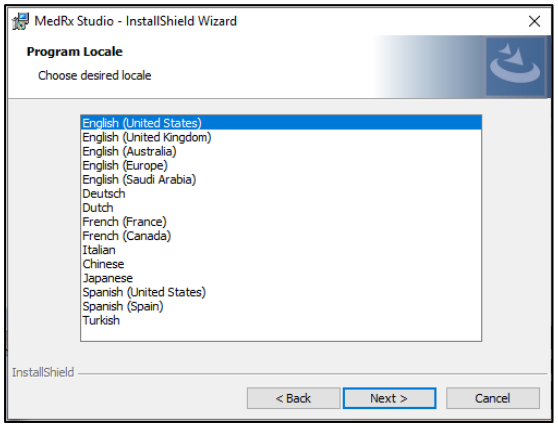


4. This is the Welcome screen.

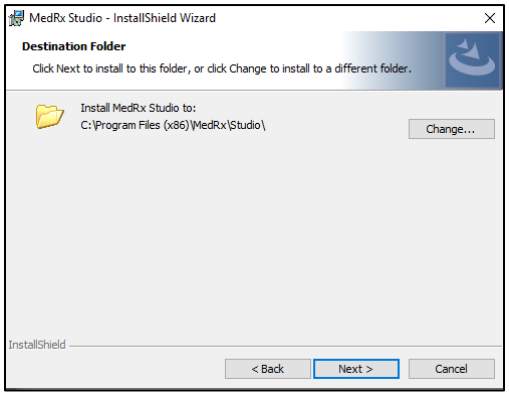
   - To continue, click **Next**.



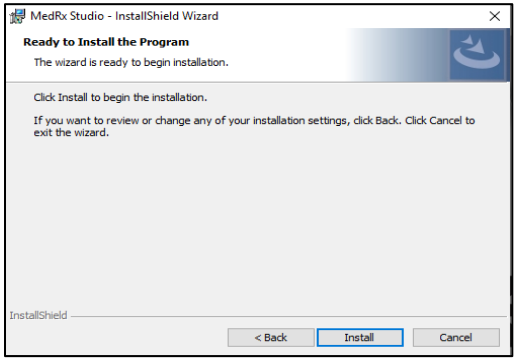
5. Read the Software License Agreement. This important document defines the acceptable usage of the Studio Software.
   - After reading the agreement, select **I accept..**.
   - Click **Next**.



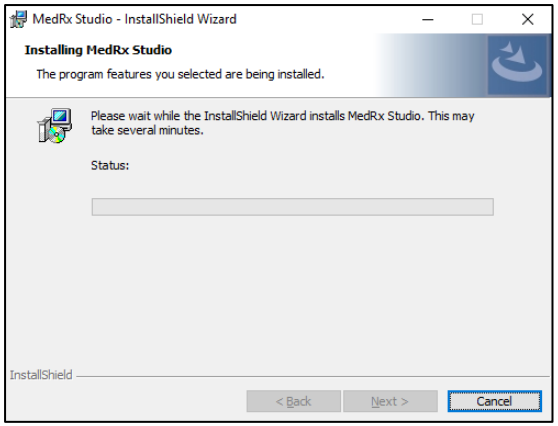
6. This screen sets the language and location choice.
   - Make a selection and click **Next**.



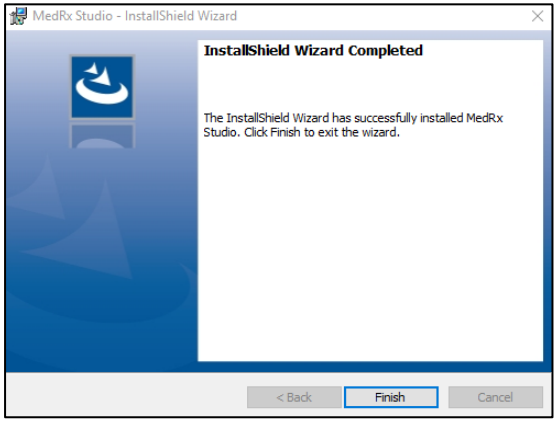
7. This screen indicates the location of the program files. The default location is recommended for most users. If necessary, this location can be changed.
   - To continue with the default settings, click **Next**.
     NOTE: To change the location of the files (advanced users or system administrators only, click Change).



8. Installation of Program is ready to start.
   - To continue, click **Install**.
   - To make changes, click Back.



9. Installation is in process.



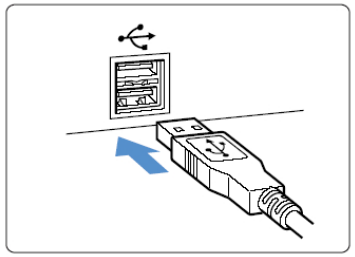
10. When the installation is complete.
    - Click **Finish**.

Connecting Device

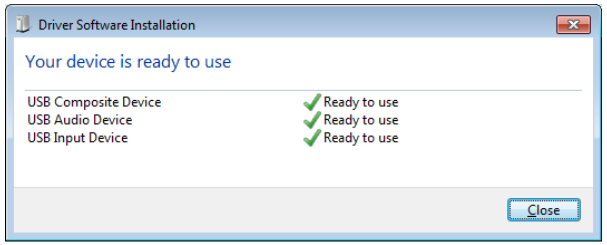
Your MedRx products are USB powered.

Connect the USB cable from the MedRx device to your computer.





Wait for the system to copy and install default Windows drivers.



When this screen appears and all devices are “Ready to use”.

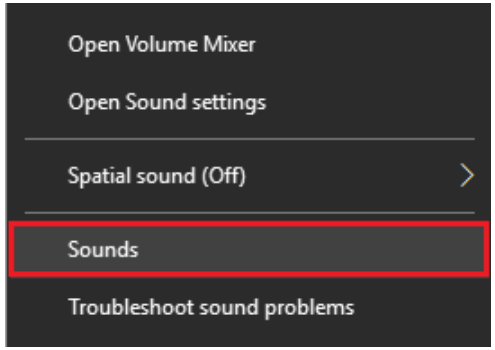
- Click **Close**.

Sound Card Settings

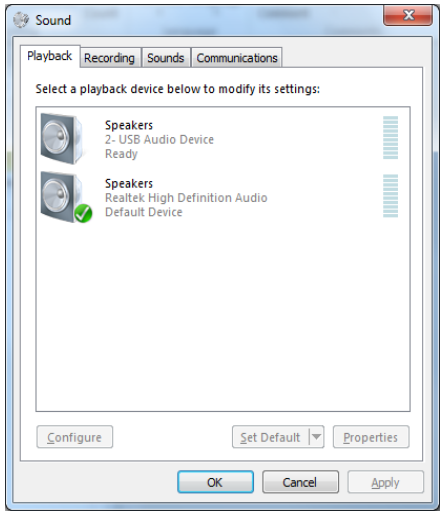
Next you need to confirm or set the default Windows sound card settings. This will route all non-MedRx Windows sounds to the internal sound card of your computer. (These sounds include event notifications such as new e-mail and error warnings as well as audio and video playback.)



1. **Right click** the speaker icon in your system tray.

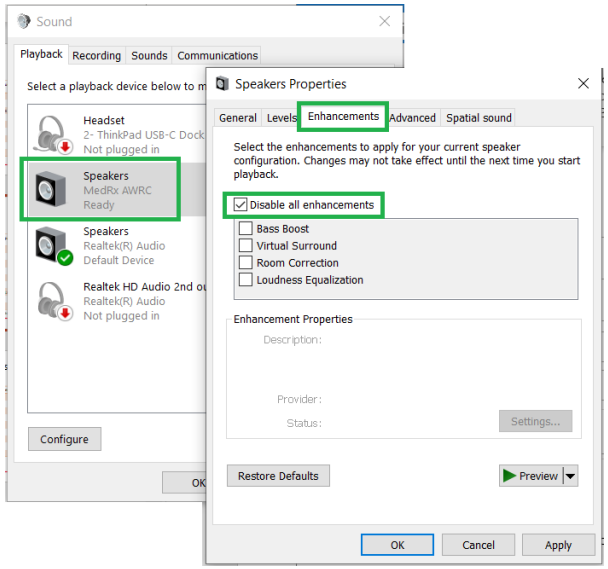


2. Select the **Sounds** option from the list.



3. In the Windows Sound control panel, under the Playback tab and the Recording tab, make sure the MedRx Audio Device is not set as default. If it is default, change this by clicking on your system (non-MedRx) audio device and then choose Set Default.

   NOTE: The internal sound card on your computer will likely not have the same name as this screen shot. Consult your computer's documentation for the name of the internal sound card and set this control accordingly.



4. In the windows sound control panel, in the **Playback** tab right click the MedRx device and select properties. Navigate to the **Enhancements** tab and **Disable all enhancements**. Then click Apply and Ok.

   Enhancements may not be available on all PCs. This does not apply to any PC without audio enhancements.

5. In the windows sound control panel, in the **Recording** tab right click the MedRx device and select properties. Navigate to the **Enhancements** tab and click **Disable all enhancements**. Then click Apply and Ok.

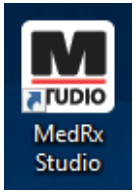
   Enhancements may not be available on all PCs. This does not apply to any PC without audio enhancements.

6. Click **OK**.

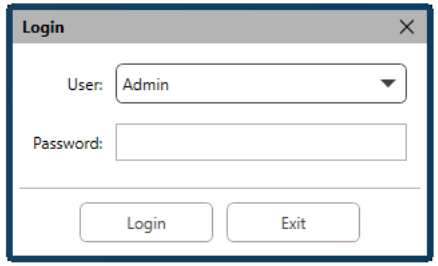
   Congratulations you have set-up your new MedRx Device

Connecting to a Database

The MedRx Studio software can run with Noah Systems, OtoAccess, MS SQL Express, or without database access.



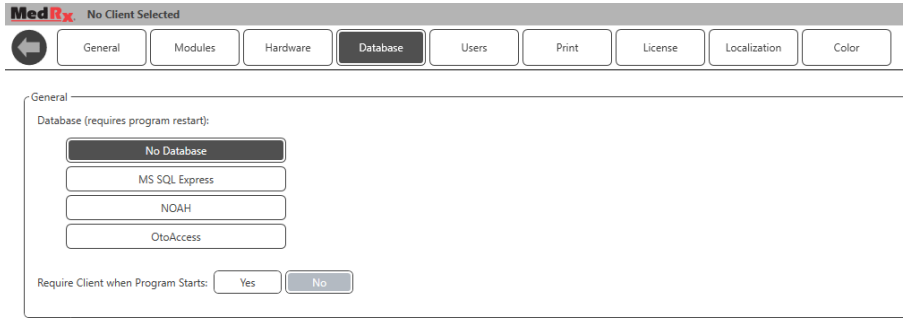
To set-up a Database, double click the MedRx Studio icon on your Windows Desktop.



If the Login window appears, click Login. No password is configured during initial installation. Administrators should configure user authentication and access controls in accordance with their organization's cybersecurity policies before clinical use.



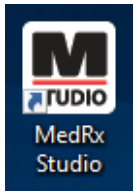
Click the settings wheel in the top right menu bar.



Select Database from the tabs. Click on your desired Database. Close the MedRx Studio software to apply changes.

Note: Only databases that are set up will appear.

Database Set Up



Without a Database

- Double click the MedRx Studio shortcut on your Windows Desktop.





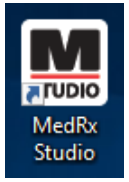
Noah

- Download and install Noah.
- Launch Noah.
- Select a patient.
- Launch MedRx Studio module following Noah procedures.



OtoAccess

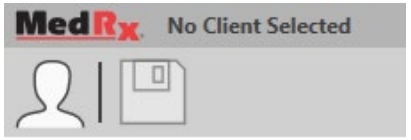
- Download and install OtoAccess.
- Launch OtoAccess.
- Select a patient.
- Launch MedRx Studio module following OtoAccess procedures.



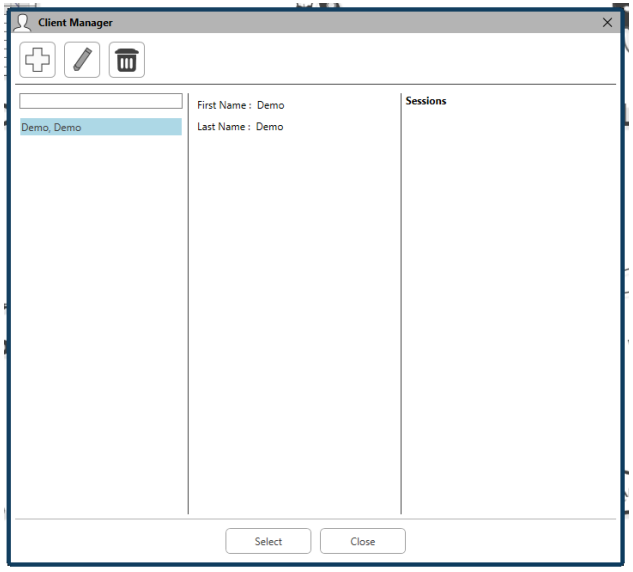
MS SQL Express

- Download and install MS SQL Express.
- Run MedRx MS SQL database set up.
- Double click the MedRx Studio shortcut on your Windows Desktop.

Note: MedRx provides access to SQL database connections. The database owner must configure the database and backup policies to meet local regulatory requirements.



- **Select Client** in the top left corner.



- **+** - Create client.
- **Pencil** - Edit client.
- **Trash** - Delete client.

Cybersecurity and Data Protection

Cybersecurity Responsibilities

NOTICE: Data Protection and Cybersecurity

The MedRx Studio software may store, process, or transmit patient and clinical information. The healthcare organization is responsible for implementing appropriate cybersecurity controls, protecting patient information, and ensuring compliance with applicable privacy, data protection, and cybersecurity regulations, as well as organizational policies.

To support protection of patient data and system integrity, MedRx recommends the following:

1. Use only Microsoft-supported operating systems and ensure operating systems and software are regularly updated with current security patches in accordance with Microsoft's recommended update schedules.
2. Enable database encryption when supported by the selected database platform.
3. Use unique user accounts and passwords within the operating system, database platform, and any connected information systems.
4. Restrict physical and network access to systems containing patient data.
5. Maintain current antivirus, anti-malware, and firewall protection.
6. Implement and maintain appropriate data backup and recovery procedures.
7. Implement and maintain appropriate audit log and record retention policies in accordance with local regulatory requirements.
8. Change any default administrative passwords and account credentials before clinical use.

Failure to implement appropriate cybersecurity controls may increase the risk of unauthorized access, data loss, data corruption, or interruption of system availability.

Database Security

When MedRx Studio is configured for use with Noah, OtoAccess, Microsoft SQL Server, or other database platforms, the healthcare organization or database administrator is responsible for:

- Configuration and maintenance of database security settings.
- User account management and access control.
- Encryption configuration, where applicable.
- Backup and disaster recovery procedures.
- Compliance with local privacy, security, and record retention requirements.

IT Network Connection Notice

NOTICE REGARDING IT-NETWORK CONNECTIONS

Connecting MedRx Studio and associated MedRx devices to a PC, database server, local area network (LAN), wide area network (WAN), cloud service, or other information technology (IT) equipment may result in the device becoming part of an IT-network.

Connection to an IT-network may introduce previously unidentified risks to patients, operators, or third parties.

The responsible Healthcare Delivery Organization (HDO) shall identify, analyze, evaluate, control and monitor such risks prior to and after network connection.

The responsible organization should ensure that the IT-network provides the necessary characteristics and performance required for safe operation of the connected medical device system.

Additional risk analysis should be carried out whenever the IT-network is modified, including:

- Changes in network configuration
- Connection of additional equipment
- Removal or disconnection of equipment
- Software updates
- Hardware upgrades
- Changes in cybersecurity controls
- Changes in database servers or storage locations

Examples of possible risks include:

- Unauthorized access to patient information
- Loss or corruption of stored records
- Delayed access to patient information
- Interruption of clinical workflow
- Reduced system availability due to network or cybersecurity events

The healthcare organization remains responsible for ensuring the security and integrity of its IT-network environment.

Complaints/Safety Reporting

Please contact your local distributor in case of any incidents related to product defects (hardware defects or software bugs) or adverse events (which does not necessarily have a causal association to the product). It is recommended for a user to report all the known facts about the incident. Upon receipt of any serious incident with serious health impact for the patient or user (serious adverse events), local distributor shall report to MedRx through its appropriate vigilance system. MedRx shall ensure that the regulatory authority in patient's home country is informed according to the vigilance requirements. MedRx shall handle all the product complaints and adverse events as per the internal procedure.

Limited Warranty

MedRx warrants this product to be free from defects in material and workmanship for two years from the time of purchase. If this system fails to perform as specified during this period, the purchaser is responsible for calling MedRx at +48 91 835 63 00. The company's representative will advise the owner to either return specific components or the entire system to:

MedRx International
DGS Diagnostics Sp. z o.o.
Rosówek 43
72-001 Kołbaskowo
Poland

MedRx International will repair or replace any defective devices, fully test the system and/or components and ship the system promptly back to the owner. There is no cost for the repair or return shipping, provided the system is two years old or less and has not been misused, abused or damaged. Such damage includes, but is not limited to, dropping, exposure to excessive heat greater than 37,78º C and water/liquid damage.

Repair or replacement of the system as provided under this warranty is the sole and exclusive remedy of the purchaser. MedRx shall not be liable for any consequential or incidental damages or for breach of any express or implied warranty. Except to the extent of applicable law, any implied warranty, merchantability or fitness of this product is limited to the duration of this warranty.

MedRx International will, at its discretion, service and repair out of warranty products at the purchaser's request, charging for parts and labor as necessary.

The limited warranty is deemed void if software or hardware is installed on this product which is not pre-approved by MedRx, Inc. Approved software includes Noah and HIMSA approved hearing aid manufacturer programming modules for fitting hearing aids.

MedRx international is not responsible for problems resulting from installation of unapproved software or hardware. In the event of unapproved software or hardware installed on the system causing a conflict, MedRx will service the product for a fee to be determined at the time of service.