



CardioVisions

1.10 or later versions

**database, holter editor and
report generator software
for Meditech recorders**

for use with

ABPM-05

ABPM-04

ambulatory blood pressure recorder

CardioTens

combined ambulatory blood pressure
and ECG event recorder

card(X)plore

combined full disclosure holter ECG,
ambulatory blood pressure and
actigraphy recorder

CardioClip

ECG event recorder

CardioBlue

ECG event recorder
with Bluetooth communication

CardioMera

full disclosure holter ECG recorder

INSTALLATION

FIRST STARTUP

REGISTRATION



This symbol on a Meditech recorder is a warning that you should read the accompanying documentation (this manual).



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Meditech recorders working with the CardioVisions software described in this manual, including

ABPM-05	ambulatory blood pressure (ABP) recorder
ABPM-04	ambulatory blood pressure (ABP) recorder
CardioTens	combined ABP and ECG event recorder
card(X)plore	combined holter ECG, ABP and actigraphy recorder
CardioClip	ECG event recorder
CardioBlue	ECG event recorder with Bluetooth communication
CardioMera	holter ECG recorder

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For further information on the recorders compatible with the CardioVisions software, read the Meditech recorders manual.

Meditech Ltd. maintains a quality assurance system certified according to MSZ EN ISO 9001:2000 and MSZ EN ISO 13485:2003.

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Meditech recorders compatible with the CardioVisions software described in this manual comply with the requirements of the EU Medical Devices Directive (93/42 EEC).
0120 is the identifier of Notified Body (SGS UK)



Certain features of the CardioVisions software require registration. Please read the chapter on registration before you start using CardioVisions.

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Recommended use of ambulatory blood pressure and ECG recorders

Indications for ambulatory ECG monitoring

The following indications are listed for non-pediatric patients in the ACC/AHA Guidelines for Ambulatory Electrocardiography, 1999.

1. To assess symptoms possibly related to rhythm disturbances

- Patients with unexplained syncope, near syncope, or episodic dizziness in whom the cause is not obvious
- Patients with unexplained recurrent palpitation

2. To assess antiarrhythmic therapy

- To assess antiarrhythmic drug response in individuals in whom baseline frequency of arrhythmia has been well characterized as reproducible and of sufficient frequency to permit analysis
- To detect proarrhythmic responses to antiarrhythmic therapy in high-risk patients

3. To assess pacemaker and ICD function

- Evaluation of frequent symptoms of palpitation, syncope, or near syncope to assess device function so as to exclude myopotential inhibition and pacemaker-mediated tachycardia and to assist in the programming of enhanced features such as rate responsiveness and automatic mode switching
- Evaluation of suspected component failure or malfunction when device interrogation is not definitive in establishing a diagnosis
- To assess the response to adjunctive pharmacological therapy in patients receiving ICD therapy

NB: there is no pacemaker spike detector in CardioTens recorders.

4. Ischemia monitoring

- Patients with suspected variant angina

Indications for ambulatory blood pressure (ABP) monitoring

The following indications are listed in the European Society of Hypertension recommendations for conventional, ambulatory and home blood pressure measurement, 2003.

- Suspected white-coat hypertension
- Suspected nocturnal hypertension
- To establish dipper status
- Resistant hypertension
- Elderly patient
- As a guide to antihypertensive drug treatment
- Type 1 diabetes
- Hypertension of pregnancy
- Evaluation of hypotension
- Autonomic failure

As CardioTens and card(X)plore are combined recorders, they offer special benefits in patients where indications apply for both ambulatory ECG and ABP monitoring.

Contraindications

- Non-cooperative patients, unconscious or otherwise incapable patients
- Patients requiring urgency / emergency cardiac care
- Patients with a sensitivity / allergy to adhesive ECG electrodes
- Patients with coagulation disturbances (for ABP monitoring)
- Patients with serious mobility or other impairments without supervision
- Children without supervision; children younger than 8 years (ABP monitoring)
- Though the blood pressure measurement algorithm used in ABP devices has been found to function properly on patients with atrial fibrillation or other common arrhythmias, the oscillometric blood pressure measurement method is generally recommended for use only with special caution in case of patients with arrhythmias, Parkinson's disease, or other diseases with tremor

Safety concerns

Electric shock hazard protection

Meditech recorders meet relevant shock hazard protection standards. Ambulatory blood pressure (ABP) and combined recorders operate with 2/4 1.5V AA batteries or 2/4 1.2V AA rechargeable batteries (2 AA size batteries for ABPM-05). Event and holter ECG recorders operate with a single AAA battery. This excludes all electric shock hazards, even in the unlikely case of multiple device errors. Use only standard long-life (alkaline) batteries, or standard NiCd or NiMH rechargeable batteries of the proper size. Do not use lithium batteries. Do not mix different battery types or new and old batteries.

Keep a safety distance of at least 2 meters from any electric devices, metallic objects or other electric conductors during application and removal of ECG electrodes. As long as any patient lead cables (with electrodes) are applied to the patient, not yet applied or disconnected lead cables must not contact potential shock hazard sources or electric conductors, as such contact may, through applied electrodes, serve as a pathway for a potentially life-threatening electric shock.

Many personal computers do not meet certain shock hazard protection standards or strict safety regulations applicable to medical devices. Therefore, during the computer-based use of Meditech recorders, keep at least a 2 meter distance between patient and computer. Meditech recorders communicate using a plastic optical cable, whose 4 m standard (and up to 10 m optional) length allows the required safety distance. The plastic optical cable ensures perfect electric separation and reduces the effects of external electric noise. It does not conduct electricity.

Risk of incorrect diagnosis

The basic intended use of Meditech recorders is to record ECG signals and blood pressure values. Recorded ECG quality depends mainly on electrode contact quality and recording conditions, so valuable recordings are to be expected from properly instructed cooperative patients, using properly applied, high quality electrodes. Patients should be informed about the rules of cooperative behaviour, proper handling of the recorder used, and expected results of monitoring in advance. ABP and ECG recorders only provide data to support diagnostic decisions of a qualified physician, they do not automatically provide a diagnosis of any kind. During the evaluation of recorded ECG, possible artefacts due to external disturbances, motion artefacts, and electrical noise should be observed and handled with caution.

Working with Meditech recorders

The recorder must be programmed from the CardioVisions software installed on the computer. Once the pre-programmed time is reached, the recorder will commence operating automatically and perform blood pressure measurements and/or record ECG signals based on the monitoring plan. To obtain reliable BP readings and high clarity ECG signals, certain rules must be observed.

Rules of monitoring

1. Inform the patient about the goal and expected results of the monitoring. Provide an event diary and rules to observe.
2. Patients should not wear synthetic clothes during ECG monitoring, as this may cause disturbances in ECG recordings due to static electricity and small discharges.
3. Patients can fit the recorder comfortably with the adjustable straps.
4. It is advisable to wear a thin shirt or blouse under ABP cuffs. This does not influence the accuracy of blood pressure measurement, but it prevents problems caused by long-time wear of the cuff (sweat, itching, soreness, etc.).
5. The cuff and/or electrodes should be properly placed and connected. Good electrode contact requires skin preparation and electrodes designed for long-term application.
6. Should an electrode become disconnected, it, or a new electrode of the same type should be re-applied to the same position as soon as possible.
7. Patients should avoid excess movement during blood pressure measurements. They should hold their arm loose, slightly away from their chest.
8. Should blood pressure measurements cause bloodshots, torpidity or pain in the hand, the cuff should be removed from the arm immediately and disconnected from the recorder. Such occurrence should be reported to the physician latest after the monitoring session.
9. Patients may start extra blood pressure measurements with the START button of ABP recorders. They should mark events such as taking medication, waking up or going to sleep with the EVENT button. They may interrupt any single blood pressure measurement if necessary by pressing either button of ABP recorders.
10. Patients should not remove the recorder even at night. By loosening the straps, they can avoid problems when turning in their sleep. The recorder does not disturb most patients at night. Removing a card(X)plore recorder will (even if the electrodes and cuff remain connected) result in the loss of actigraphy data.
11. Should the batteries run down during a monitoring session, they can be simply replaced. Monitoring will continue, and data will not be lost. The memory card should not ever be removed during monitoring from card-capable recorders.
12. Patients should never measure anybody else's blood pressure with an ABP recorder during an ambulatory blood pressure monitoring session.

For detailed information on recorders, please read the Meditech recorder guide.

Monitoring step by step

Before you begin, you must have the CardioVisions software properly installed and configured on your computer, and the recorder correctly connected. To program your recorder, you will need a Meditech optical interface cable properly connected to your computer's USB or serial port (or to a USB port using a standard USB-to-serial converter) and the communication port correctly selected in the CardioVisions software. To transfer data to your database after a monitoring session from a CardioMera or card(X)plore recorder, you will also need an SD memory card reader unit, preferably an USB2-type reader, connected to your computer. The memory card necessary for monitoring is by default supplied with the recorder itself. As different computer configurations may require different card reader models, and many computers come originally equipped with one, a memory card reader unit is by default not supplied with a card-based Meditech recorder, but is readily obtainable from local sources.

A successful monitoring session consists of the following steps:

1. Inform your patient about monitoring rules well in advance.
2. Insert the necessary number of fully charged, proper size batteries into the battery compartment and check their voltage.
3. Insert memory card properly into the card slot (where applicable).
4. Start the CardioVisions program, select the preferred recorder type for use.
5. Enter new patient data or select patient from the database.
6. Apply the cuff and/or electrodes to the patient.
7. Connect the recorder to the computer and check electrode placement.
8. Create a monitoring plan (possibly containing blood pressure measurement intervals, ECG monitoring settings and event auto-detection trigger limits).
9. Send the monitoring plan from the computer to the recorder unit.
10. Give detailed instructions to the patient who has to wear the recorder.

--- **Monitoring session (typically 24 hours)** ---

11. Check if the plan is completed.
12. Remove the unit, cuff and electrodes from the returned patient.
13. Ask for the patient diary, and ask the patient for any events, symptoms, observations or complaints.
14. Start the CardioVisions program and select the proper recorder type for use.
15. If you use a CardioMera or card(X)plore recorder, remove the memory card from the recorder and insert it into the card reader unit of your computer.
16. Transfer collected data from the recorder or card to your database.
17. Analyze ECG curves, blood pressure profile, ST trends, etc.
18. Create and print a report.

Using the CardioVisions software

The CardioVisions software package provides means to handle Meditech ambulatory blood pressure and ECG recorders as well as the data collected by such recorders. From CardioVisions it is possible to initialize (program) a recorder, check ECG signal quality of an ECG recorder applied to a patient in real time mode, and transfer (read) collected data from a recorder to your computer. CardioVisions stores data transferred to the computer in its database for easy future access. The database offers user access control, organizing patient data in folders similar in appearance to those used for normal document storage, but with a high degree of safety for sensitive medical data. It also offers a comfortable archive-and-restore feature for a safe backup of large size holter ECG recordings. CardioVisions provides detailed graphical and tabular displays of recorded data, a comprehensive set of editing features and full statistical analysis, all in a highly customizable user interface. Its efficient report generator and editor can create standard reports automatically, but also allows for free editing of any report component like a word processor.

In summary, CardioVisions lets you:

- ◆ manage (select, initialize and read data from) recorders
- ◆ browse patients and the results of monitoring sessions in a database
- ◆ view, edit and analyze data in a recording
- ◆ create, save and print a freely editable report.

CardioVisions editions and system requirements

Personal and Network Edition

CardioVisions comes in two different editions.

CardioVisions **Personal Edition** can be installed on a single computer and used only by one user at a time. The use of ABPM devices is possible without registration with an unlimited number of recorders. If used with CardioTens and event recorders without software options, the CardioVisions Personal Edition can be used completely without registration up to 10 recorders total. The use of more than 10 recorders, other recorder types (Holters), network edition use and ECG analysis functions require registration.

Multiple users can work with one database in a computer network at the same time using CardioVisions **Network Edition**. This edition has to be installed on a server computer in a network, where users have access to CardioVisions services over the network from the workstations. CardioVisions Network Edition requires registration (see under registration section).

Using the Personal Edition for demo purposes

Demo data in CardioVisions Personal Edition are specifically included so that all features which would otherwise require registration will still work in an unregistered installation, but on the special demo data only. The network functionality is not included in this, so there is no demo feature of the CardioVisions Network Edition.

Computer requirements

CardioVisions can be installed on most Windows-based personal computers, but please check before installation whether your computer meets the following requirements.

	Minimum Requirements	Suggested Configuration
CPU	350 MHz Pentium II	2 GHz P4 or equivalent
RAM	64 MB	512 MB
VGA	800x600 @ 16 bit color	1024x768 @ 16 bit color
HDD	about 40 MB for the software + disk space for database *	
LAN	10 Mbit/s	100 Mbit/s
OS	Windows 98 SE / Me / 2000 / XP	

* The disk space necessary for the database depends on recorder type, number of patients and number of examinations. Typically, it takes 75 MB to store 1000 ABPM recordings without reports. ABPM recordings are small; holter ECG recordings may require up to 80 MB each. The installation of demo data requires about 200 MB, too.

Please note that certain features of CardioVisions, especially the ECG annotation, require a lot of calculations, so the faster your computer, the shorter time you will need to get a 24-hour ECG recording analyzed. If your computer meets the minimum requirements only, it may take several minutes to complete the ECG annotation procedure. Data transfer time will depend on the reader you use, or over a network, they will depend on your network connection speed.

Installation and first start

As with any software installation, you need a proper access level to the computer on which you want to install CardioVisions. Especially with the Network Edition to a server, this usually means Windows system administrator access.

If you wish to use CardioVisions on a single stand-alone computer, the proper choice is CardioVisions Personal Edition. If you wish to store your database on a server computer and access CardioVisions on any workstation in a networked environment, possibly with several users working with the software at the same time, you will need to install CardioVisions Network Edition. Do not install both editions on the same computer. Remember that the Network Edition will not work at all without a proper registration, so if you just want to try CardioVisions, install the Personal Edition on a computer. Both editions are available on the installation CD accompanying a Meditech monitoring system. You can always download the latest release of CardioVisions from the Meditech website at <http://www.meditech.eu>.

Installing CardioVisions Personal Edition

If you have an installation CD, insert it into your CD drive and (provided the auto-run feature is not disabled) you will see a start screen where you can select which edition you wish to install. If the auto-run feature is disabled, open the CD folder and run (double-click) the setup.exe program, then select the Personal Edition to install. The selection will start a typical installation wizard. If you downloaded the Personal Edition installer from the Meditech website, start the installer directly.

Before you install CardioVisions, you need to go through the typical steps, as follows:

- ◆ Choose language to install
- ◆ Accept licence agreement
- ◆ Choose components to install
- ◆ Choose recorder type(s) you want to use
- ◆ Choose target folder of installation
- ◆ Choose Start menu folder for startup icon placement

The default installation language of CardioVisions will be that of your Windows system (if such a language version of CardioVisions is available), but setup offers you to choose another language from a list. To install CardioVisions, you must first carefully read and accept the licence agreement, which you can also read at the end of this manual. Then you can select the options you wish to install; necessary components include the CardioVisions software itself, plus small demo data for ABPM and event recorders. You may choose to install or omit demo data for combined and holter recorders as well; this requires additional disk space, of course. In the next step, you can select which recorder type(s) you wish to use with CardioVisions. All compatible Meditech recorders are listed and checked by default – just remove the tick-mark from the checkboxes of the recorder types you do not want to use. Then you will be asked to select the target folder of the installation. CardioVisions will by default be installed in your Program Files folder, in a Meditech subfolder, and finally a subfolder with the appropriate CardioVisions release version information. If you have a previously installed earlier version of CardioVisions, the setup wizard will locate it for you and will offer to install

the new version to overwrite the old one. This will not influence your database, or any program settings – they will be preserved from your previous installation. This happens only if you install the new CardioVisions to the same folder where the old installation is located. If you select another target folder, you will have two different CardioVisions installations with independent databases, which may cause confusion and should therefore be avoided. Before you perform an upgrade, as with all software, it is advisable to create a safety backup of your existing installation. In the next screen of the setup wizard, you can choose a Start menu folder where setup will place the usual shortcuts for CardioVisions: a startup icon, a help icon and an uninstallation icon. By default this is the Meditech folder of your Start menu. After finishing the setup the installation will proceed. Wait until you see a screen prompting you to finish the installation. CardioVisions setup will place a startup icon on your desktop as well.

Installing CardioVisions Network Edition

If you wish to access CardioVisions functions from several workstations in a computer network, you have to install CardioVisions Network Edition. The installation procedure looks quite similar to that of the Personal Edition (see above), but the result is rather different. While Personal Edition setup installs a typical program where you have a single executable file to start and then you can access all functions, the Network Edition setup will install two separate applications, two executable files: one for the networked CardioVisions database engine application (also called the database server), and another for the so-called CardioVisions client application, i.e., the user-end of the program to ask for data over the network from the database engine on any workstation. Therefore, the Network Edition has to be installed on a properly configured server computer. After the installation, the CardioVisions database engine will be automatically started by default whenever the server computer is started. The Network Edition has to be installed on the server computer, on the individual workstations only a shortcut has to be created. Then, as a result, the database engine will run on the server computer continuously, and the CardioVisions client can be started on any workstation with a proper shortcut (startup icon). For all normal user purposes, the CardioVisions client of the Network Edition is indistinguishable from the program used in the Personal Edition. There is one important difference in behaviour, however: if you use the Network Edition and the server computer is shut down, it will not be possible to start CardioVisions from the workstations, of course. Similarly, even if the server computer is switched on, but the CardioVisions database engine is not running (it is stopped, shut down or not started at all), it will be impossible to use CardioVisions.

Compared to the installation of CardioVisions Personal Edition, there is one additional step to take before installation of the Network Edition. After you choose the recorder type(s) to use, you will be asked to select an IP-address (a network property) through which the database engine can communicate with the client(s) running on any workstation. This is a question only if the server has multiple network adaptors, either for intra- and extranet purposes, or because of different physical subnets.

To complete your CardioVisions Network Edition installation, you have to manually share the “CLIENT” folder of your installation with read-only access from all workstations and you have to create a shortcut on each workstation pointing to the CardioVisions client application executable file in this folder (its name is CV001.EXE).

This is best done manually as automatic sharing is either impossible or could have serious security risks, and once the shortcut is created, you can simply “copy-paste” it to all workstations where you want to use CardioVisions. If in doubt, consult your computer network administrator.

It is possible to configure your CardioVisions database engine application to use different options in the unlikely case of networking problems. However, the database engine is an auto-configuring application, so change a working configuration only if it is absolutely necessary and always with the close assistance of an experienced network specialist. To change database engine configuration, first request all users to log out from CardioVisions and close all CardioVisions clients on all workstations, then bring up the database engine application from the system tray on the server computer by double-clicking its icon, then choose Server – Stop, then select the required command of the Config menu. After your changes, choose Server – Start to make the CardioVisions database engine services available to users again.

Installation results: folders, shortcuts and programs

After a successful installation, CardioVisions Personal Edition setup places a startup icon (a shortcut) with the proper name and version number on your desktop. The necessary files will by default be installed in a Meditech folder under your Program Files folder. Setup places a folder with a similar name in your Start menu, by default under the Meditech folder there. In this Start menu folder, you will find a startup icon (shortcut) for CardioVisions, another shortcut for CardioVisions Help, and a third shortcut for the removal (uninstallation) of CardioVisions. You can start CardioVisions either with the desktop startup icon, or with the one in your Start menu.

If you install CardioVisions Network Edition, you will find the same folders and icons, plus in the proper Start menu folder you will find an additional shortcut for the CardioVisions database engine. CardioVisions setup will place another shortcut of the database engine in the Autostart folder of your Start menu, to ensure that the CardioVisions database engine is automatically started whenever the server computer is switched on. Setup will also automatically start the database engine when it is successfully finished. An icon in the system tray of the server computer will show that the CardioVisions database engine is running.

The “CLIENT” folder of your CardioVisions Network Edition installation has to be shared for read-only access for everyone manually, and a shortcut properly pointing to the CV001.EXE program in this shared folder has to be created on the workstations.

First start

After a successful installation, you can start CardioVisions with the proper startup icon (shortcut). Apart from the need for the database engine to run in the background on a properly configured server computer in a Network Edition installation, there is no major difference from a user point of view between the Personal and Network Editions, so unless otherwise noted, the following information applies to both Editions.

When you first start CardioVisions, you will be logged in as a CardioVisions system administrator, and a first start wizard will guide you through the following steps to personalize your installation:

- ◆ Welcome screen
- ◆ Change CardioVisions system administrator settings
- ◆ Add a CardioVisions user
- ◆ Modify default report header
- ◆ Registration
 - ◆ Choose registration mode
 - ◆ Enter contact information for registration
 - ◆ Choose recorder type(s) and connect key recorder
 - ◆ Set network options (Network Edition only)
 - ◆ Choose registered program components
 - ◆ Add a remark
 - ◆ Review your registration summary
 - ◆ Finish registration

Please note that these settings can be modified later during the regular use of CardioVisions, but are necessary to start with from the beginning, so some steps above are a must before you start.

CardioVisions system administrator settings

After a welcome screen on first startup, CardioVisions will ask for the CardioVisions system administrator's login name and password. Please note that these can (and maybe should) differ from your general Windows administrator properties. The input boxes for both the *login name* and the *password* will be **admin** by default. Please change this to your preferred admin login name and password to prevent system security problems. Write your preferred admin login and password down on a piece of paper, and lock it away in a safe place. Do not lose the system administrator's login and password, or you will be unable to access indispensable functions, such as registration, adding new users, changing data access levels. The system administrator cannot view medical measurement data nor edit reports. If you use CardioVisions Personal Edition on your computer which only you have access to in a well protected environment, it may seem overly cautious and therefore be annoying to have to use a password protection in CardioVisions. Therefore it is possible to allow zero-length password for users in the admin settings screen, by removing the tickmark from the *password required* box. This does not mean that users cannot use a password if they like; it just means they may choose to leave the password empty.

Adding a CardioVisions user

Because his tasks are mainly administrative and technical, the CardioVisions system administrator by definition cannot open and view medical measurement data. Therefore it is necessary to create at least one “normal” user in CardioVisions, sometimes this is called a user account. More users can be added by the system administrator later; the first startup procedure lets you – that is, requires you to – create only one. The bold labels in this screen show that the *last name*, *login name* and *password* fields are necessary to proceed, others are optional. If the *password required* checkbox has been unchecked in the previous screen, it is possible to leave the *password* box here empty – technically this is known as a zero length password. In this case the label of the *password* box will not be bold. With the *create icon on desktop* checkbox it is possible to create a personalized CardioVisions startup icon on the Windows desktop with the name of the user just added here. The properties of such an icon will include the user's login name so if CardioVisions is started with such a personalized shortcut icon, the user will only have to type a password, or, if the password is empty, a shortcut so personalized will log the user in directly to CardioVisions. Please note that this can mean a serious data security risk if anyone else other than the intended user has access to the computer, so use this possibility of comfort with extra caution only. The *create personal demo* checkbox, if ticked, will create ABPM and event ECG demo data in the user's own folder in the CardioVisions database. The *create large ECG* demo checkbox will, if ticked, in addition, create holter and combined demo data there as well, requiring extra disk space.

Users can – in fact, they are strongly advised to – change their password when they log in to CardioVisions for the first time, with the password originally selected by the system administrator during user account creation. If they choose to use no password protection, that is, an empty (zero length) password. Users can change their password any time using the **New password** command of the **Tools** menu in CardioVisions.

Report header

In this screen of the first start wizard it is possible to change the default report header data to show data you would like to see on top of all printed report pages.

When you click the **Next** button after entering your report header details, CardioVisions will create the user settings, the demo data and personalized icons. Therefore, it is not possible to use the **Back** button after you click **Next** here. CardioVisions then takes you to the second part of the first startup procedure – the registration.

Registering CardioVisions

In the second part of the first startup, the Registration Wizard will guide you through the steps of registration. If used with ABP devices and event recorders without software options, the CardioVisions Personal Edition can be used completely without registration up to 10 recorders total. The use of more than 10 recorders, other recorder types, network edition use and most complex analysis functions require registration. The first recorder you manage with CardioVisions in such a case will automatically become your key recorder, or key device. If you do not wish to register CardioVisions, exit the wizard. You can start it later to register, or modify an existing registration, if you log in as system administrator. Registration is required to use the Network Edition, access certain functions or to receive technical support. The registration process consists of two phases.

In the first, or request phase, follow the instructions of the Registration Wizard, and send the resulting registration request by e-mail to Meditech (registration@meditech.hu) directly, or ask your Meditech representative to do this for you. In this phase, you select a recorder to be your “key device” that plays a part in the second phase of registration, and in any other registration process that may follow.

In the second, or validation phase, you have to enter the response code you receive from Meditech, and connect your key device to complete your registration. Please start CardioVisions, log in as system administrator (user name: admin, password: admin), start Registration from the Tools menu and follow instructions. Should the key device be unavailable at this time, it can be connected later by any user. During any communication with that recorder, the software will recognize the key device and the registration process will be completed. If the key device is not connected at all, the registration will not be validated, and will expire.

Registration welcome

In the first screen of the registration procedure you can decide to postpone the registration until a later time if you click the **exit without registration** button (in the Personal Edition only). In this case all limitations of non-registered use will remain in effect as described above, so this is advised only if you just want to use CardioVisions as a demo. If you have a Meditech recorder already, it is worth registering CardioVisions now. Only registered users are entitled to product support. In this screen you can decide whether you want to see normal or advanced registration options. Normal registration is usually enough for any typical use of CardioVisions. You need to check the *advanced options* checkbox only if you want to register more than ten units of any Meditech recorder type. Otherwise normal registration is OK.

Registration – user information

In this screen you will be requested to enter contact information so Meditech will know who the registered user is, where to send the registration response code necessary to complete your registration, and who is entitled to product support. The *institute*, *contact person* and *e-mail* boxes are necessary to proceed, others are optional. This information will be used for sending the response code and to check if a product support request is in order. This information might be forwarded to the Meditech representative responsible for the area where the registration is requested, but in most cases you would purchase Meditech recorders from that representative anyway. The information will not be disclosed to anyone else and will not be used for any other purpose.

Registration – recorder types

In this screen you can select which supported recorder type(s) you wish to use with CardioVisions. Please put a tick-mark in the checkbox(es) next to the recorder type(s) you wish to use. Select the key recorder type from the list. Connect a Meditech recorder of the proper type (with batteries in it) to your computer and click the **Connect** button in the *Key device* frame. You can choose the serial *communication line* here as well, but CardioVisions will automatically scan all available lines if it does not find a connected recorder at the line checked first. When it finds a recorder of the selected type, it will read the internally stored serial number of the unit and display it in the *key device* box here. This means the recorder so connected now became your key device. You will need the key device to complete (validate) your registration when you receive the response code to your registration request. You will need the key device, too, if you later want to modify your existing registration, e.g., by adding more recorder types or registering so far unregistered components. Therefore, choose your key device with care, so that it is not a recorder you just borrowed or not one you will probably lend or otherwise lose from sight for a long time. If you use multiple recorder types, it is advisable to select a key device of a recorder type that you meet frequently, e.g., an ABPM or a classic ECG holter recorder.

To connect a Meditech recorder to your computer, you will need an interface. Most Meditech recorders require a special optoelectronic interface cable; some can be connected using Bluetooth wireless connection. See the chapter on interfaces on page 18 for details.

If you checked the *advanced options* checkbox in the registration welcome screen previously, you can also set the requested number of recorders for any selected recorder type. This is only necessary if you wish to register and use more than ten recorders of the same type. Please remember that the registration fee for CardioVisions is based on ten-recorder packages, so register more than ten recorders only if you really will use that number, because this will mean a higher registration fee.

Registration – network

In CardioVisions Network Edition only, in this screen you will be asked to select the *number of active users* for your CardioVisions system, meaning maximum how many active users can exist and may log in to CardioVisions at the same time. The number of active users will influence the total registration fee.

Registration – program components

After you specified your recorder type(s) and selected your key device, you will be asked to select program components in this screen. Of all available program components, only those associated with your selected recorder type(s) will be active. Please put a tick-mark in the checkbox(es) next to the program components you wish to register. Please note that some components may have prerequisites; e.g., you can register the *annotation editing* component only if you have an *annotation* component registered. You can register all available Holter program components if you click the **select all components for Holter** button. Please remember that the registration fee for CardioVisions depends very much on registered program components, so register only those components you really wish to use.

Registration – remark

In this screen you can add any remarks associated with your registration request.

Registration – summary

In this screen you can review which recorder type(s) and which program components you decided to register; what contact information you specified and what remark you had. You can view the *full status* of your registration, or just your *new request* currently being made with the radio buttons at the top; during the first startup they are the same, of course, but if you decide to modify your registration later, this option might be useful. With the *e-mail / file only* radio buttons below the summary you can decide whether you want the just created registration request to be e-mailed immediately to Meditech or to save it to a file on your computer only, to be sent to Meditech later. If you choose the *file only* option, you can specify the target folder for that file in the box next to the option. You can browse the folders on your computer to select the target folder for the registration request file if you click the ... button here.

Registration – finish

In this screen CardioVisions informs you that you have successfully created (and possibly e-mailed) your registration request. It reminds you that you will need to finalize the registration procedure when you receive the response code. It also tells you where you can find a copy of your registration request file.

When you click the **Finish** button after you created and possibly e-mailed your registration request, you have completed the first startup procedure of CardioVisions and are now in the main screen of the program. You are still logged in as the CardioVisions system administrator, so you cannot start working with recorders and patients. You can, however, use all system administrator tools, e.g., you can add new users. If you want to start using CardioVisions for medical purposes, use the **File – Logout** command then log in with the login name and password of the user you created during the first startup.

Registration – validation phase


In the final, or validation phase, you have to enter the response code you receive from Meditech, and connect your key device to complete your registration. Please start CardioVisions, log in as system administrator, start Registration with the dedicated large button or from the Tools menu and follow instructions. Should the key device be unavailable at this time, it can be connected later by any user. During any communication with that recorder, the software will recognize the key device and the registration process will be completed. If the key device is not connected at all, the registration will not be validated, and will expire after 1 month or 25 measurements.

Connecting a recorder to the computer: cable, wireless, card

You could connect Meditech recorders to the computer in the following ways. Most Meditech recorders are equipped with a connector slot for a special optoelectronic communication cable – with these recorders, the computer-end of the interface cable has to be properly plugged into a corresponding socket on the computer before inserting its small recorder-end plug into the socket on the recorder for communication between the CardioVisions software and the recorder. Certain Meditech recorder types are capable of wireless communication with the computer using Bluetooth technology. For successful communication, Bluetooth settings of the computer need to be properly adjusted. Some Meditech recorders are equipped with a memory card slot. To transfer data from these recorders to the computer after a monitoring session, the memory card be removed from the recorder and inserted into a properly configured card reader unit.

Optoelectronic interface cable

To register a recorder as a key device, check electrode placement, send a monitoring plan to the recorder, or transfer collected medical data to the computer, the recorder has to be connected to the computer. Steps to follow for the first connection:

1. Locate a free 9-pin serial port (also called RS232, UART, often labeled OIO) or a USB port (often labeled ) on your computer.

2. Take the optoelectronic interface unit with the optical cable out of the package.

In case of the serial interface cable, the interface unit is integrated in the serial plug with the optical cable. The USB interface unit has a small USB plug (similar to a USB pen drive) with an oblique socket for the independent optical cable.

3. Connect the interface unit to the port

If you have a serial RS232 port on your computer, just plug in the serial optoelectronic interface. If you have a USB port on your computer, and you have a serial optoelectronic interface, use a USB-to-serial converter. If you have a USB port on your computer and a USB-type optoelectronic interface from Meditech, insert one end of the optical cable into the miniature oblique optical socket on the USB interface dongle, matching the red marks on the cable and on the interface label, then insert the USB plug into the USB socket on the computer. It is advisable not to disconnect the optoelectronic interface unit from the computer if it is used on that computer regularly.

4. Connect the recorder to the optical cable

Connect the small optical plug at the free end of the optical cable into the socket on the the device matching red mark on cable to red mark on recorder labels. Insert and push it gently until it clicks in place. Simply pull to remove. Do not pull the cable itself, always handle the plug.

A recorder so connected is ready for communication with the CardioVisions software.

If you do not use the serial/USB port for other purposes, it is advisable to connect the interface unit as described above only once, during first installation. Then the interface unit with the optical cable is constantly connected to the computer, and only the free end of the optical cable has to be inserted in the socket on the recorders to establish the

connection. The interface unit converts optical signals to electric ones and vice versa. The twin optical cable transfers optical signals between the interface unit and the recorder. The cable is flexible, but it is sensitive to overfolding and to cutting forces. If you fold the optical cable in too small radius, or if a strong cutting force (e.g. by the edge of a drawer) is applied to it, the optical cable may become optically distorted, which might result in communication errors.

In the CardioVisions software, click the **Tools** menu, click the **Options** command, and in the appearing **Options** dialog, select **Communication** on the left. On the right panel, select the required recorder type, then select the **Meditech USB** or the **Serial port** option as appropriate for the interface unit you have connected to the computer. To check communication, connect the recorder (with batteries in it and switched on) to the recorder-end of the optical cable, select the required port number or enable the **Auto search com port** checkbox, and then click the **Test** button.

Wireless Bluetooth connection

CardioBlue is a recorder with wireless communication, and card(X)plore is optionally available with wireless communication, too, both using Bluetooth(R) technology. Most up-to-date computers today come with in-built Bluetooth capability, or are easily extendible using a small USB Bluetooth dongle. Bluetooth functionality works seamlessly in Windows XP Service Pack 2 or newer releases, but it usually can be added to older Windows versions as well. Windows XP Help, as well as the documentation of Bluetooth dongles, contain detailed information how wireless devices can be used, and this is described in detail in CardioVisions Help as well. However, if you use CardioBlue, you may need the following information during the first startup procedure after the installation of CardioVisions.

If you wish to use a CardioBlue or a card(X)plore with Bluetooth recorder under Windows XP SP 2, follow the steps below. With other Windows versions, please refer to the documentation of the Bluetooth device used in your computer.

1. If you wish to use a wireless, Bluetooth-capable Meditech recorder, open the **Tools - Options** dialog of CardioVisions and select the **Communication** category. Select the type of the recorder, then click on the appearing **Bluetooth settings** button. In the appearing dialog, click on the **Connect setup** button to go to the next step.
2. In the appearing dialog you can see Meditech recorders which have already been added to your computer. Place fresh batteries into the new (CardioBlue or card(X)plore with Bluetooth) recorder and make it Bluetooth discoverable.

[For this, in case of CardioBlue, press and hold the button of CardioBlue for more than 3 seconds but less than 8 seconds and then release it. The Bluetooth LED of the CardioBlue emits green light, indicating the recorder is discoverable.

In case of card(X)plore press and hold both buttons of card(X)plore simultaneously for more than 3 seconds but less than 8 seconds and then release both. The LCD of card(X)plore displays the PC-- marking, indicating the recorder is discoverable.]

Both recorders remain discoverable for a minute then switch back to stand by mode. If the recorder switches back to standby mode, make it discoverable again.

After you have made the recorder discoverable, click on the **Add** button.

3. If there is a moving torch, the PC searches for Bluetooth devices. Should the recorder switch back to stand by mode due to a timeout, make it discoverable again then click on the **Add** button.
4. After the search the found devices are listed. The name of the recorder in case of CardioBlue is HB1_XXXX, and in case of card(X)plore it is CT2_XXXX; where XXXX is the last four digits of the serial number found on the back of the recorder. Selecting the appropriate recorder, the **OK** button becomes active, please click on it.
5. As authentication key (PIN), please enter the last four digits of the serial number. After entering the PIN, click on the **Finish** button.
6. Wait until the system installs and configures the new Bluetooth device.
By clicking on the **Test** button you can check the communication. Make the recorder discoverable before the test as described above.

Memory cards

CardioMera and card(X)plore recorders use SD or MMC flash memory cards to record ECG and other data during the monitoring session. Fully insert the Meditech-supplied memory card carefully into the recorder. It is highly recommended to use a card exclusively for ECG monitoring; using the same card for other purposes may result in data loss, malfunction, or a failed monitoring session.

NB: All data stored on the card when inserted will be erased during programming!

You will need a card reader unit built into or connected to your computer to transfer the recorded data to your database after a monitoring session. It is not possible to transfer such data using the optical interface cable; the only way is to remove the card from the recorder and insert it in a card reader unit. Use of a USB 2.0 reader is recommended.

As memory cards are not necessary during installation, registration and first startup, they are not described in detail in this manual.

Verifying a successful installation

After successfully installing the CardioVisions software on your computer, during first startup, you may need to register your CardioVisions installation. Registration requires communication with a recorder (the so called key device). Therefore, if registration is successful, it is also a verification that the system is properly installed and communication between computer and recorder is successfully established. If you do not register CardioVisions, log in as a normal user, and then connect and program a recorder. If programming is successful, your system is verified to function properly.

Meditech product warranty information

- (a) **RECORDER WARRANTY.** The main recorder unit will be free from defects in materials and workmanship under normal use and service for a period of two (2) years from the date of receipt. This warranty covers the recorder unit only. This warranty does not cover any accessories that might come with the recorder unit.
- (b) **ACCESSORIES WARRANTY.** The non-disposable accessories delivered with the recorder unit will be free from defects in materials and workmanship under normal use and service for a period of one (1) year from the date of receipt. This warranty does not cover disposable accessories, packaging materials, accumulators and batteries, cuffs, or any of their components.
- (c) **CUFF WARRANTY.** The cuff(s) - if delivered with a recorder unit - will be free from defects in materials and workmanship under normal use and service for a period of six (6) months from the date of receipt. This warranty covers the cuff(s) delivered with a recorder unit exclusively.
- (d) **SOFTWARE WARRANTY.** The CardioVisions software under normal use will perform substantially in accordance with the accompanying written/electronic documents for a period of ninety (90) days from the date of receipt.

This warranty is valid at the representative address of Meditech Ltd. unless otherwise displayed upon a commercial invoice or any other valid business document duly signed by the supplier and the recipient of the Meditech product. If such business document displaying a certain site for warranty validity cannot be presented, this warranty is valid at Meditech HQ office in Budapest, Hungary. This warranty does not cover any malfunction or defects of the recorder unit or any of its accessories arising from improper use, accident, theft, or use of the recorder unit outside its operating environmental specifications and intended measurement range. Removing the closing label from the back side of the recorder unit, or opening the unit any other way voids this warranty.

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