OrthoView Orthopaedic Digital Planning



User Guide for a Workstation System

OrthoView 6.0 (WK) Issue 1.0 Web: www.orthoview.com E-mail: info@orthoview.com



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INTRODUCTION

This User Guide is intended to give you the information you need to begin using OrthoView[™]. For more detailed information on all aspects of operating the software see the Help file accessed from within OrthoView[™] by pressing the **<F1>** key or consult the Training Manual you received during your OrthoView[™] training.

For specific information on using the Wizards see the Training Guide or the context sensitive Help accessed from within OrthoView[™] by pressing the **<F1>** key.

For information on installing and setting up OrthoView[™] see the Installation Instructions supplied with your software or contact support@orthoview.com

For information on Licensing see the Licence Installation Guide supplied with your software or contact sales@orthoview.com

Important:

The OrthoView[™] software has recently been re-assessed with respect to the European Union Medical Devices Directive (93/42/EEC). As from version 5.3 onwards OrthoView[™] is now classified as Class 2A (it was previously Class 1) and has 'upgraded' CE marking requirements which means that it is officially recognised as class 2A medical device and that the Meridian Technique organisation which produces, installs and supports OrthoView[™] has been assessed and accredited against quality management system requirements (ISO9001 and ISO13485)

Intended Purpose

USA

Laution: USA Federal law restricts this device to sale by or on the order of a physician

Indications for Use: OrthoView[™] is indicated for use when a suitably licensed and qualified healthcare professional requires access to medical images with the intention of using such images, in conjunction with templates for prosthetic and fixation devices, for the purposes of choosing the nature and characteristics of the prosthetic/fixation device to be used when planning a potential surgical procedure. In addition, Trauma and Osteotomy Modules and Trauma Templates are provided to extend the range of functionality available to the healthcare professional.

Purpose of this Document

Please read the information at the end of this document entitled Regulatory Standards and Declaration of Conformity. It provides supplemental information about, and about using OrthoView[™]

Orthoview Workstation Overview

This is a description of the basic process you may use to plan Orthopaedic or Paediatric Operations using OrthoView. This describes a simple method of operation you may adopt just to get you started. OrthoView has many possible paths and "short cuts" which you can find in



the User Guide or Help system. At any point within OrthoView the **<F1>** function key will give you help about the function you are currently performing.

Getting your Images into OrthoView

Introduction

OrthoView Workstation works with digital images and understands both DICOM and JPEG types. DICOM is the standard for medical imaging but JPEG is also used. If you are no longer getting film from your imaging service but are viewing X-rays on a PC then you can use OrthoView. Even if you still get film you might want to get them scanned in so you can use OrthoView, as it offers many possibilities not available with traditional templating.

The final section of this guide tells you about using digital x-rays from the following sources: -

- DICOM CD (specially created for medical image distribution)
- Folder or 'regular' CD
- Online e.g. from a PACS; digital image archive; teleradiology system
- Film digitizer or digital camera

Getting Images into OrthoView



DICOM CD (specially created for medical image distribution)

Your imaging service may supply you with special CDs that hold x-rays for a particular patient or patients. Many digital radiology systems (often known as PACS systems) have a special facility to write CDs for clinical distribution. These CDs typically contain DICOM images and have a viewer included that automatically starts once the CD is loaded. To get the images into OrthoView load the CD, ignore the viewer if it starts, and launch OrthoView. On first screen click 'Import from CD...' A dialog appears where you can query for a particular patient or image. As there will not be so many images it is safe to simply click 'Do Query'. A list of the patients with images on the CD appears. Clicking on the '+' sign to the left of the name will show you the studies for that patient. Further '+' signs appear that can then be clicked to reveal images for



that patient. Highlight the one or ones you need and click 'Import'. Progress will be indicated by the bar in the top right of the dialog box. When this has ceased and the word 'idle' is displayed click 'Close'. You should now see an entry for the patient in the examination list and can proceed.

Technical Note: OrthoView looks for a file called 'dicomdir' on the CD. This is the 'patient index' file that most radiology systems include. It tells programs like OrthoView where to find patient images that are in DICOM format. If there is no 'dicomdir' it is still possible that there are DICOM or even JPEG images on the CD. Try 'Import from Folder' below to check.

Folder or 'regular' CD

You might want to plan from digital x-ray images that someone has manually written to a CD or copied onto a folder on your PC. If these are in either JPEG or DICOM they can be imported into OrthoView.

Once OrthoView is loaded click 'Import from folder...' At the top of a dialog box that appears there is an entry for the folder that OrthoView will look in for images. The folder could in fact be an entire CD or drive. For example it could read Look In: 'data_cd (E:)', where E: is the CD drive and data_cd is the label of the CD in the drive. Click 'Open' now and a new dialog will appear that is just like the one for 'Import CD' described above. When you find the file you are looking for click on it to select and then click 'Import'. The 'Import' button 'activates' for any individual file that is selected (not for folders) but only JPEG and Dicom files will be imported successfully.

Technical Note: DICOM images include information on size that allows you to estimate magnification if there is no x-ray marker in the image. This information is often not present in JPEG images so they need to include a true marker or at least a ruler. For a fuller description of scaling, markers, and rules please see the Help.

Film digitizer or digital camera

Depending upon the software you are using to handle the film digitizer the result may be either JPEG or DICOM images. These can be imported from a folder as described above. If the film digitizer is on a different PC then as well as the normal methods of transferring files your software might have DICOM transfer abilities. If so see below.

Digital cameras produce JPEG images (amongst other things) so in principle you digitize an xray film this way. However, unless you take great care in aligning the camera such that it is square on to the film then you will introduce distortions that may affect any measurements made.

Online connection to a PACS or image archive

There are a huge range of different computer systems and software available for storing, moving and viewing digital x-rays. A complete hospital or imaging center system for this is usually called a PACS (Picture Archive and Communication System). You might also have practice management system or electronic patient record system that stores x-rays, or perhaps a smaller system that archives images from CR, CT, MR. etc. For brevity we will refer to all these systems as a PACS. Fortunately, OrthoView can connect to most of these because of a standard for communication in medical imaging called DICOM. Setting up the DICOM connection is simple but does require a few pieces of technical information you will need to get from your PACS administrator or IT manager. These are described below.

There are two ways to get x-ray images from your PACS to OrthoView. They can be sent from the PACS (often called 'pushing') or someone sitting at OrthoView can browse

the patients on the PACS and copy the images required to OrthoView. Query and retrieve (Q/ R) is usually more convenient but it's your choice.



There are slightly different things to be set up if you plan to push compared to if you are using Q/R. With the exception of the IP address the OrthoView side is configured within its preferences setup (*File/Preferences/Dicom Network*). The default values should work.

Sending Images from PACS

Operation

Once the DICOM connection is set up an operator will select images on a PACS viewer and send them to OrthoView. Exactly how that is done depends upon the PACS. They will appear as entries in OrthoView's 'Examination List'. It's possible that the PACS viewer and OrthoView could be on the same PC.

Setup

Please request your PACS administrator to set up a 'remote location' for OrthoView with the following values: -

- IP address this is the network address of the computer running OrthoView and would have been allocated by your IT department. It is not specific to OrthoView and can not be changed within OrthoView.
- AE Title Default is **Orthoview**
- Port Number Default is 104

If you need to change these defaults do so in the 'DICOM Incoming Settings' section of DICOM Network Preferences. This is in the Preferences menu of OrthoView.

Ensure that 'Accept Incoming DICOM Files' is set to 'Yes' in the above section of preferences.

Query and Retrieval of Images from PACS

Operation

Once the DICOM connection is set up the OrthoView user can, from within OrthoView, browse the PACS patient list; select and then copy images to OrthoView for templating.

From the OrthoView Examination List click 'Query and Retrieve...' and a large dialog appears. You can now select a range of study dates; patient name; study ID; etc. When you have chosen your 'filters', click on 'Do Query'. A list of the patients with images on the CD appears. Clicking on the '+' sign to the left of the name will show you the studies for that patient. Further '+' signs appear that can then be clicked to reveal images for that patient. Highlight the one or ones you need and click 'Retrieve'. Progress will be indicated by the bar in the top right of the dialog box. When this has ceased and the word 'idle' is displayed click 'Close'. You should now see an entry for the patient in the examination list and can proceed

Setup

Please ask your PACS administrator for the following information about your PACS and enter them in OrthoView's 'DICOM Query Settings' - section of 'DICOM Network Preferences'.

- Remote AE Title
- Remote IP Address
- Remote Port Number

It is likely that the PACS needs to know about OrthoView to allow it to query. The required information is: -

Local AE Title - Default is Orthoview



Local Port Number - Default is 104

Storing Your Results

Once you have completed your OrthoView planning session and clicked 'Finish' you may 'Save' or 'Commit'. 'Saving' a session allows you to re-open it later and alter the plan. 'Committing' creates a permanent, read-only record.

If you are connected to a PACS you have the option upon 'Saving' or 'Committing' to store the results locally (i.e. on the same PC) or send them to the PACS. If initially stored locally you can subsequently send to the PACS by right clicking on it in the In Basket. This would be useful, for example, if you are working at home and can only connect to the PACS once you are in the office. The default storage location is set in preferences but you have the option to override this when you store. Note that results generated from JPEGs can only be stored locally.

Setup

Please ask your PACS administrator for the following information about your PACS and enter them in OrthoView's 'DICOM Outgoing Settings' - a section of 'DICOM Network Preferences'

- Remote AE Title
- Remote IP Address
- Remote Port Number

Note: this User Guide may include functionality which you do not have available in your version of OrthoView[™]. If you would like more information on a specific feature, please contact your supplier.

Viewing version and registration information

- To view version and registration information
- 1. On the **Help** menu, click **About**.

To view the license agreement which you have agreed to, click License Agreement.

2. When you have finished viewing, click **OK** to close the **About** window.

Templates

To use OrthoView[™] for planning orthopaedic procedures you need to obtain and install Templates for the prostheses you use in surgery.

Note: Demo users are either provided with a sample set of templates pre-installed or should follow the instructions on the CD documentation.

To request Templates as a registered user

To obtain the orthopaedic templates you require, you must have a registered account on the OrthoView website (www.orthoview.com).



If your supplier has provided you with a username and password for the website, please use this to log on and request the templates you require. If you have not been provided with a login, please follow the procedure below to create your user account.

1.Go to our website (www.orthoview.com) and select the 'Register Software' link and enter all the requested details for your hospital. In the field 'Product Key' enter the unique reference code sent to you with your OrthoView license, it is a number similar to this OR123-12345678.

2.On receipt of the registration information, OrthoView will authorize the account and send an email to the nominated email address confirming the account has been authorized. This will be done no later than close of business on the next working day following the registration.

3.Once you have a registered account you can log on to this account and select the 'Request Templates' button to request the templates you require. Upon receipt of the request(s) OrthoView will make any released templates available for download and send the user an email advising them that the templates are available. Any requested templates that were not immediately available will be added to the website as they are released.

4.To download templates, log on to the website and follow the on screen instructions.

To install Templates

Templates may be installed either locally or on a server depending on your OrthoView installation. Templates can be installed locally by simply double clicking their installer and following the instructions. To install on a server contact your system administrator.

Using windows in OrthoView[™]

Windows in OrthoView[™] have the following features:





- **Title bar**. Displays the name of the program.
- **Menu bar**. Directly underneath the Title Bar. This displays the drop-down menus available in OrthoView[™]. Click a menu name to open the menu and see the available commands. To the right hand side the Licensed Institution and current User Name are shown.
- **Generally Available Buttons**. These are the generally available buttons you can select when working in the main screens within OrthoView[™]. When you are scaling, planning, reducing or templating you can click Examination to return to the Examination panel, which is useful if you want to open additional images. (If you do this, you do not lose your work)
- **Patient Information**. Click the **1** icon at bottom left hand side of screen to view patient details and edit, if required. **Note:** If you wish to add notes to an examination, there is a separate Notes Panel which will become available once you have opened an examination.
- **Zoom options**. There are two options for this. Select the icon to the right to open the Zoom Control Box for more options or select the icon to the left to toggle between size-to-fit display or previously zoomed image.
- **Image Size**. This is only useful if you have more than one patient image open at the same time. If multiple windows are visible, click Maximize Control to expand the window to fill the whole patient image viewing area. The Control then toggles to become the Minimize Control. Click the Minimize Control to make the window share the space with all the other images.
- **Close image**. This closes the window. Note: Any work done in the window is saved, so if you re-open the window, it will be in the same state as it was in when it was closed.
- **Option Panel**. Used for a group of options where only options appropriate to current image status can be selected. This would include Scaling Tools, Planning Wizards, Reduction Facilities and Templating Selections.
- Image Area. Displays up to four opened X-rays at one time.
- SmartHelp. Context sensitive assistance when required. SmartHelp is accessed from

the *licon* shown on the status bar. It will display as a box that can be closed, unlocked (moved) or locked (return to where it initially appears)



Setting window positions and sizes

OrthoView[™] remembers the position and size of the main and Help windows. The first time you start OrthoView[™] it opens the windows at their default size and position. Any changes you make by dragging and re-sizing the windows are saved.

We suggest that you do the following when you first start OrthoView™:

- Set the size and position of the main window to a good setting for the monitor(s) you are using.
- Open the Help system (press F1) and set the size and position of the Help window. You can then close the Help window.
- Close OrthoView[™] to ensure that the window positions are saved.

Window and Leveling

At each of OrthoView's[™] stages Scaling, Planning, and Templating; it is possible to individually manipulate the contrast and/or brightness of the x-ray images to be worked with.

- To set up contrast and/or brightness
- 1. Select the image for manipulation, click the image's title bar.
- 2. Click the Window and leveling icon [•] on the right of the toolbar, so the mouse cursor changes and drag, as described in step 3.
- 3. Click-and-drag the mouse to achieve the desired effect.
 - To increase the image brightness, (or window center) drag the mouse vertically downwards away from the x-ray image title bar. Reverse the direction to reduce the brightness.
 - To increase the image contrast, (or window width) drag the mouse horizontally to your left. Move it to your right to reduce the contrast.
- 4. The figures identifying the exact window width and center achieved during the manipulation are displayed on the image.



FAMILIARIZATION

This section is designed to help you become familiar with the basic operation of OrthoView[™]. If you have not used OrthoView[™] before, we suggest that you work through this section carefully, with OrthoView[™] running.

Online Help

OrthoView[™] has two interactive Help systems, which provide all the material you need to learn and use OrthoView[™].

SmartHelp

SmartHelp gives step by step assistance while using OrthoView™

SmartHelp is accessed from the *icon* shown on the status bar. It will display as a box that can be closed, unlocked (moved) or locked (return to where it initially appears)

The following icons list available display options:

Close SmartHelp - This can also be achieved using the *concerned to the status line when* Open

Unlock - This will open the SmartHelp content in a moveable box which can be placed onscreen where convenient.

Lock - This will return the display to the locked position above the status line

SmartHelp will remember the last selected display option on subsequent usage

SmartHelp can be extended based on Users' feedback for later versions. If you require specific additional information please contact support@orthoview.com to discuss your future requirements.

F1 or What do I do next?

The Help system also provides a Context Sensitive Tracking (CST) System that tracks all mouse clicks within OrthoView[™]. Pressing **<F1>** or the **<What do I do next?>** option in the **Help** menu activates this feature and displays the most relevant area of the document.

The OrthoView[™] Help system uses Java to format and display information. Some information may require an Internet connection.



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The Help Viewer provides an integrated table of contents so you can find information easily. Double click the Table of Contents to reveal topic entries and sub-chapters. The Help Viewer has the added benefit of allowing you to see the table of contents at the same time you are viewing a Help topic. This helps you to see what other topics are available within the Help system at a glance.

The top menu and page controls helps you move around the Help system.

Help Navigation

The **Top** menu includes the following functions:

Button	Functionality
«	This steps back through pages you have already visited.
Previous	
≫	This steps forward through the Help system.
Next	
	Click to Print the OrthoView Help file.
Print	
₽	Use to configure page orientation and size for printing purposes.
Page Setup	
	Use to view and navigate through a list of available topics. The content tab displays the Help files categorized into certain areas.
Contents	



Menus

OrthoView[™] has been designed to be intuitive to the user. Software tools in the Control Panels can be sufficient to do standard planning sessions. If you need to go back and re-check your work, in earlier screens, or to manage multiple patient images, you can use the menus at the top of the application.

Keyboard shortcuts

Keyboard shortcuts allow you to perform actions with a single keystroke, making OrthoView[™] quicker and easier to use. To use a shortcut key, hold down the modifier key (or keys) indicated below, and then press the keyl

Press	Action		
<ctrl> R</ctrl>	View the Preferences Panel.		
<ctrl><t></t></ctrl>	Manage your available templates and select your "Favourites"		
<ctrl> M</ctrl>	Show/Hide Meters.		
<ctrl> P</ctrl>	Print Report		
<ctrl><alt> P</alt></ctrl>	Print current x-ray complete with superimposed items		
<ctrl> E</ctrl>	Quit OrthoView™		
<ctrl> C</ctrl>	Copy selected text.		
<ctrl> V</ctrl>	Paste selected text.		
<ctrl> X</ctrl>	Cut selected text		
<ctrl> -</ctrl>	Zoom-out on current image		
<ctrl> +</ctrl>	Zoom-in on current image		
<f1></f1>	Display the current <what do="" i="" next=""> help screen.</what>		

Preferences

OrthoView[™] can be customized in several ways for individual hospitals in which it is installed. Preferences come set up with sensible defaults but you may want to change these. if you have a multi-user license, the **Display** and **Storage** preferences settings are saved on a per user basis. Any modifications made to the **Network** preferences are global, that is the settings apply to all users.

To access OrthoView's[™] preferences, on the **File** menu, click **Preferences**. The following tabs are available:

Storage Preferences. To select the examination output folder. To select the Dicom scan folder. To select the Dicom scan folder and the X-ray image folder. To select the X-ray and Dicom import folders.

Examination Preferences. To select additional OrthoView preferences, including default



patient image settings, for standalone, single-user licenses.

Display Preferences. To select the colors and styles displayed by OrthoView[™].

Network Preferences. To select additional OrthoView preferences, including default patient image settings, for standalone, multi-user, and network licenses e-mail Preferences. To enter e-mail address details, so that you can be contacted when Templates are due to expire, for example.

DICOM Network Preferences. This panel sets

- the incoming connection between the PACS system(s) and OrthoView[™].
- the parameters needed when connecting to other device(s) for Query and Retrieve. The type of retrieval to use can be specified as either C-Move or C-Get. Which setting to use is dependent upon the capabilities of the device you are connecting to. If you do not know which setting to use consult your System Administrator or the Dicom conformance statement of the system you will be querying.
- the outgoing connection between the OrthoView[™] and the PACS system. It determines where the output is stored when you save or commit. If you choose to store the data locally the output simply remains in your X-ray folder on the local machine. If you choose to store data remotely, then the data will be sent directly to the dicom device specified in the remote options below. Note that these options only apply when Dicom images are used. If JPG images are used they are ALWAYS stored locally. Output files can be compressed in GZIP format.

Advanced. The paediatric assessment, fracture management and other advanced modules can be turned on or off from this tab.

Administration. This tab is used to set and reset password.

To close the **Preferences** panel and save your changes, click **Save**. To close without saving any modifications, click **Cancel**.

Templating stages

To Template an x-ray you need to proceed through four stages: Loading, Scaling, Planning and Templating.

- 'Examination Loading' on page 1-12.
- 'Scaling' on page 1-21.
- 'Planning and Reduction' on page 1-22.
- 'Templating' on page 1-25.

Examination Loading

This consists of selecting and then opening one or more images. OrthoView[™] can display up to four images at the same time. For hips and shoulders, you need a single AP image, unless you are also intending to work with an ML view. For knees you will normally need two images – an AP and an ML view.

Note: If you attempt to load an examination saved or comitted from a previous version and are unable to do so it might be worthwhile trying to retore it into the same version as it was created



before contacting support. If still unable to load then then the archive might been damaged in some way. (In cases of difficulty, support@orthoview may be able to assist)

You use the **In Basket** to locate and load images. There are several ways in which images can be located. From the **In Basket**, do one of the following:

- Select the examination you want to work with from the list and click **Open**.
- Double-click the examination name in the list to open it. If the required examination is not displayed in the list, click **Refresh**. If it is still not displayed, make sure that it exists in the **X-rays** folder.
- Click **Browse**. You can then navigate and select an image from the examination you want to work with.
- If you are using Dicom images exported from another system and you have not set your General/Workstation/Enterprise preferences to automatically import images to the Xrays folder, on the In Basket, click Import Dicom Images. Navigate to the image location and click Open.

When you select an image(s), the **Examination** panel is automatically displayed. Patient details can be viewed, if required. Patient details can be viewed and modified, if required. To view patient details, from the **Examination** panel, click **More**.

Note: if you have selected the wrong examination, click **Discard** to return to the **In Basket**.



Examination Panel

You use the **Examination** panel to select the procedure and the side of the patient which is to be operated on. To do this, under **Select Procedure**, hover over the relevant joint or shaft marker (red mark) which represents the correct procedure and patient side. When you do this, you receive a choice of procedures, for which you have Templates: for example, total Knee replacement or unicompartmental knee arthroplasty







USING THE EXAMINATION PANEL

You use the **Examination** panel to select the **procedure** that you are going to plan, which side of the patient is to be operated on and the prosthesis.

Starting a Procedure

Select Procedure

If the Paediatric Assessment Module is turned on in the preferences panel then the Select Procedure image is different and allows the user to choose between Infant, Child and Adult representations of the person. These also show representations of shafts as well as joints.

The life stage and basic type of procedure is selected initially from the following dialogue:

1. Select Procedure

- Select a procedure type and life stage.
- Then hover over a body area to display procedures.

Elective Procedures



Adult, Child, Infant

Deformity Procedures



Adult, Child, Infant

Fracture Management



Adult

The following is a complete list of the available life stages:



Life Stages (incl. Paediatrics, Deformity Assessment and Fracture Management Modules)

lcon	Paediatrics, Deformity Assessment and Fracture Management Enabled	Body Image
\bigstar	Adult Elective Procedure	
*	Child Elective Procedure	
*	Infant Elective Procedure	
*	Adult Deformity Assessment	*
*	Child Deformity Assessment	
*	Infant Deformity Assessment	
	Adult Fracture Management	

The following is an example list of available procedures.Left and right procedures are displayed in that order. The type column indicates the type of procedure. (Elective, Deformity or Fracture)



Procedure Icons

lcon		Procedure	Туре
Ť.	÷.	Ankle - Replacement	\bigstar
×-	×	Elbow - Resurfacing	\bigstar
Ŕ	de la	Elbow - Replacement	\bigstar
A	$\frac{d}{r}$	Finger - Replacement	\bigstar
*	r	Hip - Hemi Arthroplasty	\bigstar
Ø.	R	Hip - Resurfacing	\bigstar
ŝ	ľ	Hip - Total Hip Replacement	\bigstar
ę	Ą.	Knee - Total Knee Replacement	\bigstar
-W	Ç.	Knee - Unicompartmental	\bigstar
8	1	Shoulder - Humeral Head Resurfacing	\bigstar
٩	ľ	Shoulder - Total Shoulder Replacement	\bigstar
bi _{ll}	1 ²⁶	Toe - Total Toe Replacement	\bigstar
л. Д	1 T	Wrist - Total Wrist Replacement	\bigstar
٢	1	Planning and Assessment (all life stages)	\uparrow



	1	Osteotomy Plate	* * *
ö	-	Miscellaneous Procedure	\bigstar
#	‡.	Arthrodesis - Ankle	*
Ż	<i>~</i>	Arthrodesis - Wrist	\bigstar
P	1	Hip - Dynamic Hip Screw	\bigstar
×,	1	Nail - Intramedullary Large	\bigstar
*	-	Nail - Intramedullary Small	\bigstar
X	Ľ	Nail - Retrograde Intramedullary Large	\bigstar
**	aread.	Nail - Retrograde Intramedullary Small	\bigstar
	1	Plate - Dynamic Compression Large	\bigstar
	Ø	Plate - Dynamic Compression Small	\bigstar
and the second s	å	Plate - Peridistal Large	\bigstar
A	A	Plate - Peridistal Small	\bigstar
the second	je star	Plate - Periproximal Large	\bigstar
-	Ø	Plate - Periproximal Small	\bigstar



N	/	Plate - Tubular	*
Ť	t	Screw - Single	\bigstar

As the mouse moves over the body Image different icons are displayed to reveal the available procedures. The miscellaneous procedure icon is made available on all body areas to accommodate templates where specific area of use is unknown. Click to select the procedure on the side of the patient to plan/template. This is necessary, so that the correct templates and wizards are displayed. The patient side you select is recorded in the final **report**, and is used as a default in inserting Templates. Templates can be reversed at a later stage, however, the procedure side cannot be changed.

Note: you can not begin planning/templating until you have selected a procedure.



Legend:

(1). Hover over to view the available prosthesis. If a joint marker is displayed in blue on the blue patient image (for elective procedures) it denotes there are no corresponding Templates. On the red patient image (which denotes fracture management procedures) a blue marker indicates one or more templates are available.



When you select a procedure and the patient's side a summary of the procedure is displayed in the box below the figure.

Notes:

Orthopaedic Digital Planning

- if a blue joint marker is displayed on the blue patient image it denotes that you do not have any corresponding templates.
- The red joint markers on the blue patient image represent the procedures and patient side on which the procedure can be performed. When you hover over a red joint marker you get a choice of prosthesis, if they exist, that are installed: for example, total knee and unicompartmental knee, click to select the required prosthesis and patient side.
- On the green patient image, the various procedures are shown as yellow lines.
- On the red patient image, if a red marker is displayed it denotes that you do not have any corresponding templates.
- The blue markers on the red patient image represent the procedures and patient side on which the procedure can be performed. When you hover over a blue marker you get a choice of prostheses (if they exist) that are installed. e.g. large or small dynamic compression plate or femoral IM nail. Click to select the required prosthesis and patient side

On the red patient image, any joint markers displayed in red, as opposed to blue, denote you do not have the required Templates.

When you have selected the procedure, the digital templates for the prosthesis you normally use is displayed. If you want to use a different prosthesis for this procedure, click the template, so that the **Select a Product** dialog box is displayed. Locate the required template and click to select the preferred prosthesis.

Under **Select x-rays to open**, select the image(s) you want to open: to do this, click the name(s) in the list. You can select multiple entries: to do this, either press SHIFT or CTRL while you make your selection. To toggle the selected images, by holding down Ctrl while clicking. When you have made your selection, click **Open Selected X-rays**.

The image(s) open. If multiple images are opened, one of them will be the "Current" one and is clearly highlighted.

To change which window is selected, click the window's header. Alternatively, you can use the **Windows** menu and/or the controls at the top right-hand corner of the images to display only the current window or to show both/all of them at once.

If you close a window, you do not lose the work you have done on it. Double-click its name in the **Examination** panel to open it in the same state that it was in when you closed it. You can also use the **Examination** to open images that you did not open originally.



Scaling

Important: For most procedures OrthoView[™] expects alignment of long bones to be proximal towards the top of screen and distal towards bottom of screen. The image manipulation tools should be used before scaling to correctly align such X-rays.

When you have selected the appropriate x-ray(s) and specified the side of the patient which is to be operated on, the **Scaling** panel is displayed. From here you establish the x-ray type and calibrate the image. This stage is critical because, even if the size of the x-ray film/plate is known, the anatomical features will have been magnified by a factor that depends upon the setup of the x-ray machine and the size of the patient.

In most scenarios, OrthoView determines the projection and laterality of the x-ray. However, you must set and/or verify the following prior to scaling:

- The Templating View. (X-ray projection) Select whether the x-ray is an AP, PA, ML or LM view.
- The X-ray laterality. Select Left, Right or Bilateral.

You must then establish the scale of the x-ray. This is based either on the magnification of an object of a known size on the same x-ray plate (marker method) or it is measured by resolution, that is by identifying pixel spacing (ruler method).

Note: Once an X-ray has been scaled it is not possible to change the settings for Templating View or X-ray laterality.

Known magnification

Some radiology departments, who take x-rays for Orthopaedic purposes, can guarantee a particular magnification for each joint. If this is the case, you can click **Confirm Oversize** to commit the magnification. If you trust your radiology department to do this, you can set the magnifications they guarantee using the **General** preferences. For familiarization purposes, you can use the default settings, but you must ensure that x-rays always have the specified magnification for each joint before using the **Confirm Oversize** method for planning orthopaedic procedures on real patients.

Using markers to confirm oversize

A more accurate means of scaling is to place a radio-opaque object of known size on the patient in the same plate as the joint being imaged. When you view the x-ray in OrthoViewTM, you then place a meter on the marker and then tell OrthoViewTM how big it actually is, in millimeters. To do this, select either the circular or linear measurement tools from the toolbar in the **Scaling** panel. Drag the tool over the x-ray image of the marker. It is usually a good idea to position the measure approximately and then to click the magnify button in the top left of the window. This gives you a magnified view, so you can position more accurately. When you have set the size, click the measure display, which currently displays **unscaled**. On the **Scale Image** dialog box, enter the size, in mm and click **Marker**.

Using rulers

Use this method to establish pixel spacing on the x-ray, in the event that this information is not present on the image. To use this method, select either the circular or linear measurement tool from the toolbar at the top of the **Scaling** panel and double-click the measure display, which currently displays **unscaled**. On the **Scale Image** dialog box, enter the pixel spacing size, in mm, and click **Ruler**.



On the **Confirm Oversize** dialog box, enter the oversize percentage for the image and click **OK**.

You are now ready to enter the planning stage. We suggest that you click **zoom** to view the whole x-ray.

Planning and Reduction

Depending on whether you selected the blue or red patient image from the Examination Panel you will next be presented with a Planning Panel or a Reduction Panel.

Using the Planning Panel you can take measurements from anatomical features on the patient image with the meter tools and/or by using one or more of the specialized wizards. During the planning phase, you measure the patient's anatomy. Doing this reduces the risk of surgical errors, such as creating a difference in the length of the legs. It also assists in selecting and positioning Templates. Properly taken measurements also assist in establishing that best clinical practice was followed.

Using the Reduction Panel you can plan fracture reduction by using the image reduction tool which is accessed from reduction tool bar or plan more complicated deformity correction using the axis definers and animation tools.



IMPORTANT NOTE: the measurements displayed in small ellipses sometimes get in the way. You can hide or show them at any point by pressing Ctrl M.

Measurement tools

There will be occasions when measurements will need to be taken that are not programmed into the wizards. A variety of measurements tools are supplied in the toolbar. For more information, see 'Using windows in OrthoView[™]' on page 1-6.



The three measures, line, circle and angle, allow you to click to select the measurement display and then enter an annotation of what the measurement is for. This information is then visible as a tool tip and is displayed in the OrthoView report.

Measurement Tools

- **Toolbar**. Displays the available tools during the Scaling, Planning and Templating phases. The toolbar is located above the X-ray image(s). Some tools are specific to the Scaling, Planning or Templating stages and these tools are available from a separate toolbar at the top of the respective panel.
 - **Pointer tool**. Select to modify drawing and construction lines that have already been made.
 - Line Constructor. Select to draw lines between two points. The length can be altered by clicking/dragging the handles. To move the line, click to select it and then drag it to the required position.
 - Circle Constructor. Select to draw circles. The circle position and diameter

can be altered by clicking/dragging the handles. The circle can be moved by dragging it and can be re-sized by right-clicking and dragging it.

- Line Meter. Select this to draw lines which contain a meter to display the length of the line. To change the length of the line, click/drag the handles. It can be moved by dragging the line.
- **Circle Meter**. Select this to draw circles which contain a meter to display the diameter of the circle. To change the position and diameter of the circle, click/drag the handles. The circle can be moved by dragging it and re-sized by right-dragging it.
- Angle Meter. Select to draw two connected lines that contain a meter which displays the angle between them. The length of the lines can be altered by clicking/dragging the handles. The whole construct can be moved by dragging either line.
- **Small Angle Meter**. Select to measure two lines which do not meet at a convenient point: for example, for spinal and pelvic measurements.
- Multi Angle Meter. Select to draw multiple connected lines that contain a meter which displays the external angle between them. The length of the lines can be altered by clicking/dragging the handles. To add an additional line and angle click a point on the line and drag the point created to the new required position. Click a point using the left mouse button to remove line.



- T Annotation. Select to add annotation (short text notes) on the patient image.
- Window and Leveling Mode: Select this icon to adjust the brightness of an X-ray image. Click left mouse and drag up to darken and down to lighten image
- Image Reduction: This tool is automatically selected when you initially move into the Reduction Screen. To use it you left click at various points to encompass the area of the X-ray that you wish to manipulate.
- **Vertical Flip:** Click Icon to flip X-ray vertically. Click again to return to original orientation.
- Horizontal Flip: Click Icon to flip X-ray horizontally. Click again to return to original orientation.
- **O** Rotate Image Right: Rotate image 90 degrees clockwise.
- **Positive Image:** Switch image to positive. (Toggles with Negative Image)
- **Negative Image:** Switch image to negative. (Toggles with Positive Image)

Fracture Reduction

The Reduction screen can be used to interactively plan a fracture reduction using the image reduction tool which is accessed from the tool bar by selecting the icon shown below



To use this tool, left click at various points to encompass the area of the X-ray that you wish to manipulate.

Use the left mouse button to add points. To complete the area of the image you can either leftclick onto the point you started with or hit the ESC key. (For further information on the use of this tool use the context sensitive help within OrthoViewby pressing F1 and/or consult the Training Guide)

Joint-Specific Wizards



Hip joint

There are wizards for the AP view of hips and the ML view: however, the ML wizard is used to assist with ML template positioning, it does not take any measurements. For further information on specific wizards see the OrthoView[™] Help Menu when running the software or refer to the Training Guide.

Hip Resurfacing Procedure Wizards

Wizards are available for resurfacing the hip. An AP wizard is used with an AP x-ray to assess the femoral head diameter and center of ,the femoral neck aiding in the positioning of the stem of the resurfacing hip prosthesis. And a ML wizard is used with an ML x-ray to position the stem of the femoral resurfacing component.

Knee joint

Five wizards are available for knee measurements (total knee replacements and unicompartmental knee replacements), a femoral and a tibial wizard for each of the AP and ML views, plus a leg alignment AP wizard. For further information on specific wizards see the OrthoView[™] Help Menu when running the software or refer to the Training Guide.

Shoulder Joint

There are two wizards available for shoulder measurements. For further information on these wizards see the OrthoView[™] Help Menu when running the software or refer to the Training Guide.

Pediatric

Among the radiological lines that have been used to distinguish between the normal and the dislocated hip are the acetabular index (a measurement of the apparent slope of the acetabular roof) and the intersection of the horizontal Hilgenreiner's Line (through the triradiate cartilage) with the Perkins Line (a vertical line drawn downward from the lateral rim of the acetabulum) which is a measure of lateral migration of the femoral head. For further information on specific wizards see the OrthoView[™] Help Menu when running the software or refer to the Training Guide.

Shafts

These Wizards are designed to allow measurements to be made on a shaft. For further information on specific wizards see the OrthoView[™] Help Menu when running the software or refer to the Training Guide.

Deformity Correction

The deformity corrections wizards and tools can define the position and angle of cuts required when correcting a deformity. For further information on this see the OrthoView[™] Help Menu when running the software or refer to the Training Guide.

Note No Wizards - Elbow, Wrist, Finger, Toe & Ankle

For these small joints no wizards will be shown, after scaling you will move directly to templating, select the sizes required and use manual template positioning.

Templating

This is the core of OrthoView[™]. Under normal circumstances you get here after doing planning, or fracture reduction. If you need to save time however, you can go directly to the Templating panel, after scaling, by clicking **Templating** in the **Planning** screen without using any wizards or tools.



The Template(s) are displayed over the x-ray. The exact shape of Template is determined by the parameters selected in the options in the **Templating** panel. Selecting different options in the lists changes the Template. If you select a combination of options that don't exist in the product line, no Template is displayed and a warning message is displayed.

If the Joint Measurement has been done correctly using the Planning panel, the position and axis of the Templates will match the patient's anatomy.

For more information, refer to OrthoView's[™] Online Help using the F1 key or consult the Training Guide.

Sliding Templates

Click the mouse down on any part of the Template other than the Positioning Handle (Cross with arrows) and drag. The Template will slide along its axis.

Dragging the Template

To re-position a whole Template, drag the Positioning Handle (a cross with arrows) to the required position.

Rotating the Template

To rotate a Template (including its axis), use the right mouse button to drag on any part of it other than the Positioning Handle.

You can make the rotation less sensitive by moving the mouse away from the center of rotation while still holding the button down.

Changing the Templated side

Some Templates are asymmetric. If you have a bilateral x-ray, you can use the change laterality button to select the contralateral side for the current procedure to allow you to template the contralateral side.



Finishing an examination

This section describes how you can get permanent output from OrthoView™.

Important Warning

Reports and committed archives are time stamped with the Operating System date. If you want to rely on these dates in the future (e.g. for legal defense purposes) you must ensure that the date can only be set by the system administrator and be able to prove that it has not been subsequently tampered with.

Making a report

OrthoView[™] can generate a pre-operative report. To do this, you click the **Report** button. This displays the report summary. There is further information on this in the OrthoView[™] Help when running the software, and in the Training Guide.

Closing and committing

When you have finished any planning, scaling, templating and report generation, you need to decide whether to save or abandon the session. To do this, click:

- **Save Session**. Click to save any scaling, planning or templating you have done to date, so that you can return at a later date and finish off the procedure. Not available on all versions.
- **Commit Session**. Click to make a permanent record of the procedure. **Note**: when you do this you are unable to make any further modifications, as the archive is read-only.
- **Discard**. Click to abandon any scaling, planning or templating you have done so far.

Deleting examinations or archives

To delete an examination, or an archive, right click on its name in the examination list. Select option to delete.



REFERENCE

This section provides information on:

- Online Support and Information
- Regulatory Standards
- Management of Encryption Keys
- Declaration of Conformity

Online Support and Information

Please visit:

- http://www.orthoview.com
- or http://www.myorthoview.com (registered users only).

Product support

For support, please contact your OrthoView[™] supplier.

Suggestions: we would be delighted to hear your suggestions for product and feature enhancements. Please contact us via your supplier or email us at sales@orthoview.com

Management of Encryption Keys

To comply with data protection legislation and in the interests of preserving patient confidentiality, you must take all reasonable steps to ensure that files CANNOT fall into the hands of unauthorized persons. When you **commit** or **save** an examination, patient details are written into an archive file so that you can read them when re-opened. Since these files may be stored off site or even sent by you to other authorized people, they represent a confidentiality risk. To ensure that people who obtain these files cannot read them in a text editor, OrthoView[™] always encrypts the patient name, gender, date of birth and National ID and Patient Notes.

Encryption is a mathematical technique that uses a key to lock data in such a way that it is impossible for anyone who does not have the key to read it. An Encryption Key is a string of keystrokes that are kept secret, and ensures the data is only read by authorized people and computers.

The Key used by OrthoView[™] to protect patient information can be set in the **Examination Preferences** tab. If you do not enter a key then an internal key that is common to all other copies of OrthoView[™] is used.

Before changing the key it is vital that you understand the implications:

 Once a file is written, it can only be read by a version of OrthoView[™] that has the same key as the one in effect when it was written. If you enter a key and then lose it, neither you nor anyone else will be able to retrieve the patient information. Note that the Patient ID number is never encrypted so you should still be able to identify the patient if you have access to the hospital or practice record system that can decode this number.



- If you use the default key, you are sure that anyone else can read patient information. They can do this, even if they have set a key, by temporarily removing it. But you must now personally ensure that these files remain in a secure environment where OrthoView[™] users who are not authorized to see the patient details cannot gain access to them. In particular, do not send them over the Internet or to physicians in other institutions.
- If you set a key, you are now certain that only people who have the same key can view the patient data. You can now freely send the files to such people over insecure channels such as the Internet. But you must not share your key with unauthorized persons and all authorized persons must have the same key.

Suggestion for managing keys

The best way to manage keys securely is to have a single person or authority (such as the PACS System Administrator) who knows the key and who is responsible for entering it into all workstations of a group of people who need to access each other's archives. This person (or department) should:

- Keep the key secret and secure.
- Take responsibility for ensuring that all OrthoView[™] workstations are secure.
- Enter the key on to each workstation and not share it with the users.

Regulatory Standards and Declaration of Conformity



Distributors and Maintenance

Approved distributors and how to obtain service and maintenance

In the first instance, please contact your Customer Support Engineer. In case of difficulty, please contact the Customer Support Department at Meridian Technique as shown below



Meridian Technique Ltd

2 Venture Road

Chilworth Science Park

Southampton

Hampshire

SO16 7NP

Great Britain

Telephone +44 (0)2380 762 500

Accessories

Accessories recommended for use with the equipment

There are no accessories recommended for use with OrthoView™

Installation

Installation and Commissioning

The installation and commissioning of OrthoView[™] is performed by Installation Engineers as part of the Implementation. As such, you do not have to carry out any installation of the product.

If you use the supplied with a CD ROM containing the software, handle it with care and do not touch the under surface. Keep the CD ROM in its protective sleeve when it is not in use. Protect it from frost, extremes of temperature and humidity. Protect the CD from exposure to direct sunlight or fluorescent lighting. Observe the warnings printed on the CD. Do not attempt to insert the CD into the PC if it appears damaged or if the IT equipment appears damaged



Explanation of symbols

Symbols Used

The symbols appearing on OrthoView[™] are shown below together with their meaning:



0843 This symbol shows that OrthoView[™] is marketed as a medical device in the European Union and that it complies with all of the applicable requirements of the Medical Device Directive (93/42 /EEC). The '0843' is the reference of the assessment body (Notified Body) used to substantiate the claim (in this case Underwriters Laboratories)

REF This symbol identifies the reference of part code/software release version of OrthoView[™]

I	LOT

This symbol identifies the Lot or manufacturing work order reference which manufactured the CD containing your software



This symbol identifies the date of release of your software

-

This symbol identifies the Manufacturer of the CD and the software

The symbol means 'Refer to Accompanying Documentation. Wherever it appears, it is drawing your attention to the fact that you should be fully conversant with the operation and use of Orthoview and that you should be familiar with all associated documentation and that you have documented training acceptable to the authority using OrthoViewTM

This symbol means that OrthoView[™] software delivered on the CD is fragile - do not drop, crush, bend or distort or subject the CD to abrasion.



22.

This symbol means Orthoview Software on the CD must be protected from moisture -Always store the CD in its sleeve when not being used and protect it from extremes of temperature and humidity, frost and direct sunlight or fluorescent lighting

Inspection and Maintenance

Preventive inspection and maintenance

OrthoView[™] is software only - there are hence no parts requiring inspection, service or maintenance

The software does not require calibration

Units of Measure

OrthoView[™] displays measurements in SI units legally acceptable within the European Union. Where applicable, the user may select alternative non-standard units where medical convention, for instance, uses such units

Explanations of functions and controls

Explanation of the function of each control and display.

Each control and display has associated context sensitive help. Lay the pointer over the control and an explanatory pop-up box will appear. Refer also to the system help for an explanation of OrthoView[™] and the sequence of operation

Disposal

Disposal of Orthoview

The OrthoView[™] CD and packaging must be disposed of according to local regulations for the disposal of plastics and should be in compliance with the prevailing hospital regulations. Otherwise, it may be returned to OrthoView[™] at the address shown on www.orthoview.com for disposal. Contact the manufacturer for disposal of the associated IT equipment and other hardware. This is not the responsibility of Meridian Technique Limited.

Special Instructions

Special Operating Instructions

- To prevent misuse or abuse by others, protect your user access codes and do not disclose them to others. Always log off the system or otherwise lock the use of the work-station when you are away from it
- Technicians, particularly Administrators, must not attempt to alter code or settings that would be entered by Clinical Users. They must not use the software as an Operator when logged on as an Administrator in case this overwrites any Clinical User data or settings
- Operators must not attempt to provide extremes of data input for instance by pressing keys continuously or providing intentionally incorrect input, toggling IT equipment power etc.



• Persons operating and installing Orthoview must not have sensory/physical impairment to a degree that the IT equipment cannot be operated effectively and warnings and cautions cannot be discerned or acted upon.

Warnings

- Any diagrams or pictures used in the Help and in accompanying documents associated with the product and in promotional literature are for illustrative purposes only and any readings, displays or indications may not be the same as those obtained during actual use
- Any user settable parameters in the software or on the PC must be checked and deemed acceptable by the operator before use.

Regulatory Standards

OrthoView[™] has been designed to comply with the product standards shown below. These standards represent requirements for the way in which the design, development and validation of medical software is carried out. These requirements are embodied in the Meridian Technique Quality Management System which is accredited to ISO9001 and ISO13485. OrthoView[™] itself cannot be certified to these product standards, but it is confirmed that OrthoView has been produced in accordance with Meridian Technique's ISO9001 and ISO13485 Quality Management System (See Declaration of Conformity) – thereby demonstrating compliance with these product standards

IEC62304-2006: Medical Device Software - Software Life-Cycle Processes

Declaration of Conformity



EC Decla	ration of Con	formity 93/42/1	to Medic	al Devices D	irective
		75/44/1			
Manufacturer:	Meridian Technique Ltd 2 Venture Road Chilworth Science Park		Telephone	+44 (0) 2380	762 500
Hampshire SO16 7NP Great Britain			Fax	+44 (0) 2380 762 550	
EC Pro	duct Class	Description	n'		
IIA	Rule 10	OrthoView	,		
Software Version	5.3 onwards				
Meridian Techni	ique Ltd at the add	dress shown	above here	eby:	
Declares that:	The above device co	onforms to the	following rele	vant provisions of the	EC Council
	Directive	Amendment	Date	OJ Reference	SI Reference
	93/42/EEC		14 June 1993	L169 12 7 1993	3017:1997
	98/79/EC	MI	27 Oct 1998	L331 1 7 12 1998	618:2002
	2000/70/EC	M2	16 Nov 2000	L313 22 13 12 2000	618:2002
	2001/104/EC	M3	7 Dec 2001	L6 50 10 01 2002	1697:2003
	1882/2003/EC	M4	29 Sep 2003	L284 1 13 10 2003	400:2007
	2007/47/EC	M5	5 Sep 2007	L247 21 21 09 2007	2936:2008
	Annex II elements a requirements as veri	re in conformi ified by Notific	ty with ISO90 ed Body Under	01:2008 and ISO1348 writers Laboratories	85:2003 - reference 0843
	The Device is in cor	formity with A	Annex I requir	ements	
Confirms that:	No medicinal produ	cts/drugs or an	imal tissues ar	e incorporated in the	device
Undertakes to:	Develop, implement System to ensure co	t and maintain ntinued adequa	a formal Quali acy and efficad	ity Management :y.	
	Develop, implement and maintain a documented post-production experience monitorin, programme, along with notification of incidents deemed necessary under the European Medical Device Vigilance system guidelines.				
	Inform the Competent Authority of any planned or unplanned significant change to the Device, including any significant design changes.				
Name:	John Chambers		Signed	Signed: Thambers	
Title:	Chief Executive	Officer	Date: 24 th Ma	arch 2010	

EC Declaration of Conformity to Medical Devices Directive 93/42/EEC

USA

A Caution: USA Federal law restricts this device to sale by or on the order of a physician



Indications for Use: OrthoView[™] is indicated for use when a suitably licensed and qualified healthcare professional requires access to medical images with the intention of using such images, in conjunction with templates for prosthetic and fixation devices, for the purposes of choosing the nature and characteristics of the prosthetic/fixation device to be used when planning a potential surgical procedure. In addition, Trauma and Osteotomy Modules and Trauma Templates are provided to extend the range of functionality available to the healthcare professional.

(Trauma and Fracture Management are interchangeable terms within the software and Osteotomy Wizards form part of Deformity Correction)