1 Connection to computer networks and other devices (ValedoMotion 2.0)

Any and all electronic devices, including the computing device and potential network connections, that are connected to ValedoMotion must comply with applicable standards and regulations, e.g. IEC 60950.

For further information on connecting these devices, please refer to the user manual of these devices.

Other devices may include, monitors, projectors, printers, etc.

When connecting to an external monitor, the display setting must either by "Duplicate" or "Projector Only".

Configuring the external display

1. Connect the computing device to the external display (monitor, TV, projector, etc.).
2. Click ⊞ +P to bring up the display options (see below).
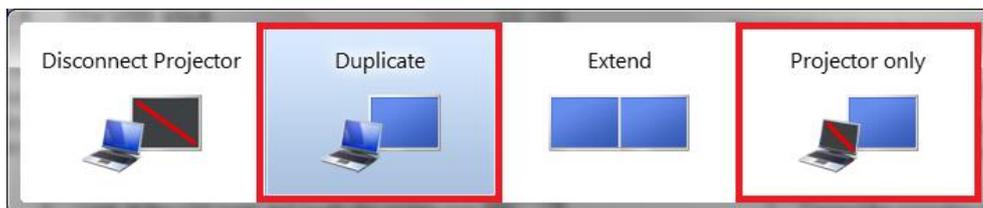
3. Choose either Duplicate or Projector Only.

1.1 Introduction

The availability of this feature depends on your system configuration. This section is intended for the person assigned by the responsible organization to connect the ValedoMotion computing device to a computer network. It is assumed that the person has professional knowledge of medical device and IT technology and regulations, especially electrical safety and computer network operation.

This section covers information according to IEC 60601-1:2012 for ValedoMotion as a medical device. Conformity to additional local or regional regulations for medical devices has to be ensured by the responsible organization. Similarly the responsible organization has to ensure conformity with applicable regulations and standards for protection of classified health information and data security. The sole responsibility for connecting the computing device to a computer network lies with the responsible organization and not with Hocoma as the ValedoMotion manufacturer. If the constraints described in this document are met, the computing device with the ValedoMotion software installed may be connected to a computer network.

The responsible organization has to ensure that only authorized persons connect the computing device with the ValedoMotion software to a computer network.

ValedoMotion does not require network connection to achieve its Intended Use (see Chapter 1). All data are stored on the local hard disk of the computing device, which may include patient information, the exercises and assessments done, the results and calculated performance indices; anonymized data may be used for analysis purposes should the computing device have a working Internet connection. The ValedoMotion database must not be stored on a remote or network drive because delays or loss of data might make ValedoMotion inoperable. Please note that Hocoma can only offer service support for issues that relate to ValedoMotion software and not general computing device issues

1.2 Acceptable usage of computer network

Below are examples of intended uses of connecting the computing device with the ValedoMotion software installed to a computer network

Printing

Printing through a network enabled printer, e.g. printing of reports, is acceptable.

Connection to a printer may be achieved through a computer network to which both the computing device on which the ValedoMotion software is installed and the printer are connected or alternatively by a direct connection between the computing device on which the ValedoMotion software is installed and the printer. The selection of the appropriate printer driver and its installation are responsibilities of the responsible organization. Service actions by Hocoma that are caused by inappropriate selection, installation or use of drivers not supplied by Hocoma may be charged.

Back up to a network drive

Backup and restoration of the computing device through a network is acceptable.

Virus scanning

Running virus scans of the computing device via the computer network is acceptable provided virus scans do not take place while the ValedoMotion software, especially during a training, is running. Installation, updates, scanning and other actions related to virus scanning and protection are the responsibility of the responsible organization.

Note that many virus scanners start system scans at regular time intervals. This has to be prevented, because it could degrade the response time for file access during ValedoMotion training, thus possibly degrading software performance.

2 Connecting the computing device to a computer network

The network connection may only be established through the Ethernet port or Wireless receiver. Connected devices have to comply with applicable IEC standards, which may include 60065, 60601-X, 60950. The firewall should be only opened as far as necessary, preferably not at all, in order to minimize intrusion risk.

In any case, the computing device on which the ValedoMotion software is installed must not be connected to the Internet without an appropriate external firewall because intrusions might modify software settings thus degrading the safety of the system.

If appropriate steps have been taken to prevent intrusions from sources within the local network or the internet, prevent virus or similar infections from sources within the local network, prevent virus or similar infections from the internet, especially instructions to personnel restricting the use of Internet browsing, and limit and restrict network communication to the computing device on which the ValedoMotion software is installed from within the local network or the Internet as far as possible, it is acceptable that the network connection remain continuously connected and active. Otherwise, the connection has to be unplugged during operation of the ValedoMotion software, especially during training.

Deviation from these guidelines can lead to corruption of data or software, or loss of processing power for the ValedoMotion software, which can degrade software performance and might cause serious injury to your patients.

3 Risk management

Connection of ValedoMotion or the computing device on which the ValedoMotion software is installed to a computer network that includes other equipment could result in previously unidentified risks to patients, operators or third parties, the responsible organization should identify, analyze, and control such risks (refer to IEC 60601-1:2012).

Subsequent changes to computer network could introduce new risks and require new analysis.

Changes to the computer network include:

- Changes in computer or data network configuration
- Connection of additional items to computer network
- Disconnecting items from computer network
- Update of equipment connected to computer network
- Upgrade of equipment connected to computer network

The term computer network used here corresponds to the term network/data coupling in IEC 60601-1:2012.