DVS
Dose Verification System

DVS® DOSE VERIFICATION SYSTEM
Operators Manual

Caution: Federal Law restricts the use of this device to sale by or on the order of a physician.

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Part Number: 934-00553-00 rev. 05

DVS
DVS-R-100
FCCID TS9-DVS-R-100

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This product is covered by one or more issued or pending U.S. patents including one or more of the following:

U.S. Patent Nos. 6,047,214; 6,345,203; 6,263,247; 6,402,689; 6,963,770; 6,963,771; 7,010,340, and 7,011,814.

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1 WELCOME

The Dose Verification System Operators Manual includes information about the setup and use of the DVS® (Dose Verification System). The intended users of this manual are radiation oncologists, medical physicists, dosimetrists, radiation therapists, and other personnel that may be assisting in the setup and use of DVS.

This manual is organized into the following sections:

Section 1 Welcome – provides a brief overview of the product, a list of indications, contraindications, cautions and warnings, and summaries of the conventions, symbols and terms used in the Operators Manual and the device.

Section 2 Dose Verification System Overview – provides a detailed description of the components of DVS and how it is used.

Section 3 Installation and Setup – provides instructions for installing and configuring the DVS Software and setting up the DVS Reader.

Section 4 Quick Start Instructions – provides an overview of the workflow for testing, implanting, and scanning the DVS dosimeters.

Section 5 Using the Plan and Review Software – provides the instructions for using the Plan and Review Software to enter patient, dosimeter, and plan information and review patient results.

Section 6 Using the DVS Reader – provides the instructions for using the DVS Reader to test dosimeters and scan patients.

Section 7 Imaging and Therapeutic Compatibility – provides a chart describing the interactions of an implanted dosimeter with various imaging and therapeutic modalities.

Section 8 Troubleshooting – provides guidance if you encounter issues or errors while using DVS.

Section 9 Maintenance and Technical Support – provides information on maintaining DVS and getting technical support.

Section 10 Specifications – provides the technical specification for the DVS system.

1.1 Product Description

DVS provides an oncologist with information about the actual radiation dose delivered to a patient's tissues and organs, and it provides charts and statistics for comparing the actual dose to the prescribed dose. DVS uses an implantable dosimeter and an external reading system to determine the absorbed dose near a tumor within a patient. DVS provides the oncologist with dose information that may be used in conjunction with other clinical information to make decisions regarding treatment plans or to identify the need for further investigation.

1.2 Intended Use

DVS is intended for use in radiation therapy to verify treatment planning and radiation dose to tissue and organs in or near the irradiated areas of a patient.

1.3 Contraindications, Warnings, Cautions, and Notes

The following section explains the contraindications, warnings, cautions and notes for DVS.

The terms Warning, Caution, and Note have specific meanings throughout this manual:

- A Warning advises against actions or situations that could result in personal injury or death.
- A Caution advises against actions or situations that could damage equipment or produce inaccurate or invalid data.
- A Note provides useful information regarding the operation or function of the system.

Contraindications

- **DVS may not be used in patients who are already implanted with other electronic devices such as pacemakers or insulin pumps. The impact of the potential electronic interference is unknown.**

- **Not calibrated for use in electron beam therapy or brachytherapy.** The DVS Dosimeter is pre-calibrated for external beam photon therapy in the energy range of 6-18 MV and daily fraction range of 150-250 cGy.

- **Do not use for patients receiving microwave mediated therapy.**

- **Do not use in blood or central nervous system.**

- **Do not allow patients with a DVS Dosimeter to receive the following treatments: shortwave diathermy, microwave diathermy, or therapeutic ultrasound. These could result in serious injury.**

Warnings

The DVS system is not intended to specify adjustments to dose.

Dose measurement data obtained using the DVS system should be used in conjunction with existing planning and delivery tools to verify delivered dose rather than as a stand alone tool for determining dose adjustments.

- **Electric Shock Hazard – Do not remove the covers of the Reader or Reader Wand assemblies. The DVS Reader and Reader Wand contain no user serviceable internal parts. Contact technical support for return information.**

- **Electric Shock Hazard – The Dose Verification System is grounded with a three-conductor cable and three-prong plug. Insert the power cable only into a properly grounded three-contact outlet.**

- **Only use the manufacturer-supplied power cord.**

- **Replace fuse only with same type and rating: 250V 5 AMP, Type T or 250V 5 AMP, Type 3AG. Failure to replace the fuse with the same type and rating may pose a fire hazard.**

- **The DVS system is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen, or nitrous oxide.**

- **Be sure that the cables do not pose a trip hazard.**

- **The Reader Wand is not for use in direct contact with the patient – especially near wounds. Contact with gowns or other clothing is acceptable. The Reader Wand is not intended to be sterile. Disinfect the Reader Wand after direct skin contact using isopropyl alcohol-based disinfectants.**

- **Do not use in a wet environment – could cause electrocution.**

- **Only qualified personnel should attempt to implant the dosimeter.**

- **The DVS Insertion Tool is extremely sharp. Using medical imaging, note critical structures in the pre-determined implant area. Avoid inserting the radiation dosimeter near critical structures such as veins and arteries.**

- **Store dosimeters in a cool dry environment.**

- **Do not use product if there is evidence of sterile packaging damage, expiration, or contamination of the dosimeter or insertion tool – inspect for damage or breaches of the packaging prior to use.**

- **The dosimeter and insertion tool are single-use devices – do not attempt to re-use.**

- **Do not use locking forceps, a hemostat, or a similar locking instrument to handle the radiation dosimeter; may cause mechanical damage to the glass.**

Cautions

- **Proper use of this system depends on careful reading of all instructions and labels.**

- **Do not use cellular phones or hand held two-way radios in close proximity to the DVS Reader.**

- **Keep CRTs at least 3 feet from the DVS Reader to prevent the DVS Reader from interfering with the CRT image.**

- **Turn OFF the system power before connecting or disconnecting any system components or accessories. Connecting components with power applied may cause damage to the connectors or connecting circuitry.**

- **If the dosimeter is tested prior to implantation, (1) do not remove the dosimeter from its package as this will compromise sterility and (2) do not place the dosimeters near metal.**

- **Do not use a dosimeter near implanted metal objects. Read range may be compromised.**

- **Enter the predicted dose in cGy, not monitor units. Entry in monitor units will cause a false error in the planned vs. actual dose report.**

- **The DVS Reader Wand should not be used within 1-2 feet of large metal objects. Using the Reader Wand close to large metal objects has the potential to reduce the read range of the Reader Wand.**

- **Do not conduct the pre-dose or post-dose reading while the patient is on a metal table. If the treatment table is metal, conduct the pre-dose reading before the patient is placed on the table and the post-dose reading after the patient is removed from the table. A metal table or other metal objects will interfere with the functioning of the DVS Reader Wand.**

- **Take the post-dose reading within 10 minutes after the end of therapy. Readings taken beyond 10 minutes decrease dose accuracy.**

- **The presence of dosimeters causes MR image artifacts. If an MRI scan is required in the vicinity of the area in which dosimeters will be implanted, it is recommended that the scan be performed prior to dosimeter implantation. Subsequent imaging of the affected area may require removal of the dosimeters.**

- **There are three considerations with regard to implantable devices and MR imaging: localized heating, movement due**

to interaction with the magnetic field, and image distortion or flare.

Non-clinical testing has demonstrated that the DVS Dosimeter (device size: 2.1 mm diameter by 20 mm length) is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla or less
- Spatial gradient field of 250 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 3.5 W/kg for 15 minutes of scanning

In non-clinical testing, the DVS dosimeter produced a temperature rise of less than 1.8° C at a maximum whole body averaged specific absorption rate (SAR) of 3.5 W/kg for 15 minutes of MR scanning in a 1.5 Tesla MR . system: Symphony Siemens Medical Solutions.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the DVS dosimeter (following ASTM standard F2119-01 the largest artifact area in the device long axis: T1 weighted spin echo, 16.6 cm^2; gradient echo, 31.1 cm^2). Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

It is recommended that where MRI is deemed medically necessary that MRI be performed prior to implantation of the dosimeter. Where subsequent MRI is deemed medically necessary in the vicinity of the dosimeter, the dosimeter may require removal.

- **Do not implant the dosimeter deeper than 12 cm or less than 3 cm from the surface of the skin. Implanting deeper than 12 cm may result in the inability of the Reader to communicate with the implanted dosimeter. Implanting at least 3 cm deep ensures adequate build-up and minimizes potential for mechanical damage.**

- **Do not store dosimeters near stray radiation.**

- **Implant dosimeters approximately parallel to the long axis of the body.**

Notes

The dosimeter is factory calibrated and does not require calibration during use.

1.4 Symbols

SYMBOL	DESCRIPTION
⚡	Indicates the Presence of a DANGEROUS VOLTAGE within the enclosure. This voltage may constitute the risk of an electric shock if the device is connected to a service outlet.
⚠	Indicates an attention to users to consult accompanying documents (Operators Manual) for more information on the device.
🯅	Indicates that the Dose Verification System is a Type B Applied Part.
⏚	Protective earth (ground) – Indicates the point where the safety ground wire connects inside the Reader assembly.
|	Indicates the ON position of the AC power switch.
○	Indicates the OFF position of the AC power switch.
☢ ☀	Indicates that the parts should be protected from heat and radioactive sources.
STERILE EO	Indicates that the DVS Dosimeter is ethylene-oxide sterilized.
②	Indicates the DVS Dosimeter or Insertion Tool is for single use only.
LOT :	Indicates the Lot number of the DVS Dosimeter or Insertion Tool. The ID includes the date of manufacture and a 4-digit code.
⌛ DD MM YY or YYYY-MM	Indicates the sterilization expiration date of the DVS Dosimeter (DDMMYY) or Insertion Tool (YYYY-MM).

SYMBOL	DESCRIPTION
🏭	Manufacturer
REF	Catalog Number
⊘	Do not use if package is damaged.
2 STERILIZE	Do not re-sterilize
SN	Serial Number
🍷	Fragile
ℹ	Consult Instructions for Use

1.5 Glossary of Terms

Base Station – The main part of the DVS Reader, which contains the touch-screen display for operating the Reader.

cGy – Centi-Gray (hundredths of a Gray (Gy)) unit of radiation

CT – Computed Tomography

Dosimetry Database – The database used by the DVS system for storing patient, dosimeter, planning, and result information.

Fraction – One radiation treatment session. A treatment plan is made of one or more fractions.

Isodose Curve – The plot of the radiation dose plan showing lines of equal radiation dose in cGy.

Insertion Tool – Used for percutaneous and intraoperative implant procedures.

MRI – Magnetic Resonance Imaging

Plan – A set of fractions where the dose delivered for each fraction is the same.

Predicted Dose – The dose, in cGy, expected at a dosimeter for a treatment session.

Reader – The DVS Reader system, which is composed of the Base Station and the Reader Wand.

Reader Wand – The hand-held part of the DVS Reader that contains the electronics to read the dose measurement from a dosimeter.

1.6 Statement of Compliance

DVS has been tested and complies with the following safety standards:

- UL 60601-1
- CSA C22.2 No. 601-M90
- Medical Directive 93/42/EEC
- FCC Part CFR 15

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Changes or Modifications to the System

Changes or modifications to the DVS system not expressly approved by Sicel Technologies could void the user's authority to operate the equipment.

1.7 User Equipment Requirements (Not Supplied)

The following equipment and software are required to use DVS:

- Personal Computer with LAN or network access for DVS Dosimetry Database
- Operating System Requirements:
  - Windows XP Pro or later version

2 DOSE VERIFICATION SYSTEM OVERVIEW

The Dose Verification System consists of five components:

- DVS Dosimeter
- DVS Insertion Tool
- DVS Reader
- DVS Software (Plan and Review Software and Dosimetry Database)
- Bar Code Scanner

The implantable dosimeter measures *in vivo* dose from external beam, photon radiation therapy. The dosimeter uses a semiconductor device called a MOSFET (metal oxide semiconductor field effect transistor) to measure radiation. Radiation within the human therapeutic dose range causes a shift in the threshold voltage of the MOSFET. By measuring the threshold voltage before and after radiation dose therapy, the dose fraction can be calculated. Cumulative dose can be calculated by tabulating the radiation dose measured at each fraction.

To measure absorbed dose, a pre-dose and post-dose reading must be taken. The pre-dose reading is taken before the radiation treatment and the post-dose reading is taken after the radiation treatment. The pre-dose and post-dose threshold voltage readings are then used to calculate the daily dose fraction that is reported for each treatment session. The daily fractional dose values are stored in the Dosimetry Database and are added together to calculate a cumulative dose.

The dosimeter is powered by the Reader Wand utilizing electromagnetic energy and does not contain a battery. The dosimeter derives all power from the Reader-generated electromagnetic field. The dosimeter modulates the electromagnetic field to send the digitized threshold voltage readings back to the Reader.

2.1 DVS Dosimeter

The dosimeter is powered telemetrically and measures the radiation using two MOSFETs. The MOSFETs are hermetically sealed in a biocompatible glass capsule. The dosimeter is covered by a polyester surgical mesh for handling, suturing, or fixating the dosimeter *in vivo*. The dosimeter is subsequently sterilized with ethylene oxide. In the tissue, the dosimeter provides a radio-opaque image that registers on a dose planning computed tomography (CT). The measured dose data can be compared with the prescribed dose plan.

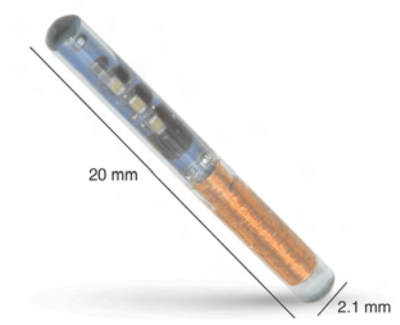


Figure 1 — DVS Dosimeter

Each dosimeter is factory calibrated by correlating to a NIST-traceable ion chamber. The calibration information for each dosimeter is included in a bar code on pre-printed calibration labels.

Dosimeters are provided in sterile packages. The expiration date printed on the dosimeter package is the date when the dosimeter is no longer considered sterile. Electrical functionality of the dosimeter is not affected by the sterility expiration.

2.2 DVS Reader System

The DVS Reader system is used to take the pre-dose and post-dose readings from the dosimeter during each treatment session. The DVS Reader system consists of a Reader Wand and a Base Station (Figure 2). The Base Station includes a touch screen to view instructions and enter data. The Reader Wand sits in the cradle of the Base Station and is removed for reading a patient’s radiation dose. The highlighted end of the Reader Wand under the LED indicators is the active reading area.

The DVS Reader can be used on a table top or on a pole mounted to the wall. The pole should be 1.25” in diameter and able to support 25 pounds.

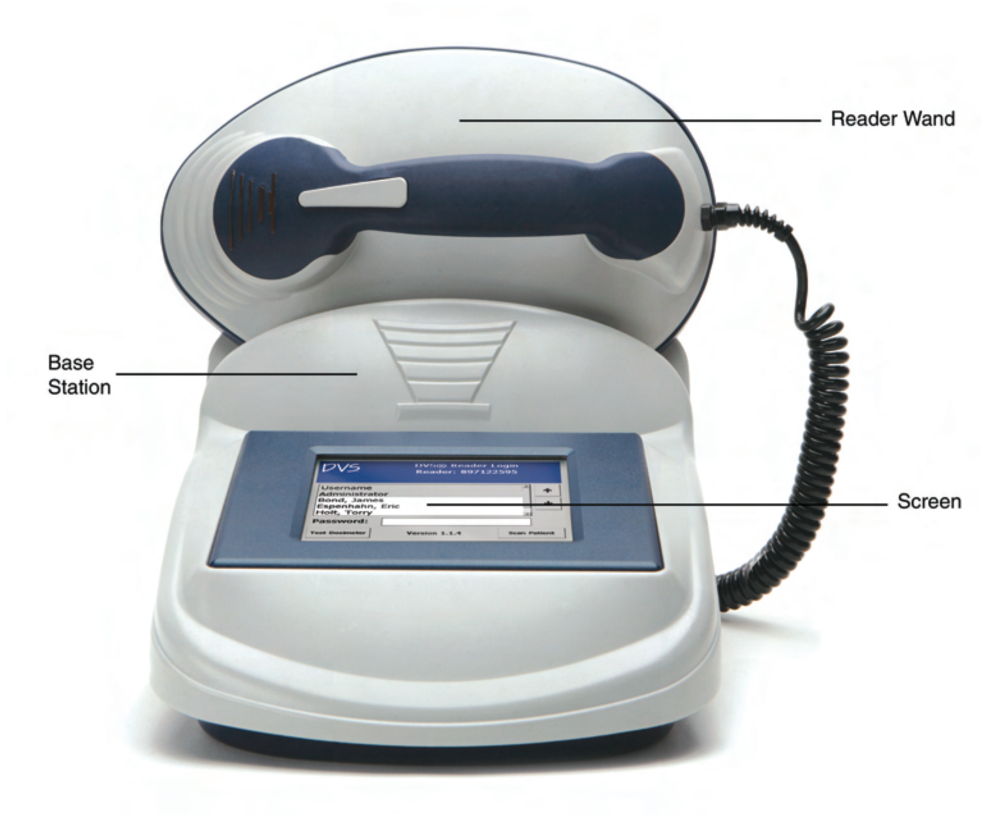


Figure 2 — DVS Reader

2.3 DVS Software

The DVS Software consists of Plan and Review Software and a Dosimetry Database. The Plan And Review Software is used to enter patient treatment information and to access patient data for viewing and reporting. The Dosimetry Database is a centralized database to which the Plan and Review Software and the DVS Reader connect through a local area network (LAN) connection. All patient information and dosimeter measurements are stored in the database. A bar code scanner is used to enter calibration information for the dosimeter. Up to 25 users can simultaneously access the database.

2.4 Bar Code Scanner

The bar code scanner is used to read the dosimeter serial number and calibration values from a 2D bar code into the Dosimetry Database. The 2D bar code is packaged with each dosimeter so it is easy to scan the calibration values into the DVS system. The bar code scanner does not require any external power.

2.5 DVS Insertion Tool

The Insertion Tool is an 11 (eleven) gauge needle similar in design to a bone biopsy needle. It is used for percutaneous and intraoperative implant procedures and consists of a cannula, trocar, and plunger.

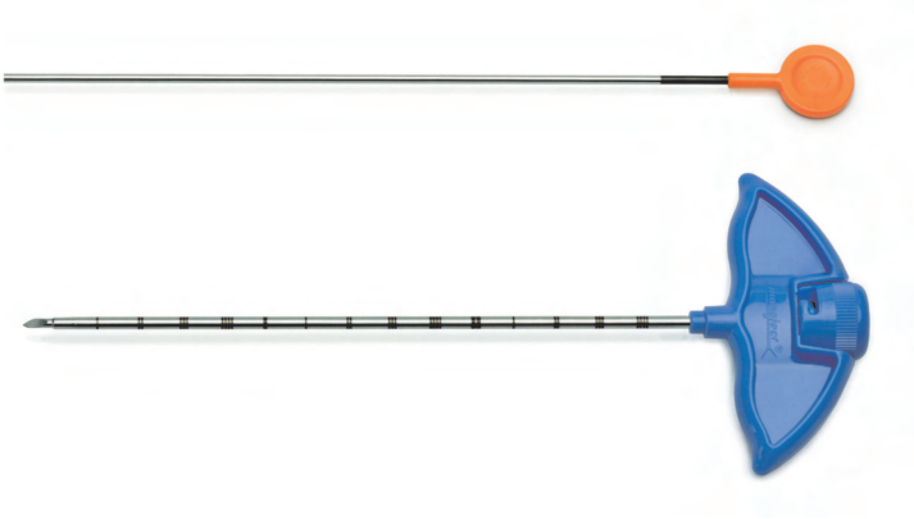


Figure 3 — Insertion Tool

3 INSTALLATION AND SETUP

The Dose Verification System has three main components that you need to setup:

- DVS Plan and Review Software
- DVS Dosimetry Database Server
- DVS Reader

This section contains the following steps for installing and setting up the DVS Software and Reader:

- DVS Software Installation Overview
- Installing the DVS Plan and Review Software
- Installing the DVS Dosimetry Database Server
- Configuring the DVS Software after Installation
- Setting up the DVS Reader

3.1 DVS Software Installation Overview

The DVS Software has two parts: the DVS Plan and Review Software (client), and the DVS Dosimetry Database (server). You can install the DVS Dosimetry Database on the same computer as the Plan and Review Software or you can install it on a separate computer on a network. For example, you can install the DVS Dosimetry Database Server on a computer in the server room and then install the Plan and Review Software on a workstation or laptop in a central location. You can install the Plan and Review Software on multiple computers and connect to the one database server. For administrative purposes, a version of the Plan and Review Software needs to be installed on the same computer as the DVS Dosimetry Database Server.

System Requirements

- Plan and Review Software – must be installed on computers running Windows XP with a minimum of 200 MB of disk space.
- Dosimetry Database – must be installed on a computer running Windows XP Pro with a recommended minimum of 5 GB of disk space. The Windows XP Firewall must be turned off on the computer where the Dosimetry Database is installed.

Corequisite Software

The two parts of the DVS Software each have several corequisite software components that are installed with the DVS Software:

DVS Plan and Review Software

- Microsoft .NET Framework (.NET)
- Microsoft Data Access Components (MDAC)

DVS Dosimetry Database Server - This uses Microsoft SQL Server.

- Microsoft .NET Framework (.NET)
- Microsoft Data Access Components (MDAC)
- Microsoft SQL Server Desktop Engine (MSDE)
- Microsoft Internet Information Services Web Server (IIS)
- Microsoft SQL Server CE Tools (CE Tools)

Windows Administrator Login

To install the DVS Software, you must be logged into the computer with Administrator privileges. Check with your system administrator for instructions on setting up a user ID with Administrator privileges.

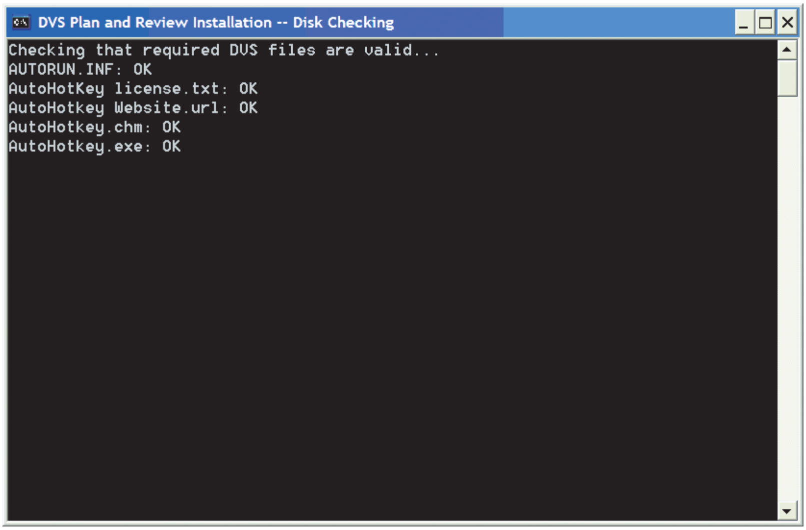
3.2 Installing the DVS Plan and Review Software

The DVS Plan and Review Software is installed on a laptop or workstation connected to your network. It is the interface for accessing the patient and dosimeter information stored in the DVS Dosimetry Database.

To install the DVS Plan and Review Software, perform the following steps:

1. Place the DVS Software Installation CD into the CD-ROM drive. The installation program should start automatically. If it doesn’t, browse to the CD-ROM drive using Windows Explorer and double-click **setup.exe**.

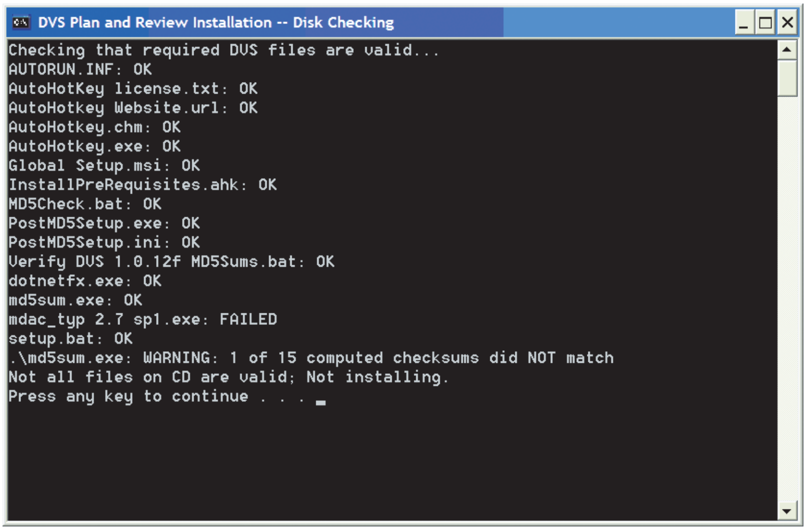
   Shortly after inserting the DVS Software Installation CD, a command window appears. The installation program automatically verifies the files on the CD-ROM.



```
Checking that required DVS files are valid...
AUTORUN.INF: OK
AutoHotKey license.txt: OK
AutoHotkey Website.url: OK
AutoHotkey.chm: OK
AutoHotkey.exe: OK
```

Figure 4 — CD File Checking

If the verification process ends with a failure message, press any key to exit the program, and contact Technical Support.



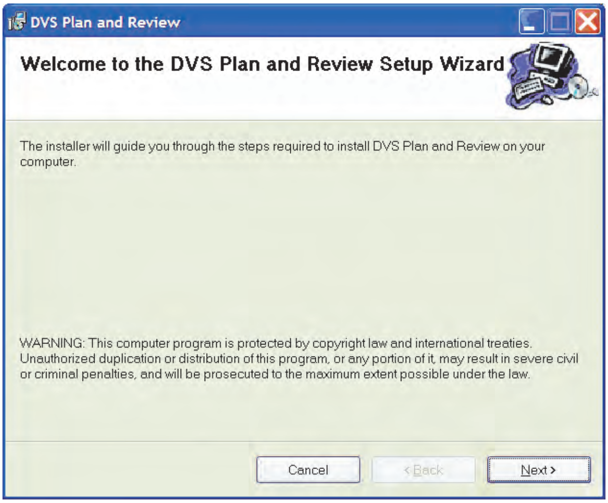
```
Checking that required DVS files are valid...
AUTORUN.INF: OK
AutoHotKey license.txt: OK
AutoHotkey Website.url: OK
AutoHotkey.chm: OK
AutoHotkey.exe: OK
Global Setup.msi: OK
InstallPreRequisites.ahk: OK
MD5Check.bat: OK
PostMD5Setup.exe: OK
PostMD5Setup.ini: OK
Verify DVS 1.0.12f MD5Sums.bat: OK
dotnetfx.exe: OK
md5sum.exe: OK
mdac_typ 2.7 sp1.exe: FAILED
setup.bat: OK
.\md5sum.exe: WARNING: 1 of 15 computed checksums did NOT match
Not all files on CD are valid; Not installing.
Press any key to continue . . .
```

Figure 5 — CD File Checking Failed

If all files are verified, the **DVS Plan and Review Setup Wizard** opens and displays the **Welcome** panel.

2. On the **Welcome** panel, click **Next**. You can click the **Next** and **Back** buttons on the setup wizard to move forward or backward

through the setup panels. You can click **Cancel** to exit the setup wizard without making any changes to your computer.



DVS Plan and Review

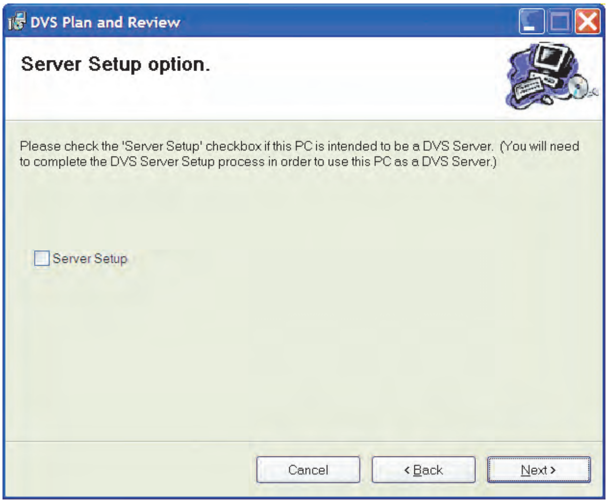
Welcome to the DVS Plan and Review Setup Wizard

The installer will guide you through the steps required to install DVS Plan and Review on your computer.

WARNING: This computer program is protected by copyright law and international treaties. Unauthorized duplication or distribution of this program, or any portion of it, may result in severe civil or criminal penalties, and will be prosecuted to the maximum extent possible under the law.

Figure 6 — Welcome

3. On the **Server Setup Option** panel, select the **Server Setup** check box if you want to install the DVS Dosimetry Database on the computer. If selected, the DVS System Server Setup program installs the database after the Plan and Review Software installation finishes. If you want to install only the Plan and Review Software, clear this check box.



DVS Plan and Review

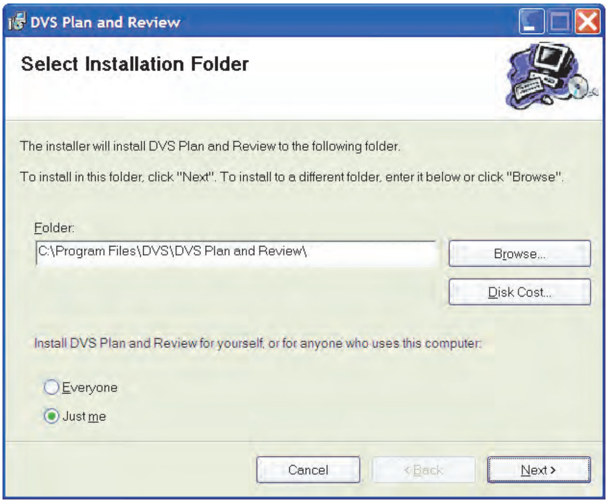
Server Setup option.

Please check the 'Server Setup' checkbox if this PC is intended to be a DVS Server. (You will need to complete the DVS Server Setup process in order to use this PC as a DVS Server.)

☐ Server Setup

Figure 7 — Server Setup Option

4. Click **Next** to display the **Select Installation Folder** panel. By default, the setup wizard installs the Plan and Review Software in the C:\Program Files\DVS\DVS Plan and Review folder. To change the location where the Plan and Review Software is installed, click **Browse** to select a new location using the **Open** dialog box.



Select Installation Folder

The installer will install DVS Plan and Review to the following folder.

To install in this folder, click "Next". To install to a different folder, enter it below or click "Browse".

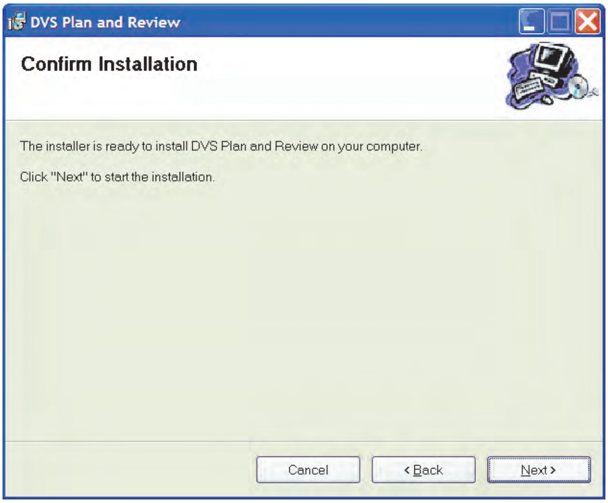
Folder:
C:\Program Files\DVS\DVS Plan and Review\

Install DVS Plan and Review for yourself, or for anyone who uses this computer:

○ Everyone
● Just me

Figure 8 — Select Installation Folder

5. Select **Everyone** or **Just Me** to indicate whether everyone who logs into this computer can use the Plan and Review Software or just users logged in with the current user ID.
6. Click **Next** to display the **Confirm Installation** panel. If you want to change any of the setup information you entered into the setup wizard, click **Back** to change the information.
7. When you are ready to start installing the software, click **Next**.



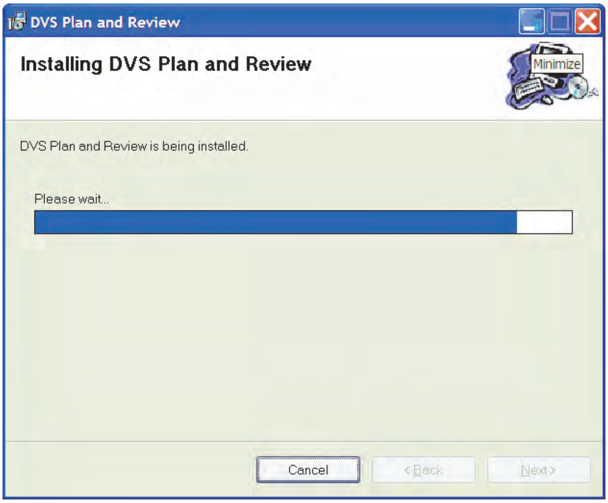
Confirm Installation

The installer is ready to install DVS Plan and Review on your computer.

Click "Next" to start the installation.

Figure 9 — Confirm Installation Panel

The next panel that appears displays a progress bar for the installation program. If you need to stop the installation before it finishes, click **Cancel**.



Installing DVS Plan and Review

DVS Plan and Review is being installed.

Please wait...

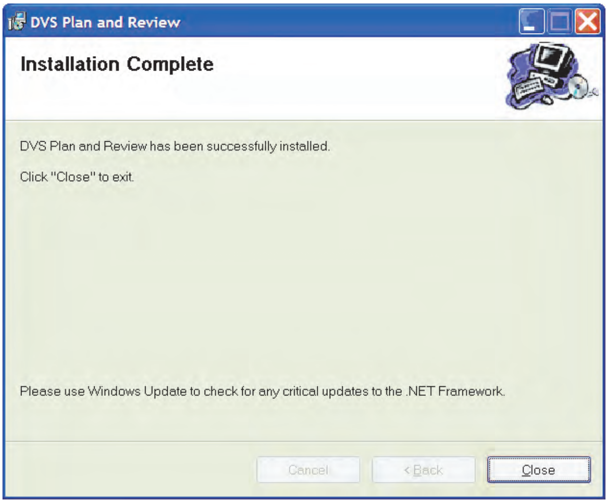
Figure 10 — Installing DVS Plan and Review Software

If the installation program encounters any errors during installation, the installation is aborted and an error message appears. If an error occurs, fix the problem and restart the installation program. The following issues may prevent the software from installing and result in an error message:

- Low disk space – reinstall the software in a location where you have enough disk space. The Plan and Review Software requires at least 200 MB of disk space.
- Inadequate write permissions. – Make sure the user ID you used to log into the computer has Administrator privileges. The user ID needs the rights to install applications and modify the application folders.
- Corrupted files on the installation CD—Contact Technical Support.

8. When the DVS Plan and Review Software installation finishes, the **Installation Complete** panel appears. Click **Close** to exit the setup wizard.

   If the **Server Setup** checkbox was selected, the **DVS System Server Setup** starts. See section 3.3 *Installing the DVS Dosimetry Database Server* on page 21.



DVS Plan and Review has been successfully installed.

Click "Close" to exit.

Please use Windows Update to check for any critical updates to the .NET Framework.

Figure 11 — Installation Complete

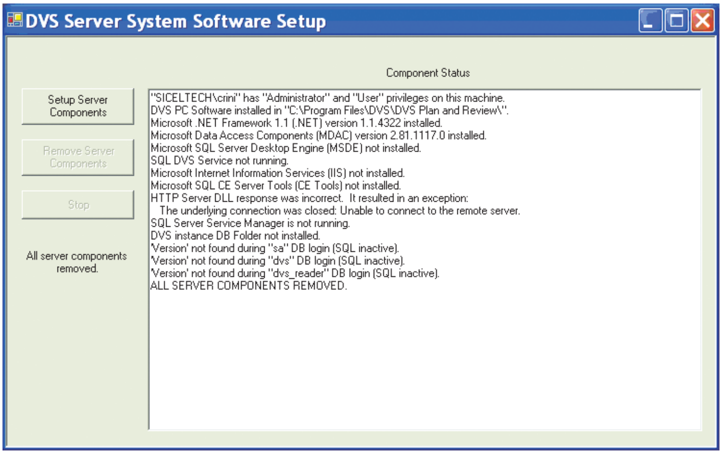
If you already installed the DVS Dosimetry Database Server or installed it with the DVS Plan and Review Software, perform the steps in **Configuring the DVS Software after Installation**. If the DVS Dosimetry Database Server has not been setup, see section 3.3 *Installing the DVS Dosimetry Database Server* on page 21.

3.3 Installing the DVS Dosimetry Database Server

The DVS Dosimetry Database stores the client and dosimeter measurement data. It is accessed using the DVS Plan and Review Software. Even if you plan to use the Plan and Review Software on a separate computer, you need to install the Plan and Review Software on the same computer as the DVS Dosimetry Database Server.

To install the DVS Dosimetry Database Server and the Dosimetry Database, perform the following steps:

1. On the computer where you want to install the DVS Dosimetry Database Server, perform the steps for *Installing the DVS Plan and Review Software* on page 15. Be sure to select the **Server Setup** check box on the **Server Setup Option** panel in the **DVS Plan and Review Setup Wizard**.
2. When the **DVS Plan and Review Setup Wizard** completes, the **DVS Server System Software Setup** window appears. If the **DVS Server System Software Setup** window does not appear, rerun the installation program and make sure you selected the **Server Setup** check box on the **Server Setup Option** panel.

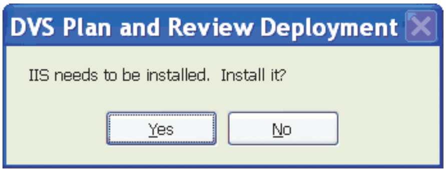


All server components removed.

```
"SICELTECH\crini" has "Administrator" and "User" privileges on this machine.
DVS PC Software installed in "C:\Program Files\DVS\DVS Plan and Review\".
Microsoft .NET Framework 1.1 (.NET) version 1.1.4322 installed.
Microsoft Data Access Components (MDAC) version 2.81.1117.0 installed.
Microsoft SQL Server Desktop Engine (MSDE) not installed.
SQL DVS Service not running.
Microsoft Internet Information Services (IIS) not installed.
Microsoft SQL CE Server Tools (CE Tools) not installed.
HTTP Server DLL response was incorrect.  It resulted in an exception:
   The underlying connection was closed: Unable to connect to the remote server.
SQL Server Service Manager is not running.
DVS instance DB Folder not installed.
'Version' not found during "sa" DB login (SQL inactive).
'Version' not found during "dvs" DB login (SQL inactive).
'Version' not found during "dvs_reader" DB login (SQL inactive).
ALL SERVER COMPONENTS REMOVED.
```

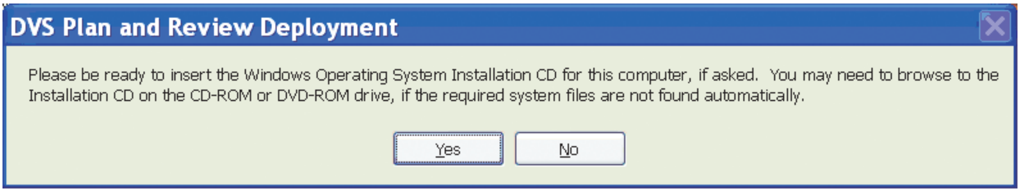
Figure 12 — DVS Server System Software Setup

3. Click **Setup Server Components**. Several windows appear while SQL Server Desktop Engine installs.
4. If the setup program determines that you need to install Microsoft Internet Information Services Web Server (IIS), the following dialog box appears. Click **Yes**.


DVS Plan and Review Deployment

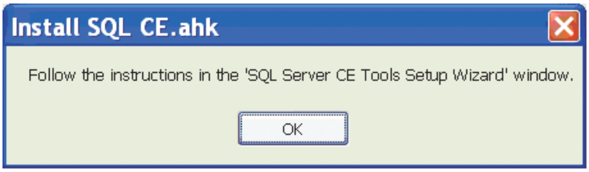
IIS needs to be installed. Install it?

5. For the IIS installation, the following dialog box appears to alert you that the setup program might need system files from the Windows XP Operating System Installation CD if they are not found on the computer. Click **Yes**.


DVS Plan and Review Deployment

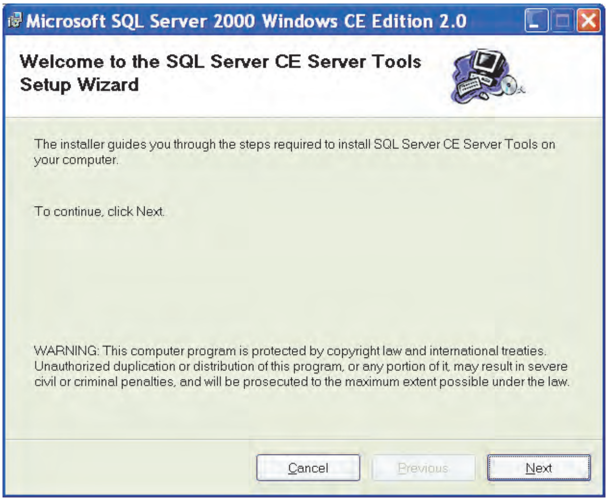
Please be ready to insert the Windows Operating System Installation CD for this computer, if asked. You may need to browse to the Installation CD on the CD-ROM or DVD-ROM drive, if the required system files are not found automatically.

6. When the IIS installation completes, the following dialog box appears. Click **OK** to start the **SQL Server CE Tools Setup Wizard**.


Install SQL CE.ahk

Follow the instructions in the 'SQL Server CE Tools Setup Wizard' window.

7. Click **Next** on the first panel of the **SQL Server CE Tools Setup Wizard**.



Welcome to the SQL Server CE Server Tools Setup Wizard

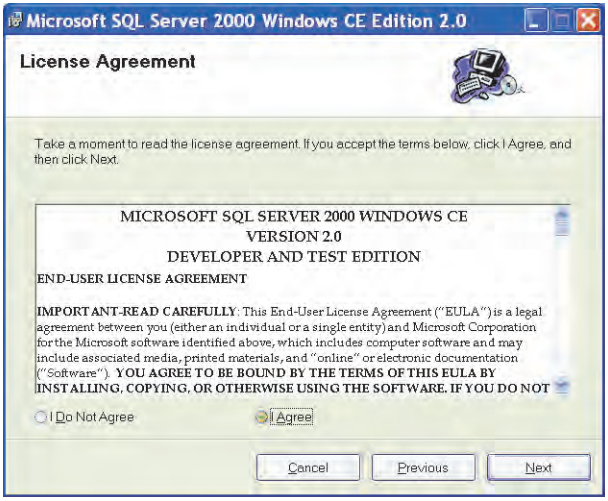
The installer guides you through the steps required to install SQL Server CE Server Tools on your computer.

To continue, click Next.

WARNING: This computer program is protected by copyright law and international treaties. Unauthorized duplication or distribution of this program, or any portion of it, may result in severe civil or criminal penalties, and will be prosecuted to the maximum extent possible under the law.

Figure 13 — Welcome

8. On the **License Agreement** panel, select **I Agree** and click **Next**.



License Agreement

Take a moment to read the license agreement. If you accept the terms below, click I Agree, and then click Next.

MICROSOFT SQL SERVER 2000 WINDOWS CE
VERSION 2.0
DEVELOPER AND TEST EDITION

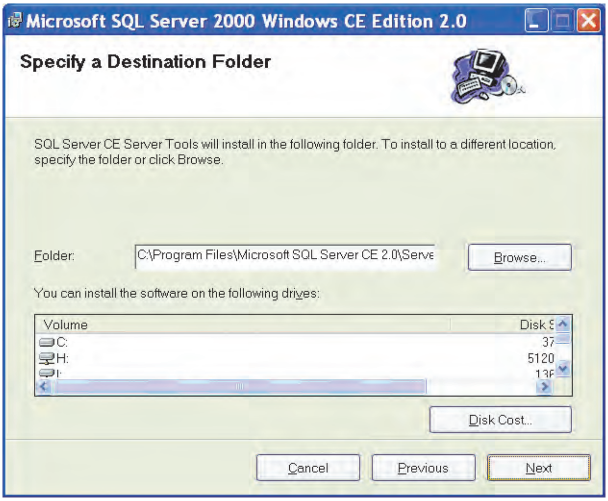
END-USER LICENSE AGREEMENT

IMPORTANT-READ CAREFULLY: This End-User License Agreement ("EULA") is a legal agreement between you (either an individual or a single entity) and Microsoft Corporation for the Microsoft software identified above, which includes computer software and may include associated media, printed materials, and "online" or electronic documentation ("Software"). **YOU AGREE TO BE BOUND BY THE TERMS OF THIS EULA BY INSTALLING, COPYING, OR OTHERWISE USING THE SOFTWARE. IF YOU DO NOT**

○ I Do Not Agree ● I Agree

Figure 14 — License Agreement Panel

9. On the **Specify a Destination Folder** panel, click **Next**.



Microsoft SQL Server 2000 Windows CE Edition 2.0

Specify a Destination Folder

SQL Server CE Server Tools will install in the following folder. To install to a different location, specify the folder or click Browse.

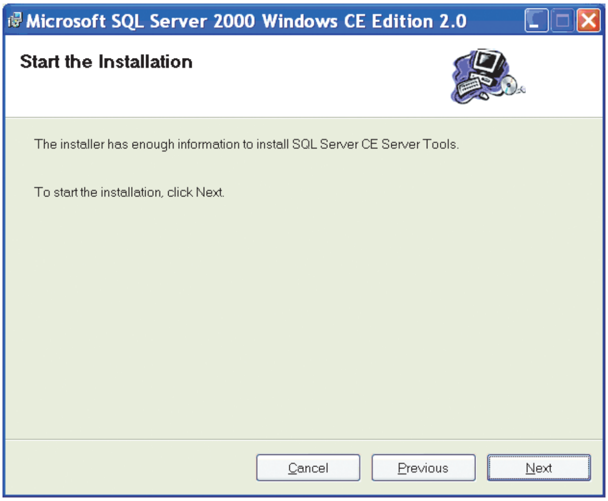
Folder: C:\Program Files\Microsoft SQL Server CE 2.0\Serve

You can install the software on the following drives:

Volume	Disk S
C:	37
H:	5120
I:	13

Figure 15 — Specify a Destination Folder

10. On the **Start the Installation** panel, click **Next**.



Microsoft SQL Server 2000 Windows CE Edition 2.0

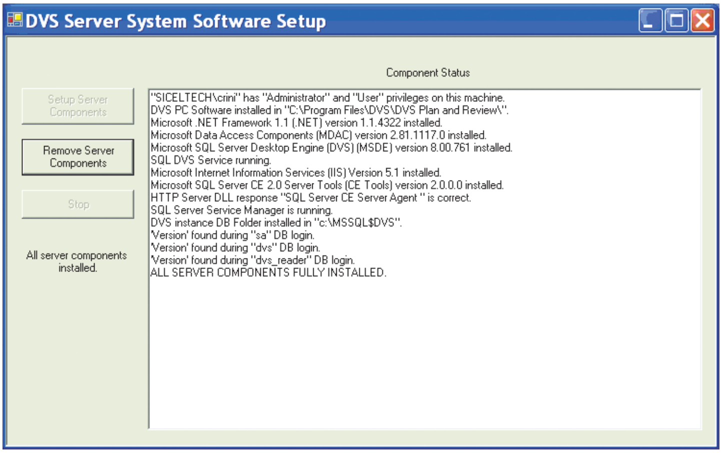
Start the Installation

The installer has enough information to install SQL Server CE Server Tools.

To start the installation, click Next.

Figure 16 — Start the Installation

When the **SQL Server CE Tools Setup Wizard** begins, the setup program displays a number of windows as it completes the installation. When the setup program completes, the **DVS Server System Software Setup** window displays **ALL SERVER COMPONENTS FULLY INSTALLED** in the last line of **Component Status** window.



All server components installed.

```
"SICELTECH\crini" has "Administrator" and "User" privileges on this machine.
DVS PC Software installed in "C:\Program Files\DVS\DVS Plan and Review\".
Microsoft .NET Framework 1.1 (.NET) version 1.1.4322 installed.
Microsoft Data Access Components (MDAC) version 2.81.1117.0 installed.
Microsoft SQL Server Desktop Engine (DVS) (MSDE) version 8.00.761 installed.
SQL DVS Service running.
Microsoft Internet Information Services (IIS) Version 5.1 installed.
Microsoft SQL Server CE 2.0 Server Tools (CE Tools) version 2.0.0.0 installed.
HTTP Server DLL response "SQL Server CE Server Agent " is correct.
SQL Server Service Manager is running.
DVS instance DB Folder installed in "c:\MSSQL$DVS".
'Version' found during "sa" DB login.
'Version' found during "dvs" DB login.
'Version' found during "dvs_reader" DB login.
ALL SERVER COMPONENTS FULLY INSTALLED.
```

Figure 17 — All Server Components Fully Installed

11. Click close (X) to exit the setup program.

3.4 Configuring the DVS Software After Installation

After you have installed the DVS Plan and Review Software and the DVS Dosimetry Database, you need to configure the DVS system. Configuration steps include the following:

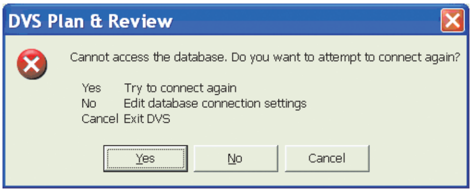
- Setting up the Database Connection (only required if the Plan and Review Software is installed on a different computer than the database server)
- Editing the Admin User
- Entering Institution Information and Preferences

Setting up the Database Connection

If you installed the Plan and Review Software on a different computer than the DVS Dosimetry Database Server, you must set up the connection to the database. If the Plan and Review Software is only installed on the same computer as the DVS Dosimetry Database Server, skip this section and perform the steps in Editing the Admin User and Entering Institution Information and Preferences.

On the computer (or computers) where the Plan and Review Software is installed without the database server, perform the following steps:

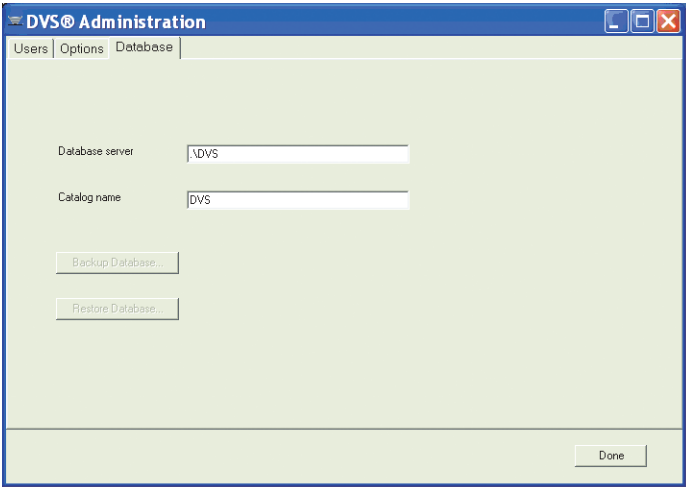
1. Click the **DVS Plan and Review** icon on the Desktop or select **Start>Programs>DVS>DVS Plan and Review**. After a 30 second pause, the following error dialog box appears.


DVS Plan & Review
Yes
No
Cancel

Cannot access the database. Do you want to attempt to connect again?

Yes Try to connect again
No Edit database connection settings
Cancel Exit DVS

2. Click **No**. The **DVS Administration** window appears.


DVS® Administration
Users
Options
Database
Backup Database...
Restore Database...
Done

Database server .\DVS

Catalog name DVS

Figure 18 — DVS Administration

3. Click the **Database** tab.
4. Enter the name of the SQL Server instance with the DVS Dosimetry Database in the **Database Server** field. For example:

   `<servername>\DVS`

   By default, the **Database Server** field is set to `.\DVS` which indicates that the DVS Database is installed locally on the same computer as the Plan and Review Software.

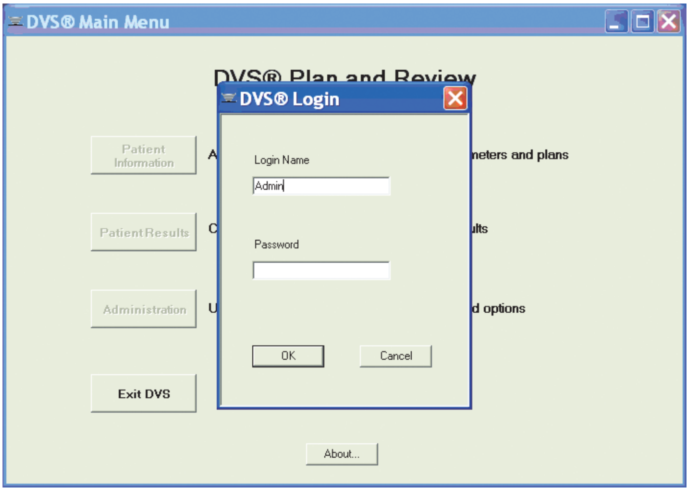
5. Click **Done**. The **DVS Login** dialog box appears.

Editing the Admin User

By default, an Admin login name with no password is setup in the DVS system so that you can login to the DVS Software initially. After installation, you should login using the Admin login and set the Admin user password, user information, and authorizations.

To edit the Admin user, perform the following steps:

1. Click the **DVS Plan and Review** icon on the Desktop or select **Start>Programs>DVS>DVS Plan and Review**. The **DVS Main Menu** and **DVS Login** dialog box appears.

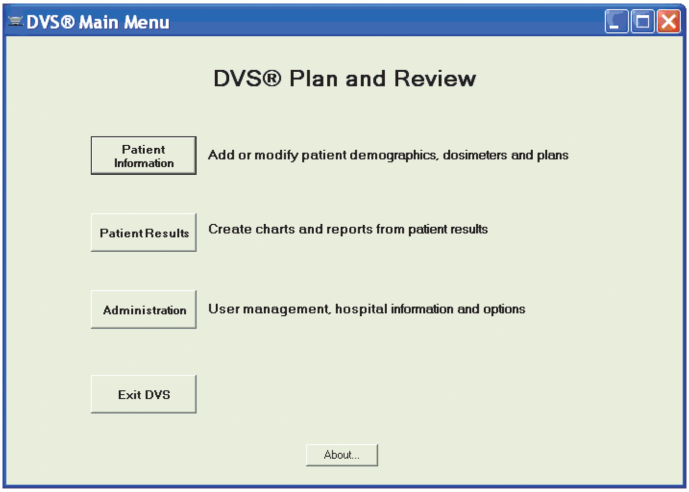

DVS® Main Menu
DVS® Plan and Review
DVS® Login
Patient Information
A
neters and plans
Patient Results
C
ults
Administration
U
d options
Exit DVS
OK
Cancel
About...

Login Name: Admin

Password:

Figure 19 — DVS Login

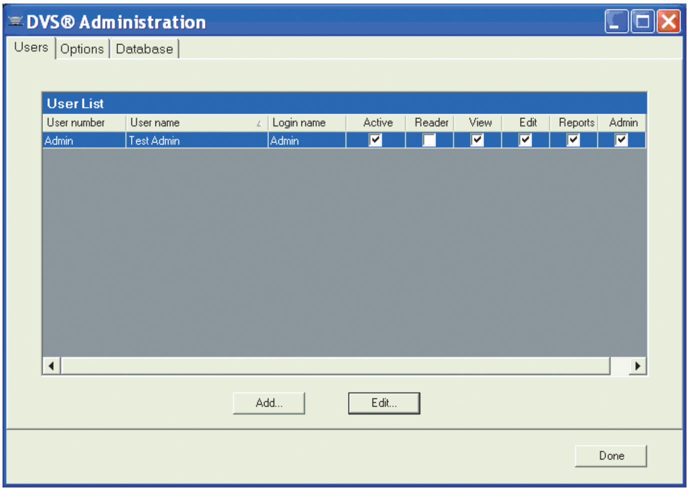
2. In the **Login** field, enter **Admin** (case sensitive) and leave the **Password** field blank.
3. Click **OK**. The **DVS Main Menu** for the DVS Plan and Review Software appears.


DVS® Main Menu
DVS® Plan and Review
Exit DVS
About...

Patient Information	Add or modify patient demographics, dosimeters and plans
Patient Results	Create charts and reports from patient results
Administration	User management, hospital information and options

Figure 20 — DVS Main Menu

4. Click **Administration** to display the **DVS Administration** window.

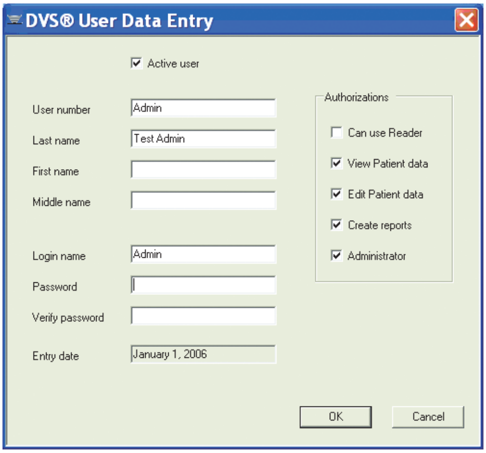

DVS® Administration
Users
Options
Database
Add...
Edit...
Done

User List

User number	User name	Login name	Active	Reader	View	Edit	Reports	Admin
Admin	Test Admin	Admin	☑	☐	☑	☑	☑	☑

Figure 21 — DVS Administration

5. Click the **Users** tab.
6. Select the Admin user from the **User List** and click **Edit**.



DVS® User Data Entry

☑ Active user

User number: Admin

Last name: Test Admin

First name:

Middle name:

Login name: Admin

Password:

Verify password:

Entry date: January 1, 2006

Authorizations

☐ Can use Reader

☑ View Patient data

☑ Edit Patient data

☑ Create reports

☑ Administrator

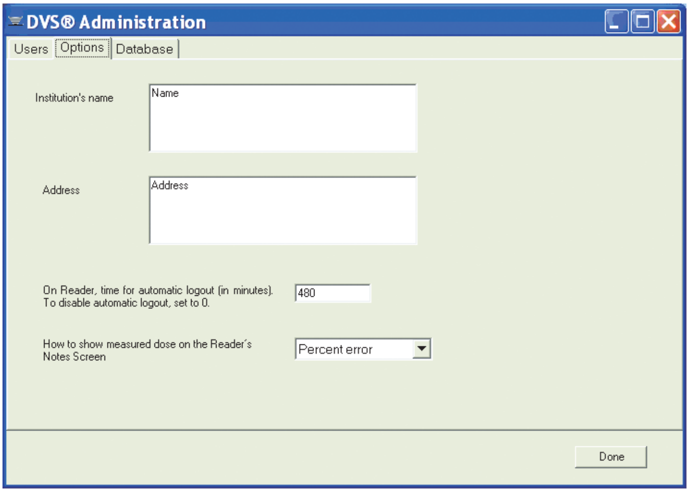
Figure 22 — User Data Entry

7. In the **User Data Entry** dialog box, edit the user information, password, and authorizations.
    - Password - must be numeric (0-9) and at least 4 digits long. Be sure to set a secure password for the default Admin user.
    - Authorizations – select the tasks you want the user to be able to perform. The Admin user should only have Administrator authorization. Administrator authorizations let the user access the **Administration** dialog box.
8. When you are finished editing the user, click **OK** to close the dialog box and return to the **Users** tab.
9. Click **Done**.

Entering Institution Information and System Options

To enter institution information and set the options for DVS, perform the following steps:

1. Click the **DVS Plan and Review** icon on the Desktop or select **Start>Programs>DVS>DVS Plan and Review**. The **DVS Main Menu** and **DVS Login** dialog box appears.
2. In the **DVS Login** dialog box, enter the Admin login name and password.
3. Click **OK**. The **DVS Main Menu** for the DVS Plan and Review Software appears.
4. Click **Administration**.
5. Click the **Options** tab.



Institution's name: Name

Address: Address

On Reader, time for automatic logout (in minutes). To disable automatic logout, set to 0. 480

How to show measured dose on the Reader's Notes Screen: Percent error

Figure 23 — Options

6. Enter the **Institution Name** and **Address**.
7. Enter the time in minutes after which you want the DVS Reader to automatically logout. To disable automatic logout, set the value to 0 (zero).
8. Select how you want to display measured doses on the **DVS Reader Notes** screen:
   - None
   - Percent Error
   - Absolute Dose
9. Click **Done** when finished.

3.5 Setting Up the DVS Reader

To set up the DVS reader perform the following steps:

- Choose a Location
- Make the Connections
- Power on the Reader
- Connect to the DVS Dosimetry Database

Choose a Location

Find a location for the DVS Reader in or near the treatment room. The DVS Reader can be placed on a counter top or attached to a pole mounted to the wall. The pole should be 1.25” in diameter and able to support 25 pounds.

Choose a place that is:

- Near an electrical outlet
- Near a local area network (LAN) connection
- **Not** in the radiation path of the linear accelerator

Make the Connections

There are three connections that you must make:

- Reader Wand - Connect the Reader Wand cable to the back of the Reader Base Station. Turn the connector 1/4-turn to lock it in place.
- Ethernet Cable - Connect the Ethernet cable to the back of the base station and then to a LAN connection in the room.
- Power cord - Connect the power cord to the back of the base station and then to the wall outlet.

Note: The USB connection on the back of the Base Station is for field service.

Power on the Reader

To power on the Reader, use the switch on the back of the base station near the power cord.

Connect to the DVS Dosimetry Database

After powering on the reader, you need to setup the connection to the DVS Dosimetry Database.

1. Contact Sicel Technical Support, and get the Administrator password-of-the-day.
2. Power on the DVS Reader. The **Power On** screen appears briefly.

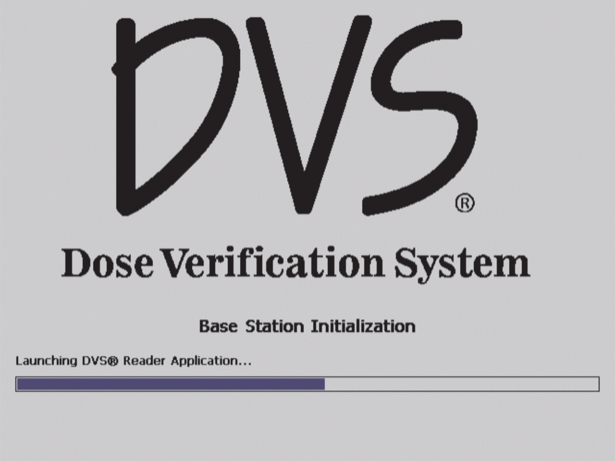

DVS®
Dose Verification System
Base Station Initialization
Launching DVS® Reader Application...

Figure 24 — Power On

3. On the **Initializing DVS Reader** screen, press **Login as Administrator**.

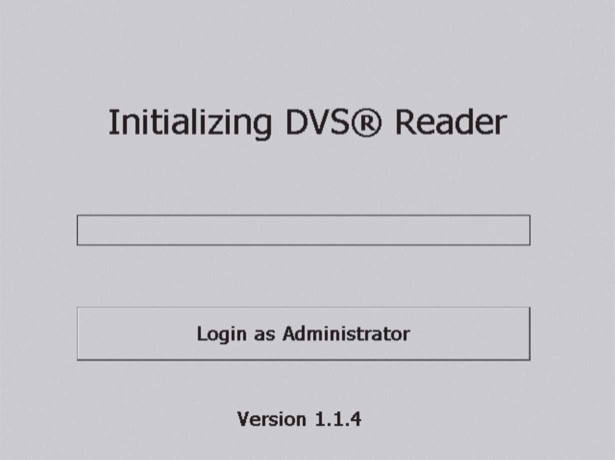
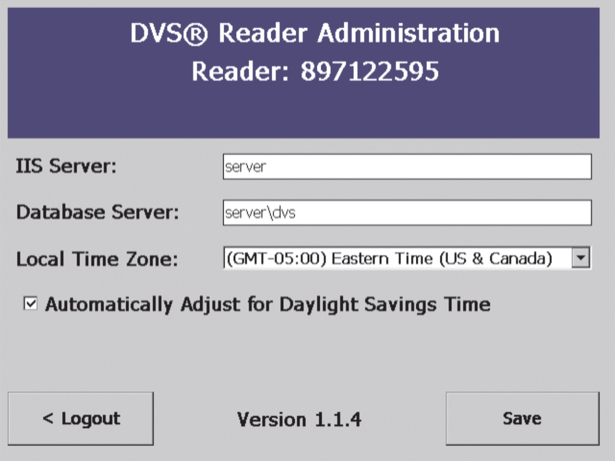

Initializing DVS® Reader
Login as Administrator
Version 1.1.4

Figure 25 — Initializing DVS Reader

4. Select the Administrator user in the users list.
5. Enter the password-of-the-day received from Technical Support.
6. On the **Reader Administrator** screen, enter the name of the server computer in the **IIS Server** field. This is typically the same as the name of the server entered in the Database Server field, but without the \DVS instance name.



DVS® Reader Administration
Reader: 897122595

IIS Server: server

Database Server: server\dvs

Local Time Zone: (GMT-05:00) Eastern Time (US & Canada)

☑ Automatically Adjust for Daylight Savings Time

Figure 26 — Administration

7. In the **Database Server** field, enter the server name and SQL server instance . For example:

   <server>\DVS

   where <server> is the name of the database server computer.
8. Select the local time zone from the drop-down list box.
9. **(Optional)** Select the **Automatically Adjust for Daylight Saving Time** check box. The date and time is automatically set when the DVS Reader connects to the DVS Dosimetry Database Server.
10. Press **Save**.
11. Wait for the **Initializing DVS Reader** screen to appear and then turn off the power to the DVS Reader.
12. Power on the DVS Reader.

4 QUICK START INSTRUCTIONS

This section provides an overview of the workflow for using the DVS system:

- Step 1 – Test Dosimeters (optional)
- Step 2 – Implant Dosimeter and Record Implant Information
- Step 3 – Enter Patient Information into the Plan and Review Software

- Step 4 – Measure Radiation Pre-Dose and Post-Dose Values Using the DVS Reader

4.1 Step 1 - Test Dosimeters

Using the DVS Reader, you can test dosimeters before sending them to surgery. This assures that the dosimeters are working properly. This step is encouraged but not required.

Important: Do not remove the dosimeters from the package because this will compromise sterility. Dosimeters can be scanned through the package. Check the expiration date on the outer package to ensure sterility.

1. Login to the DVS Reader.
2. Press **Test Dosimeter** on the **Reader Login** screen.
3. Hold the Reader Wand near the dosimeter.
4. Press the button on the Reader Wand to scan the dosimeter. Below the status bar, the DVS Reader displays one of the following messages:
    - Dosimeter <number> was found – the dosimeter is functional
    - No Dosimeter found – the dosimeter could not be read
5. Press **Logout** to exit.

4.2 Step 2 – Implant Dosimeters and Record Implant Information

Verify that the DVS Dosimeter and insertion tool package sterility have not been compromised, are not expired, and that the items have not been contaminated prior to implantation.

At surgery, specify the implant location of each dosimeter on the transfer labels provided. The transfer label information aids the dosimetrist in identifying the dosimeters on a CT scan. For each dosimeter, retain one transfer label in the surgical records and return the other to Radiation Oncology.

4.3 Step 3 – Enter Patient Information Into the Plan and Review Software

Using the Plan and Review Software, enter the patient's demographic information and dose planning information. Ensure that the predicted dose at the dosimeter was obtained by measuring the point dose 1.3 mm from the end of the capsule *opposite* the antenna (Figure 27). Use a CT scout film or radiograph to determine dosimeter orientation within the patient (Figure 28).

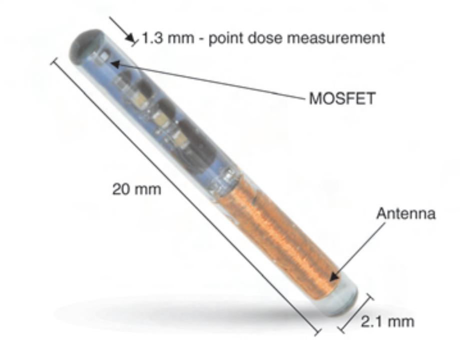


Figure 27 — DVS Dosimeter Sensitive Volume