

Materialise OrthoView



User Guide

OrthoView 7.4 - Issue 1.4

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Intended Purpose

Intended Use: The Intended use of OrthoView™ is when a suitably licensed and qualified healthcare professional requires access to medical images with the intention of using such images for pre-operative planning of a potential surgical procedure.

Indications for Use: OrthoView is indicated for use when a suitable licensed and qualified healthcare professional requires access to medical images with the intention of using such images to plan or review a surgical procedure. OrthoView provides a set of tools and templates (representing prosthetic and fixation devices) to assist the healthcare professional in planning their surgery.

The device is not to be used for mammography.

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 using, OrthoView.

Minimum Hardware Specification

Computer	PC
Operating System Windows	Windows 7, 8, 8.1, 10 or 11
Processor	1 GHz CPU
Memory	2GB RAM
Free Hard Disc Space	2GB free disk space
Graphics/Display	1280 x 1024 colour graphics display
(Optional) Intranet Connection to PACS	100MBit/Sec
(Optional) Internet Connection (required for case management, auto template update and anonymous stat collection features only).	2MBit/Sec

Requirements for Dicom Connectivity

- DICOM conformance to support C-ECHO, C-FIND, C-MOVE, C-STORE, Study Level Retrieve, Series Level Retrieve, Image Level Retrieve
- Modality connection required on PACS to allow Query, Retrieve & Store images (PACS supplier may charge for this)

Peripherals: Keyboard & Mouse.

Internet Connectivity: For Software & Template download, tutorial videos and guides.

OrthoView Server: HTTP server or Network folder share (NFS) to use Web Deployment, Concurrent licensing, FollowMe or ImageShare. (not all features are compatible with all builds/versions)

DICOM Modality Connection: To import/export images with a PACS archive, modality connection(s) may be required, for which your PACS supplier may charge.

Supported Browsers (for OrthoView Web): Internet Explorer 11, Microsoft Edge and Google Chrome.

Introducing OrthoView™

(English)

Important Notice: All diagrams and pictures shown are for illustrative purposes only and readings or indications may not be the same as those obtained during actual use. Not all options described are available in all versions of the software.

OrthoView provides the necessary tools for both Orthopaedic and Orthognathic surgery planning.

OrthoView is fully configurable to suit individual surgeon requirements. A license must be installed when starting the software. (Except for Demonstration versions where a license is installed automatically)

Orthopaedic Planning Tool

OrthoView is a leading orthopaedic digital planning solution, used in hospitals and clinics across the globe. The innovative software provides orthopaedic surgeons with access to a comprehensive library of digital templates for joint replacement, trauma procedures, limb deformity correction, spine deformity assessment and (subject to license) paediatric assessment.

Developed in conjunction with the orthopaedic community and supplied by the major PACS suppliers, OrthoView is a digital preoperative planning solution designed specifically for orthopaedic surgeons and consists of several specialist modules, offering a complete solution for orthopaedics.

The OrthoView templating process uses a technique like the techniques that many surgeons previously practiced with acetate templates over x-ray film. OrthoView can assist with planning operative procedures by scaling, planning, reduction, and templating on one or more patient images and will generate reports that can accompany patient notes.

OrthoView template wizards help you to get from an image of a patient's x-ray quickly and easily to the approximate template size needed. The visual templating features then let you quickly review multiple template sizes, against the x-ray, and obtain an accurate view of the implant size required.

Installing a Temporary License

When you buy the software you will be issued with a temporary license that will activate OrthoView enabling you to install and configure the software. You will also have been supplied a unique product key which should be quoted in all correspondence; the code will be similar to this: OR123-12345678.

The steps to installing a license are set out below:

1. When OrthoView is run for the first time an alert message will prompt you to enter details for the first user, click **<OK>** and you will be presented with a registration screen to enter the user details. Once entered click **<OK>** OrthoView will then display the License Agreement.
2. After reading the License Agreement, click the **<I Agree>** to continue. The software will report Valid License Not Found.
3. Click the **<Install License...>** button and the License Manager screen will appear.
4. Select the **<Install License...>** button on this screen as well and it will open a File Browser window which will enable you to navigate to the location of the supplied license.
5. Select the license by highlighting the license file name and clicking **<Select>** OrthoView will then install a copy of this license in the Network Server location you selected, in a folder named License.

Congratulations! Your license has been installed correctly.

Major Work Flows

OrthoView has several major work flow stages:

- **Loading** - Using the InBasket Panel (if available) to select the patient, and selecting specific images and the procedure from the Examination Panel. (All versions)
- **Scale** - Scaling images to use within OrthoView in the Scaling Panel.
- **Analyze** - Analyzing a procedure by measuring anatomical features using tools and wizards in the Analyze Panel.
- **Reduce (Orthopaedic Only)** - Performing reduction by manipulation of image regions and/or fragments in the Reduce Panel.
- **Simulate (Orthognathic Only)** – Simulate both skeletal and soft tissue movements within the cranial, maxillary and mandible regions in the Simulate Panel.
- **Template (Orthopaedic only)** - Adding and adjusting suitable prosthesis components in the Templating Panel.
- **Saving** - Saving your work. This could be as work in progress that can be added to later or committed as an unalterable examination.
- **Restart** – Allows you to restart the current examination from the state it was originally received by OrthoView.









Other panels which may be displayed to access other functionality include:

- **Query and Retrieve from PACS** – (Not available in all builds) In some systems images are sent directly from the PACS to the InBasket or Examination panel. Otherwise images will need to be imported using this panel.
- **Template Management** - The Template Management panel displays information regarding installed and available digital templates. It is accessed from the File menu drop-down or by pressing the <CTRL/CMD><T> key combination.
- **User Management** – The User Management panel is used to create User Accounts, Edit the Current User or Delete a User.
- **Preferences** - The Preference Panels allow you to configure the software to suit your personal Preferences and work practices. To begin setting Preferences press <CTRL/CMD><R/> or on the <File> menu, select <Preferences> to open the Preferences panel.
- **License Manager** – The License Manager is used to install a license, save the system details for applying for a license and to review the License Agreement.
- **About** - Displays information about your version of the software.








SmartHelp

By default, OrthoView displays SmartHelp which is designed to assist you during your use of the software and can be hidden or unlocked from the main display if required. It will remember your last settings but is displayed as docked by default and the options described below are available. This section describes all the possible display options available from the SmartHelp toolbar.

The following are available from the SmartHelp toolbar when docked:

	Only available when SmartHelp displayed. Selecting this will hide the display.
	Only visible when SmartHelp is hidden. Selecting this will redisplay the SmartHelp.
	Undock the SmartHelp from main display. The undocked display can be moved to any place on multiple displays by dragging the top bar of the display. The undocked display can be re-sized by dragging the edges of the window.
	View previous displayed page.
	View next page if available.
	Increase the font size.
	Decrease the font size.
	If enabled, the help displayed will follow your use of the software and show the most appropriate help for the current activity. If disabled, the help for the current activity can be displayed by pressing the <F1> key. (Pressing <F1> when tracking is selected will not change the current display)

If SmartHelp is undocked then the following are available from the toolbar:

	Docks the SmartHelp back to the right of the main display.
	View previous displayed page.
	View next page if available.
	Increase the font size.
	Decrease the font size.
	If enabled, the help displayed will follow your use of the software and show the most appropriate help for the current activity. If disabled, the help for the current activity can be displayed by pressing the <F1> key. (Pressing <F1> when tracking is selected will not change the current display)
	Selecting this will force the SmartHelp to always be on top of other windows displayed by the software. Deselecting this will return the window to normal behavior.

Moving around in OrthoView

You can move around OrthoView using your mouse and keyboard shortcuts. OrthoView has a standard menu bar which allows access to a number of commands.

There are five basic methods of using a two button mouse within OrthoView:

- (1) Move the cursor on the screen by moving the mouse.
- (2) Clicking the left mouse button will select an object such as a tool or wizard. Selecting a tool from the toolbar then clicking the left mouse button on the image will place the tool. (Selecting a previously positioned tool or wizard will make that the active one)
- (3) Pressing the left mouse button and without releasing it, but moving the mouse, will drag the selected object on the image. This is called left-dragging.
- (4) Clicking the right mouse button over a selected object will display a menu selection for that object if available.
- (5) Pressing the right mouse button and without releasing it, but moving the mouse, will allow various operations specific to that tool or wizard to be performed. This is referred to as right-dragging.

Main display

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.
- **Generally available buttons.** These are the generally available buttons you can select when working in the main screens within OrthoView. When you are scaling, analyzing, 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 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.** There are two options for this; Select the slider to adjust the Zoom or select the button to toggle between size-to-fit display or previous zoom level.



- **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. Hide image will close the image which can then be reopened by returning to the Examination Screen.
- **Close image.** This closes the window. Note: any work done in the window is lost, so if you re-open the window, it will not 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.

Control Panels

The Control Panel controls the current state of OrthoView and changes as you use OrthoView. This panel can be:

- **InBasket** (not all versions) - controls access to patient information and patient images.
- **Procedure Selector** – allows the user to select a procedure or service.
- **Examination Panel** – Displays the following:
 - Current procedures and services in use.
 - Patient x-ray images.
 - The preoperative report.
- **Notes** - allows notes to be made during analyzing.
- **Report** - displays a report of your procedure.
- **Scale Panel** - scales the selected patient image.
- **Analyze Panel** – uses wizards to help identify skeletal landmarks.
- **Simulate Panel (Orthognathic only)** - Simulate both skeletal and soft tissue movements within the cranial, maxillary and mandible regions in the Simulate Panel.
- **Reduce Panel (Orthopaedic only)** - allows Fracture Management using Image Reduction and/or Limb Deformity Correction using procedure-specific wizards, tools and animators.
- **Template Panel (Orthopaedic only)** - controls the displayed template size.

Hiding displays

Many individual displays within the software can be minimized to allow better display of adjacent areas. Such displays have an arrowhead icon  beside their title. Clicking this arrowhead will hide that display. The arrowhead will change to another shape  and clicking that arrowhead will make that display visible again.

Each control panel has various controls on it, and these are explained in further detail in the corresponding panel sections of SmartHelp.

With the exception of the InBasket panel, the other main panels within the software contain generally available buttons which allow you to switch between views and actions.

Generally available buttons

Several buttons are provided along the top of the active panel on either side of the toolbar. These help you control the active panel and allow you to move to other parts of the program or apply tools to the active image. They are described in the SmartHelp.

Loading images

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 or PA image unless you are also intending to work with an ML or LM view. For knees you will normally need two images - an AP (or PA) and an ML (or LM) view.

Note: In order to load and query from a PACS system, links must be established between OrthoView and the PACS system using the Preferences panel in OrthoView. The PACS system also will need to be setup to connect to OrthoView.

Drawing

Most of the things you do in OrthoView involve manipulating various types of drawings over an x-ray. These drawings include tools, wizards and templates. This section tells you about the common themes that run through manipulating all of these.

Everything that is displayed above an x-ray is called a figure. Each of these has at least one handle and some other graphical elements such as lines, curves and text. The selected figure is normally the last one you created or changed. Note: you can only select one figure at a time.

All handles define a single point, usually in the center, from which the body takes its position. To make them visible, handles display as a shape that is larger than the point.

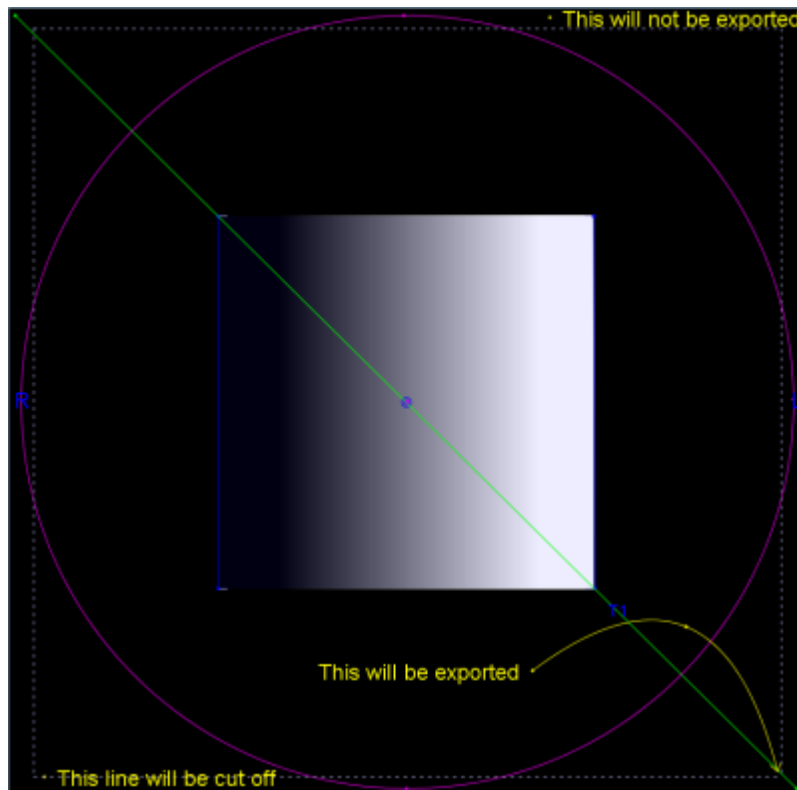
You can tell which figure is selected because the handles will be more obvious; they change from a tiny dot to a square, cross or some other shape. The selected figure is the one which is deleted when you press Delete or moves when an arrow is pressed.

Exportable Image Area

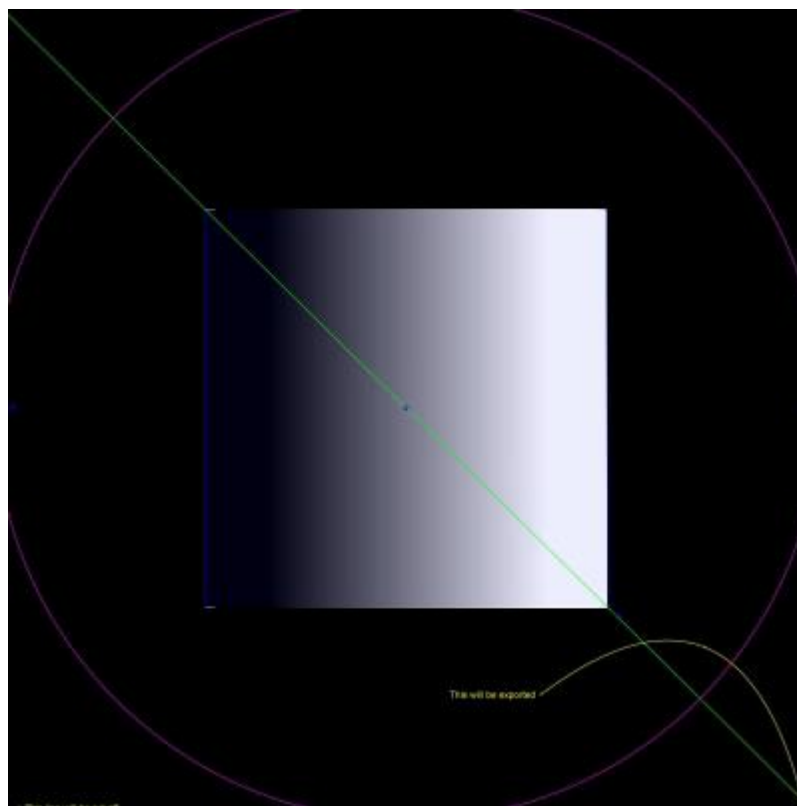
If an image is zoomed out so that the X-ray does not occupy the whole displayed image area the User can add figures such as Annotations, Lines etc onto the additional area. There is a limit to how much additional space can be exported when Saving or Printing and if the exportable area is less than the overall viewing size of the image window a dotted line will be displayed within the image window.

Any figures that extend beyond the dotted line will be "cut" at approximately that point.

The first image shows the image window as seen within OrthoView



The example below shows the likely final output exported by OrthoView.



Selecting/Moving a figure

Selecting a figure:

To select a figure, left-click any part of it with the mouse. Any other figure that was selected will become deselected. To deselect all figures left-click somewhere on the x-ray that is not inside a figure.

Moving a figure with the mouse

Use the mouse anywhere on the figure, except inside a handle. Keep the mouse button pressed and move it, so the figure follows the mouse pointer. Note: in templates and wizards, this motion may sometimes be constrained such that the figure slides along an axis. When it is in the correct position, release the mouse. The figure remains selected.

Moving a figure with the keys

Select the figure with the mouse then press an arrow key. The figure moves by small increments. If you hold the shift key down and then press an arrow key, the figure moves further in the arrow direction.

Modifying or deleting a figure

Modifying a figure

Most figures (except templates and annotations) can be modified by dragging their handles. To do this, press the mouse button down on the handle and then move the mouse. The 'hot point' of the handle follows the mouse cursor. There are several things to notice in this process:

- As soon as you press the mouse button anywhere on the handle, the handle moves so that its defining point lies under the mouse cursor.
- Sometimes a handle lies inside another figure. When this happens, it can be difficult to select it. To resolve this, select the figure and click anywhere not inside the other figure: this selects all of the handles. You are now able to click the handle of your choice.



Deleting a figure

Select the figure with the mouse and press Delete or Backspace. The figure is deleted. Note: Wizards and Templates cannot be deleted.

Meters

Many wizards and tools display numbers derived from the positions of the handles. The value displayed depends upon the tool or wizard, but is either a distance in millimetres or angles in degrees.

Many Meters are also buttons.

In the Scaling panel, click either the  Circle Meter or  Line Meter tool, and enter the known size: for example, 30.5 mm. OrthoView then automatically scales the x-ray to the correct magnification factor.





In the Analyzing and Templating panel, right click a Meter (except those that are parts of wizards) to display a dialog box that allows you to attach an annotation to it. This results in the report and the tool tip displaying the annotation.

Left clicking on Meters where values can be changed (such as Axis Definers) will open a dialog so that a new value can be entered. In most cases the input value is restricted to sensible values.



If handles or small items become hidden behind meters, you can temporarily hide all Meters: to do this use **<CTRL><M>** which toggles between hide and show meters. It is also possible to enable meter dragging with **<CTRL><D>** which allows you to move the meters on the x-ray. Disable it to lock meters in place.

Layering

If you have multiple tools or wizards and they overlay each other they can be individually arranged and brought forwards or backwards in respect to each other for the active item by selecting arrange from the right click drop down and selecting your requirements from the available options. When using a default properties box these options are displayed as buttons.

	Bring to Front
	Bring Forwards
	Send Backwards
	Send to Back

Show/Hide Panels

The default view is to display the Control panel on the left, the Image viewing area in the center and the SmartHelp on the right of the screen. To hide the Control or SmartHelp and increase the Image viewing area, click  Hide Panel. The panel will then be hidden until you click  Show Panel to toggle the view back to display the hidden panel and the viewing area.

Drag Bar

Additionally, the bar between the image display and options can be dragged to make either the options panel or image display larger. Hover the mouse over the bar and the cursor will change to a horizontal double arrow. Drag the mouse cursor to adjust the desired view.

Image Windows

The Image viewing area within OrthoView is where opened patient X-rays are displayed. A maximum of four views can be opened simultaneously.

Each window can be maximized to fill the complete image area or minimized to display all four.

Using either the Window menu, or the controls on the image title bar, you can control the individual windows, using Toggle Zoom, Zoom, Hide, Maximize/Minimize and Close.

Working with the X-ray Image Windows

By default X-ray windows are opened in a "Size to fit" mode (this can be disabled in the Preferences). Zooming will increase the magnification of the X-ray and display scroll bars to pan (move) around the work space. To pan, either use the side scroll bars or click and drag on the image.

Zooming out will reduce the X-ray and display a black canvas around it. This canvas area can be used to position tool, wizards, templates or image reduction fragments that are not, or cannot be, superimposed on the X-ray image.



Using the Toolbar

The tool bar is located above the image panel. It contains a collection of drawing, measuring and presentation tools. Only one of any of the tools can be selected at a time. Drawing and measuring tools are aligned in a row starting from the left, and presentation tools are on the right. Use the toolbar icons to determine what happens when you click or drag the mouse on the patient image.

Note: Tools used for further image manipulation are located in the scaling panel.

Tool Status

When a tool is selected, the icon changes to the selected state. These are examples of the status of the Pointer Tool:

	Pointer tool available for selection.
	Pointer tool selected (Active for use)

The individual tools are described within SmartHelp.

Setting Default Tool Properties

Tool properties can be set by selecting the item on toolbar and using a right click on the mouse to open the default properties window for that specific tool. This will affect all future instances of that tool until changed. Example for angle tool:

Label:	<text>
Show meters:	On/Off
Show bisector:	On/Off
Color	Select
Arrange:	see Layering

On-image tool properties

Properties of tool already drawn on an image can be assigned individual characteristics by a right click on a handle of the tool already present on an image. A window display opens to add/remove features for the specific tool, display help or display properties box as required. Example for angle tool:

Label...	<text>
On/Off	Show meters
On/Off	Show bisector
On/Off	Lock Position
Select	Color
Arrange	see Layering
Help...	Show help

The default property options listed also apply to specific tools applied to an image.

Keyboard Shortcuts

Keyboard shortcuts allow you to perform menu actions with a single keystroke, making OrthoView even quicker and simpler to use. To use a shortcut key, hold down the Modifier Keys indicated below, and then press the key. (Not all options are available in all builds)

Windows Modifier Keys are:

<CTRL> (Control keys at either end of the keyboard).

<ALT> (either of the Alt keys).

<SHIFT> (either of the shift keys).

or a combination of the above.

The following table tells you which shortcuts are generally available.

Windows Keys	Action
<CTRL><R>	View the Preferences Panel
<CTRL><T>	Open Template Management Panel
<CTRL><U>	Open User Management Panel
<CTRL><M>	Show/Hide Meters
<CTRL><D>	Enable/Disable Meter Dragging
<CTRL><P>	Print Report
<CTRL> <ALT><P>	Print current x-ray complete with superimposed items
<CTRL><E>	Quit program
<CTRL ><Z>	Undo last action (or actions) of tool or wizard applied to image
<CTRL><Y>	Redo last Undone action(s) of tool or wizard
<CTRL><0>	Display image in size to fit display window
<CTRL><-> (minus)	Zoom-out on current image
<CTRL><+> (plus)	Zoom-in on current image
<F1>	Display contextual help screen if not already displayed
<S>	Toggle "Snap To" ON or OFF
<space bar>	Toggle "Blue Lens" ON/OFF

OrthoView Work Process

OrthoView is used in four stages for orthopaedic planning. When Orthognathic planning is selected the Reduce Panel is replaced with the Simulate Panel and the Template panel is removed.

Note: Reduction during Elective Hip procedures can be performed directly within the Template Panel.

Scaling stage

The scale of the x-ray must be established. In the ideal situation the x-ray is scaled from a marker or ruler of known size in the correct plane.

Analyze stage

Anatomical wizards have been designed to allow quick identification of key bony land marks.

Orthopaedics only: Once the wizards have been placed OrthoView recommends the template most likely to fit, and inserts it in the correct position (this is done in the Template Panel).

Note: It is not necessary to use the planning wizards. If scaling is complete it is possible to go directly to the Templating stage.

Reduction stage (Orthopaedic only)

The reduction screen is used to animate limb deformity wizards used in the analyzing screen previously described and also supports the image fragment tool for moving bone fragments for re-alignment.

Simulate stage (Orthognathic only)

The simulate screen is used to animate facial reconstruction of both soft and hard tissues.

Templating stage (Orthopaedic only)

The chosen template is then inserted and automatically placed on the x-ray in the correct position according to the wizard. All the suggested sizes and positions are easily changed and adjusted. The final templating solution can be saved with the patient image as part of the patient's electronic record.


Templating and Planning with OrthoView

OrthoView has a variety of methods to help a surgeon plan for many types of procedures. Elective, deformity and fracture are available to plan within

OrthoView with a choice of digital templates, wizards and tools to help choose the correct type and size of implant.

3D services are also available; if selected the user is taken to an external site where a number of different custom made 3D options can be purchased depending on the patient's needs.

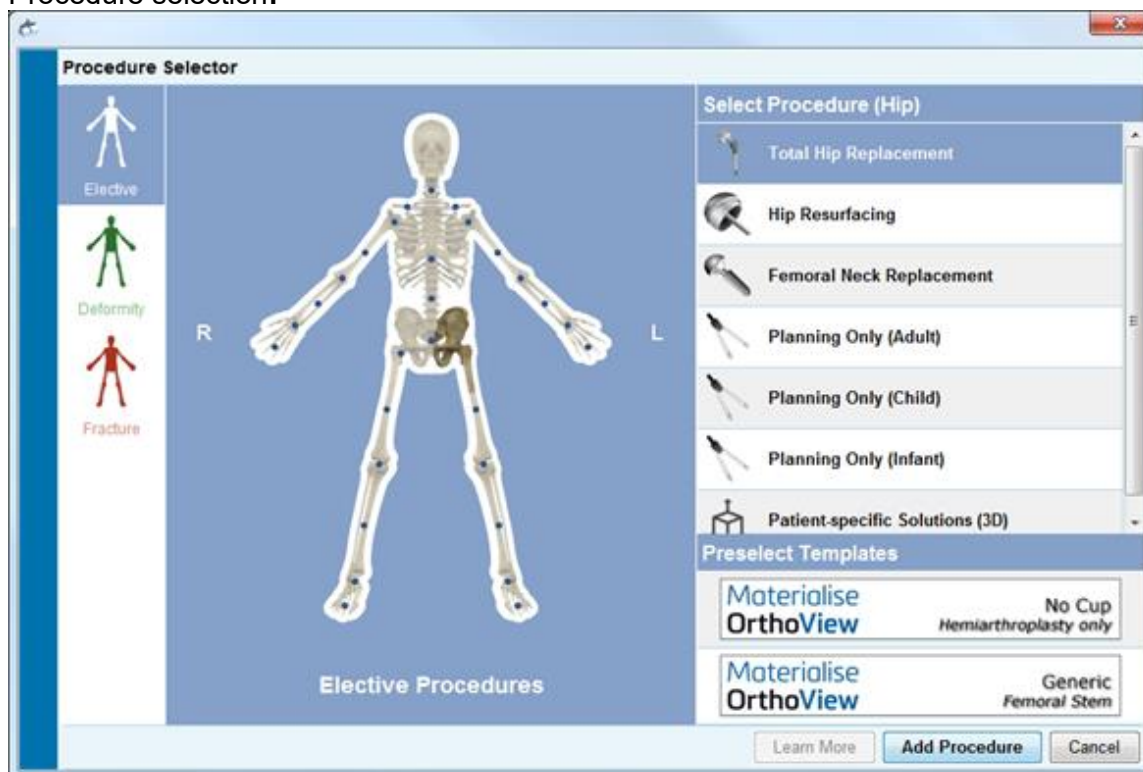
The Examination Panel

The Examination panel is used to select the Procedure & Services and the X-ray images. To add an additional Procedure or Service click the  add icon.

To start planning, in the Examination List select the patient and click Open.

Selecting a Procedure

A procedure or 3D service is selected initially from the following dialog:
Procedure selection:



Starting from left to right:

1. Select either Elective (blue skeleton tab), Deformity (green skeleton tab) or Fracture (red skeleton tab).
2. Click the desired part of the body (hovering with the mouse displays the body part e.g. "Hip")
3. Click the chosen procedure on the side of the patient to plan with (double clicking opens up the x-ray panel instantly). The chosen procedure will be highlighted (as shown in the image above "Total Hip Replacement").
4. If applicable, select templates for the procedure (you can still select or change them at the templating panel).
5. Click "Add Procedure" at the bottom right of the dialogue and this will open up the x-ray panel.

Note: you cannot begin scaling/analyzing/templating until you have selected a procedure.

Select X-rays to Open

You also need to select the patient image or images that you are going to template. You do this by selecting the file names under Select X-rays to open section.

This area displays the patient x-ray in the examination. To preview an x-ray, under Select X-rays to open, select the x-ray's name. A preview of the x-ray is then displayed.

To select a single patient image for templating, double-click its name. Alternatively, select the image's name and click Open Selected X-rays. To select more than one patient image for templating, press <CTRL/ CMD> and click to select all the images you want to open. When all the required x-rays are selected, click Open Selected X-rays.

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

The panel to the left hand side will reflect the state of the currently selected window

To change which window is selected, click the window's header. Alternatively, you can use the Window 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.

The Scale Panel

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.

Scaling options are described within the SmartHelp.

Note: Once scaling is complete your scaled image(s) will be automatically moved into the analyze or reduce panel so you can continue your work in the appropriate Panel.

The Analyze Panel

Depending on your selection of procedure from the blue, green or red patient representations in the Examination Panel, after Scaling you will be presented with the Analyze Panel or the Reduce (Orthopaedic only)/Simulate (Orthognathic only) Panel.

Using the Analyze Panel you can take measurements from anatomical features of the patient image with the meter tools and/or by using one or more of the specialized wizards for the anatomical area you are working with.

Select the appropriate tool in the tool bar, click-and-drag the tool over the patient image: or, under Wizards, select the wizard you want to use.

Panel Controls

In addition to the Generally Available Buttons there are specific Planning Controls displayed immediately below the procedure tabs. These are described in the SmartHelp.

Help with Planning

To plan the procedure, you need to select the correct measurement tools, or wizards, and then position them on the patient image. This information is then visible as a tool tip and is displayed in the preoperative report.

IMPORTANT: The measurements displayed in the meters sometimes get in the way. You can show or hide them at any point. To do this, on the Windows menu, click Show/Hide Meters: alternatively, press <CTRL><M>. You can also enable Meter Dragging with <CTRL><D> which allows you to move meters on the x-ray. Disable Meter Dragging to lock them in place.

Using the Toolbar

To select a tool, such as line or circle, select the appropriate tool from the tool bar. To create measurements, click or drag the tool over the appropriate area on the patient image. If you need to create a measurement in a position already occupied by something else, create it in an empty position and then drag it into place.

Moving and re-sizing measurements

To select a measurement tool, click anywhere on it. All measurements tools, such as a line or circle, have one or more handles. When a tool is selected, the handle(s) are displayed as hollow boxes. Only when a tool is selected can you re-size it.

Changing a tool's size, position or properties

To change the size and position of a tool, click to select the tool and then use the handles to re-size it. To change the tool's position, without changing the tool's size, click to select the tool, making sure you do not click a handle and pressing the left mouse button with the mouse pointer on the tool, drag the tool to the required position.


Right-clicking on a tool will display a menu which will allow settings to be changed or for the tool to be locked. A property box can also be selected which will remain on the screen until closed. Selecting a different tool (or wizard) while the property box is displayed will change the display to the newly selected tool or wizard.

Circular tools are re-sized differently: click to select the tool and right-click. The circular tool re-sizes itself so that the circumference passes through the mouse position. If you right-click anywhere inside the circle it also re-sizes it, so that the circumference passes through the selected point.

Clearing a selection and deleting tools

To clear the selection, click anywhere on the patient image, away from the tool: when a tool is not selected, the handles display as small solid squares.

To delete a selection, click to select the tool and either press Delete or Backspace.

Orthognathic only: Reset landmark positions by clicking  the Reset Positions icon.

Annotating tools

From either the Analyze or Template panels, click the meter's label to display a dialog box, which allows you to enter the required text. Note: the text you enter is displayed as a tool tip when you position the mouse over the label. The annotated value of the meter is also displayed in any reports that you print.

Messages area (Orthopaedic only)

The display area shows OrthoView's current state. For example, when you use the Transischial Line Wizard the following information is displayed, when available:


Preoperative values.
Plan shortening.
Predicted distance between two legs after surgery.

Measurements

Measurements are displayed on the left of the x-ray image providing the user has set the wizards appropriately.

The measurements calculated by the wizards are also displayed in the Report Panel.

Orthopaedic only:

Individual results can be removed from display by clicking the  Hide icon.

The  Show all button restores the results to the display.

Orthognathic only

Measurements can be shown and hidden using a collapsible tick box

Select Template

If you have selected an elective procedure, the digital templates for the prosthesis you normally use are displayed. If you want to use a different prosthesis for this procedure, click the template banner so that the '*Select a digital template*' dialog box is displayed.

The dialog box will first list your recently used templates, with a full list underneath. You can use the search box to help find a template. Locate the required template and click to select the preferred prosthesis. If there are no other suitable prostheses then only the current one will be shown.

The Reduce Panel (Orthopaedic only)

Using the Reduce Panel you can access the image reduction tool for manipulating image fragments and/or specialized animators for limb deformity procedures.

The toolbar remains available to take measurements from anatomical features on the patient image with the meter tools and/or by using one or more of the specialized wizards for the current procedure.

Using the Reduce Panel you can also plan fracture reduction by using the image fragment tool which is accessed from the Reduce Panel. (All other normal planning tools are available from the toolbar)

Select the appropriate tool in the tool bar, click-and-drag the tool over the patient image: or, under Wizards, select the wizard you want to use.

If your procedure includes templates that you selected in the examination panel then once you have completed your Reduction Planning you can access the Templating Panel by clicking the appropriate selection above the image.

Display Area

The display area shows OrthoView's current state. For example, if you are using the Limb Deformity animators there will be handles displayed to animate your planned reduction.

Image Region Tool

This is an additional tool only available in the Reduce Panel which is described in the SmartHelp.

The Simulate Panel (Orthognathic only)

Using the Simulate Panel you can access the Facial Repositioning and Cut tools for manipulating image fragments for Orthognathic reconstruction.

The toolbar remains available to take measurements from anatomical features on the patient image with the meter tools and/or by using one or more of the specialized wizards for the current procedure (All other normal planning tools are available from the toolbar).

No templates are available within the Simulate Panel.

For more information on how to use the Simulate Panel please refer to the SmartHelp.

The Template Panel (Orthopaedic only)

In the Templating panel, you insert Templates on to the patient image. To insert Templates, select the options for the Template you want to view on the patient image from the selection panel.

Additional Controls



Accept Recommendations - OrthoView Wizards when correctly applied can make recommendations for some Template Options. If you have already elected to accept recommendations in your Templating Options within your Preferences then this control will not be visible.

When templating a Hip Procedure, additional controls may be available.



Reduction - This will articulate the Head. When activated, the option will change to



Remove Reduction - This will undo the reduction (When selected the option will return to Reduction)

When templating a Knee Procedure, additional controls may be available.



Reduction - This will articulate the Head. When activated, the option will change to



Remove Reduction - This will undo the reduction (When selected the option will return to Reduction)

Automatic display of Templates

If the current examination includes one or more digital templates OrthoView will immediately display the template outline(s) in the Template Panel. In most cases this will not be a fully specified Template. See Prosthesis Options below for further details.

Selecting Alternative Template

By clicking on the template banner any other templates available for that group of prostheses for example Hip Stems will be visible and an alternative can be selected and positioned.

Prosthesis Options

The various options for the selected digital Template for the current procedure are displayed in option areas that can be minimized (on a complete component assembly basis) if required. This is achieved by selecting the hide or show icons previously described.

Where more than one component assembly is available (e.g. Acetabular Cup and Femoral Stem) then these options areas can be individually minimized. This is useful when there are several options for a component which are not always easily available when all prosthesis option displays are visible.

Until all options for all available prostheses for the active procedure are selected by the user, any incomplete component is displayed with a faint outline and an 'incomplete' warning is also shown.

- If the Preference to accept recommendations is set and appropriate wizards have been used, then the displayed component options will be preselected based on those criteria and other options that OrthoView cannot recommend will be preselected with a red dashed outline in that option list panel, and the panel background will also be shaded.
- Where the user has elected not to accept any recommendations or no appropriate wizards have been used, these options will not be preselected and all options will be denoted by red dashed outlines and the panel backgrounds will also be shaded.

Important: In either of the above situations, the User must select clinically appropriate combinations of options before OrthoView will display a full outline of the component. When this is done, the component outline will become darker. The 'incomplete' warning for the entire procedure will only be removed when all unspecified component options (as denoted by red dashed boxes and shaded panel backgrounds) have been correctly specified.

Prosthesis Properties

Selecting the Prosthesis Properties box allows the properties for the current prosthesis component to be adjusted.

- The **Color** option allows the user to select the color for this prosthesis component.
- The **Arrange** option allows template, tools and wizards to be layered.
- The **Lock** option locks this component in this procedure to prevent it being unintentionally moved on the image. (The Laterality and Color can still be changed even when locked)
- The **Show** option toggles the display (Hide/Show) of this component. It can be made visible again using the Hide/Show icon from the Templating Panel.
- **Help** displays help for the specific component.
- The **Properties** option displays a property box on the image for this component. This box will remain open until closed and will change dependent on which component is selected.

Additional Prosthesis Controls

There are additional template controls within the Prosthesis Selector panel for each individual prosthesis dependent on the type of procedure and any wizards used.

These include buttons for aligning the templates to appropriate wizards and bending (or canceling bending) of suitable plates. (Other buttons may also be available and their purpose will be self-explanatory)

Moving Templates on the Screen


Automatic Positioning of Smart Templates

If the planning wizards have been used, generally for arthroplasty, the first template set will be sized and positioned by OrthoView.


- OrthoView will size and position the digital templates. Final adjustments to the position or size of the templates may be made by selecting different options.
- To make the digital templates hide or show on multiple x-ray images, select Hide/Show icon for the individual template component. This icon is located to the right of the template banner above the padlock symbol and resembles an eye.

Hip Reduction

In Hip examinations with Acetabular and Femoral Head components, OrthoView enables the user to Articulate the Femoral Head within the Acetabular component in order to animate the proposed reduction.

Once enabled using the  Articulate button, the femoral stem can be adjusted by dragging using the mouse to compensate final fixation. The Femoral component will remain locked to the acetabular component during this process. The entire component assembly of Stem and Cup can also be adjusted by dragging the Acetabular cup component using the mouse.

Any changes to leg length discrepancy or offset during these adjustments will be reflected in the results panel.

Selecting the  Unarticulate button will undo any changes.

Surgical Knee Options

Depending on the settings within the Preferences, the posterior or anterior referencing selection for knees is evident in the ML Femoral prosthesis positioning. As the template size is altered it references to the anterior femoral surface or posterior condyle surface.

Aligning Smart Templates to wizards

When more than one prosthesis set is added to an image, or when manually positioning additional template sets, it will be necessary to align the additional components to the position of the wizard. Using this button will move an unlocked prosthesis component to the wizard position. (Prosthesis sets are, by default, unlocked when first selected)

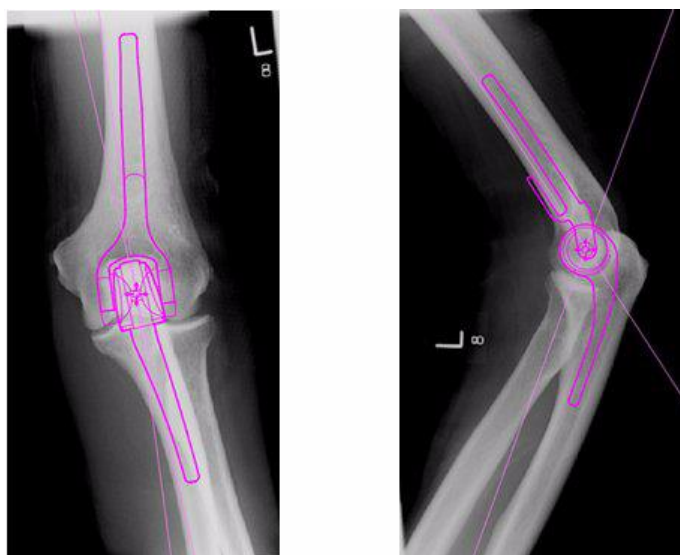
Manual Positioning of Templates

- If the planning wizards have been omitted, manual sizing and positioning of the smart template proceeds as if it were an acetate template.
- To make the graphics appear on the image if the planning wizards have not been used, make a choice from each of the tables listed to the left of the Image display under the digital template banners. The graphics will appear in a random position. To move the templates use the mouse as directed below.
- To move the template along the line of axis indicated by the broken line, move the mouse cursor inside the template, click and drag with the left mouse key.
- To move the digital template freely about the image, click and drag the four point star with the left mouse key.
- To rotate the template move the mouse cursor inside the template, click and drag with the right mouse key and a red line appears during this action.
- To make fine rotational adjustments hold down the <CTRL/CMD> key and use the right or left arrow keys.
- For fine positional adjustments use the arrow keys on the keyboard.

Manual Sizing of Templates for Arthroplasty

- To make size and type adjustments to the templates make selections from the tables to the left of the Image display. Note that the graphics will reflect the adjustments made, but the position of the digital template does not change.
- The smart templates incorporate the surgical guides so, for a specific prosthesis, only the combination of choices displayed in bold within the tables are available. If a combination of user choices is not physically available from the manufacturer, OrthoView will display a warning and remove the graphics.

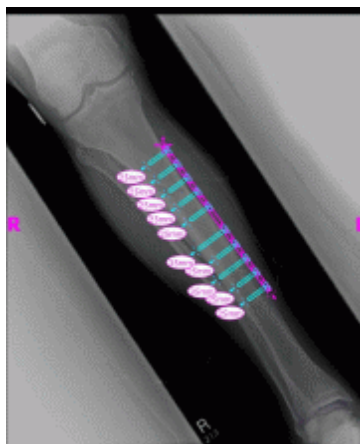
The example below shows the elbow joint templated with manual sizing and positioning.



Positioning and Sizing of Templates for Trauma Fixation

- Choose a sizing option from the Prosthesis Selector under the digital template banner.
- Click on the four point star handle and drag one end of the template into an appropriate position on the bone. Change side or orientation as required.
- **Smart Template:** Use the arrow ended handle to drag the plate or nail to the appropriate length and OrthoView will adjust the prosthesis graphic to the nearest matching size for you rather than needing to change it manually in the selector panel. Screws behave in the same way, snapping to the length options available from the manufacturer, as you click and drag the arrow ended handle away from the screw head.
- **Basic Template:** Any changes for size (etc) must be made manually from the selection panel.

The displayed sizes or lengths etc., shown on a component can be switched on or off by using the Hide Meters keyboard shortcut. **<CTRL><M>**



Template Properties

There are properties associated with all templates and they can be accessed by either right clicking on the template graphic or by using the drop down box to the right of the template banner in the Prosthesis Selector panel.

Default Template Properties

These are the usual options available from the dialog obtained by right-clicking on the template graphic and also in the dialog box subsequently displayed by selecting Properties.

- **Color** - choose the template graphic color from the selection offered, useful if multiple templates are used to avoid confusion.
- **Orientation** - where appropriate, allows setting the template view to anterior, posterior, lateral or medial. Useful when not templating in the expected plane. (This option not available for all prostheses)
- **Lock** - fixes the template position, toggle to allow movement again.
- **Show** - hides the template, this can also be done by clicking the colored button next to the template banner. Toggle to show again.

- **Arrange** - Arrange multiple templates in front or behind each other.
- **Help** – displays contextual help.
- **Properties** - if selected, a dialog box remains on the screen until the 'x' is clicked to close.

Basic templates have an additional option to add required screws.

Properties Dialog Box for Screws

These are accessed by right clicking on the screw graphic and the following options are available.

- **Type** - one of the various types can be selected including none if this screw is not required.
- **Insertion Order** - the order of insertion in the plate can be associated with each screw.
- **Properties** - a properties dialog box will remain open if selected.

Basic Screw Templates have additional options to change the screw diameter or delete the screw from examination.

General Screw Behavior

Screws can be added to all templates that accept the addition of screws. In basic templates screws initially appear Lateral-Medial and the user must adjust appropriately.

Screws can be moved and positioned by dragging on the outline. Screws can be lengthened and shortened by pulling the tip handle, even when the associated template is locked.

Screws can be rotated by the tip handle and rotated around the screw head. Smart templates allow only manufacturer approved angle of rotation. Basic screw templates have no restriction.

Most screws can have their type and insertion order changed. Additionally, basic screw templates can have their diameter changed.

Screw lengths are displayed in meters on the tip of the screw. Clicking this meter allows the insertion order to be added.

Unknown Screw Types

The functionality for displaying screw types within OrthoView is constantly updated. If OrthoView displays a digital template containing a screw type that your version of OrthoView is currently unaware of then a green screw outline will be displayed.

Each list of individual prosthesis sizes (etc) displays all the possible values for a single parameter: offset, diameter, and so on. If you used a wizard, some entries in the lists might be already selected in blue. This selection provides you with a suggestion of the size of component that might be appropriate. This suggestion is based upon the wizard position and the recommendations from the Orthopaedic prosthesis manufacturer.

You can modify your Template selection at any time using the mouse. To select alternative list entries, either click to select the required option or use the UP or DOWN arrows.

Adjusting screws

The screws will maintain their correct angle to the plate as specified by manufacturer. The screw length, type and insertion order can be changed in the normal way by right clicking on the screw to open screw properties dialog.

Changing the size of the plate during bending via the template selection panel will, in the case of bigger templates, extend the plate to the new bigger size where further bending can be performed. In the case of selecting a smaller template, the current bending of plate beyond the new smaller size, will be lost.

If you wish to straighten the plate without changing size, select <**Cancel bending**> from the Prosthesis selector panel (There is no undo option for individual bends)

Details of the bend angle and direction of each bend is available in the Report

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 or the tabs across the top of each individual image display panel.

The Menus are organized into broad categories, making it easy to find the appropriate function.

File Menu

This menu contains items that allow you to work with external files.

Windows Keys	Action
Preferences <CTRL><R>	Opens the Preferences Panel
Template Management <CTRL><T>	Opens the Template Management Panel
User Management <CTRL><U>	Opens the User Management Panel
Open	Opens the selected X-ray from the Examination List that the InBasket is pointing to. (InBasket versions only).
Import Folder	Import an examination from a specific Folder
Import DICOM CD	Import examination(s) from a Dicom CD Drive.
Query PACS	Import specific examination(s) from a PACS system using the Query and Retrieve dialog
Add Image	Adds an image to the currently open examination. Look at the Examination Panel to work with it. (InBasket versions only)
Page Setup	Sets the printing settings
Print Report <CTRL><P>	Print a Report for the opened examination
Save Report	Saves a Report in JPEG, for the opened examination
Print Current x-ray <CTRL><ALT><P>	Print the current x-ray together with any Templates or planning tools displayed on it
Save Current x-ray	Use to save an x-ray
Exit <CTRL> <E>	Quits OrthoView

Panel Menu

This menu contains access to the main Control Panels

Examination	Displays the Examination Panel for the selected examination
Notes	Displays the Notes panel for the current procedure
Report	Displays the Report panel for the current procedure
Scale	Displays the Scale Panel for the selected window. This is unavailable if you have not selected an image
Analyze	Displays the Analyze Panel for the selected window. Unavailable until you have scaled
Simulate	Displays the Simulate panel for the selected window (Orthognathic only)
Reduce	Displays the Reduce screen. This screen replaces the Analyze Panel if Fracture Management has been selected. It is unavailable until you have scaled. (Orthopaedic only)
Template	Displays the Template Panel for the selected window. Unavailable until you have scaled (Orthopaedic only)

Image Menu

This menu controls the active image

Windows Keys	Action
Undo <CTRL><Z>	Undo last action(s) of tool or wizard applied to image
Redo <CTRL><Y>	Redo last Undone action(s) of tool or wizard
Flip Horizontal	Flips image horizontal
Flip Vertical	Flips image vertical
Rotate 90deg Clockwise	Rotates image 90 degrees clockwise
Rotate 90deg Anticlockwise	Rotates image 90 degrees anticlockwise
Reset Window and Leveling	Resets contrast and brightness to original setting
Size to Fit <CTRL><0>	Resize image to best fit available window
Zoom In <CTRL><=>	Make image larger
Zoom Out <CTRL><-> (minus)	Make image smaller
Hide Meters <CTRL><M>	Hides or shows meters on the selected window
Meter Dragging	Enables/disables Meter Dragging
Hide Screws <CTRL><S>	Hides or shows screws on the selected window

Window Menu

This menu controls the windows

Windows Keys	Action
	Toggle Full Screen
Expand Window	Expand the selected window to be only one visible.
Next Window	Tabs to the next open window
Hide Window	Hides the selected window
Close Window	Closes the selected window
<Window Name>	Selects that window

Help Menu

This menu accesses the OrthoView SmartHelp System

Windows Keys	Action
Not available in Windows	Search
What do I do next? <F1>	Accesses the relevant Help for the area that you are in
Start Here	Help displays Introduction to OrthoView
Templating with OrthoView	Help displays Template panel overview
Product Support	Help displays Product Support information
Declaration of Conformity	Help displays Declaration of Conformity
Open User Guide	Opens user guide
Request printed User Guide	Opens form to request printed user guide
License Manager	Starts the license manager dialog
Send Feedback	Opens browser to Contact Us page
Welcome Screen	Activates Welcome Screen
About	Displays the About Panel

The Preference Menu

The various Preference options are fully described within the SmartHelp. These allow you to configure OrthoView to suit your personal Preferences and work practices.

Cybersecurity Setup

User Authentication and Access Control

The recommended way of authentication is Windows Authentication.

OrthoView provides a layered authorization model with the following roles:

- **Administrators:** technical professionals who are entitled to configure and change the system behaviour
- **Users:** trained medical professionals intended to create pre-operative plans

Setup the OrthoView administrators security group

OrthoView comes with a locked and encrypted system configuration for a Windows security group whose members are granted with OrthoView Administrator role. The group name by default:

OrthoView Admins

The group has to be added to the Windows Active directory as a security group. The name can be changed but it requires the assistance of OrthoView Support. It is recommended this is done right after the installation.

Enable Windows Authentication

Please make sure that the “OrthoView Admins” or the related administrator group has been created in tWindows Active Directory and the current user is a member of that group. The membership can be checked via running “whoami /groups” in a Windows command line and manually checking the result. **Note: if the Windows security group has been recently added, you may be required to re-login on the same computer if there was no logout since.** If you miss this step you risk locking yourself out from OrthoView temporarily.

The steps to enable Windows Authentication:

1. Log into a workstation with a user who is an OrthoView Administrator
2. Run OrthoView
3. Click File -> Preferences
4. Click the Advanced Tab
5. Tick the Box Windows Authentication
6. Restart OrthoView

Setup OrthoView Users

OrthoView users can be managed through a GUI panel available for Administrators only.

1. Log in to a workstation with a Windows user who is an OrthoView Administrator
2. Run OrthoView
3. Click File -> User Management
4. Select the second tab

5. Add, remove or edit the Windows users or groups who are entitled to access OrthoView with a User role.

Note: in case of managing the users by groups, it is very important to always use Windows security groups. It will not be possible to use email groups created in Windows domains as they are designed for other usages.

Channel Encryption

Communication with Remote File Stores

During the installation, Network File Share can be selected as a central data repository. For the data communication OrthoView recommends and supports Server Message Block 3.0 and later which provides an end-to-end channel encryption with AES based signing algorithm.

OrthoView does not contain restrictions on using alternative ways of encrypting the communication channel toward remote file stores.

Communication with Remote Service Endpoints

OrthoView supports and recommends to use Transport Layer Security 1.2 (TLS 1.2) when communicating with entities over a network.

There are no restrictions on using self-signed certificates, but we recommend complying with the latest industry standards and regulatory recommendations.

Data Encryption

In general it is recommended that data at rest is encrypted for all application data. This can be achieved by using storage technologies which support the latest encryption standards and provide sufficient prevention against physical or malware intrusion. OrthoView is not bound to a particular technology or vendor.

The [Software Data](#) chapter contains the details of the application data folders. The following table contains a classification by Protected Health Information (PHI):

Data folder type	Can contain PHI	Comments
Software binaries	No	The binaries are locked for modification by a timestamped signature, any malicious alteration is designed to be detected.
Software configuration	No	The content is encrypted and locked by its own.
System configuration	No	Critical data parts are encrypted in content but may contain other textual information.
Prosthesis templates	No	The files are in a proprietary format and do not contain PHI.

Workstation application data	Yes	It can temporarily contain transactional PHI data from the PACS during a planning session.
XRays folders (if not stored in PACS)	Yes	It contains Protected Health Information.
System log (technical)	Yes	By default any PHI is redacted, an administrator can configure PHI appearance via a GUI.
Audit Log	Yes	By default any PHI is redacted, an administrator can configure the level of PHI association to the log entries via a GUI.

Anti-Virus Policy

We recommend that all computers where OrthoView is installed or run have an anti-malware program running. There is no restriction about the program and OrthoView does not contain a specific integration; the protection must be provided on file level.

The following table can assist with establishing optimal local settings. It is recommended that the administrators make their own choice at their discretion which complies with the local IT policy, the actual regulations and the expected business performance or effectiveness. Under no circumstance do we recommend lowering the security settings if there is a concern over possible intrusion.

Data folder type	On-access scanning	On-demand scanning
Software binaries	It may be excluded, any malicious alteration is designed to be detected (binaries are signed and timestamped)	It is recommended to include in a regular (periodical) scanning
Software configuration	It may be excluded, the content is encrypted by its own	
System configuration	It may be excluded, textual (non-executable) data	
Prosthesis templates	It may be excluded, it is not intended to include any infectable file type	
Workstation application data	It may be excluded, it is not intended to include any infectable file type	
XRays folders (if not stored in PACS)	It may be excluded, it is not intended to include any infectable file type	

System log (technical)	It may be excluded, textual (non-executable) data	
Audit Log	It may be excluded, textual (non-executable) data	

Firewall

The following tables summarize the incoming and outgoing traffic which can appear during the software usage. The local IT firewall configuration should allow the traffic mentioned here on workstations where OrthoView has been installed.

Outgoing

Purpose	Destination	Port	Data
DICOM Query and Retrieve	Configured PACS server	Configured PACS port	DICOM messages and DICOM binary
Windows Authentication	Domain Controller	88	Kerberos messages
Access software data on a shared network drive	Configured Network File Share	445	SMB messages and binary files
Automatic Template Update ¹	live.orthoview.com, s3.amazonaws.com	443	HTTPS with JSON content, Binary data
Data Export for Mobile Applications ²	live.orthoview.com, s3.amazonaws.com	443	HTTPS with JSON content, Binary data
Case Management ²	casemanagement.materialise.com, s3-eu-central-1.amazonaws.com	443	HTTPS with JSON content, Binary data

¹ – Automatic Template Update can be turned off in the system configuration

² – The feature is not part of the standard installation, available on-demand

Incoming

Purpose	Source	Port	Content Type
DICOM retrieve (C-MOVE)	Configured PACS server	Configured C-MOVE port	DICOM binary

Intrusion Detection and Prevention

The following ruleset can be defined to assist the intrusion detection and prevention systems deployed in the hosting environment:

- The operating system process associated with the software is intended to be relatively short. The approximate planning time may be 10-30 minutes per case which may increase on case complexity but must fit into the normal employee schedule (shift or working hours)
- The software should not run when there is no workforce in the premise (e.g. no intended midnight activity in a room which is intended to be used daytime only)
- On a workstation, OrthoView is always bound to an active operating system login session and never appears as a background process
- OrthoView does not communicate with any other remote entities except the ones listed in the [Firewall](#) chapter
- The software does not open any port on a workstation other than the ones listed in the [Firewall](#) chapter

In addition to the above ruleset which can be used instructing the local Intrusion Detection and Prevention System, OrthoView provides the following cybersecurity controls to further ensure the safety use of the device:

- The software binaries are signed and timestamped, any malicious alteration is detected and the software does not start
- The software configuration is locked and encrypted (in content), any alteration is detected and invalidates the related setting. OrthoView may decide to start if it does not risk the safety use or the intended use of the device
- Finalised pre-operative plans are immutable, any malicious change in the content is detected and invalidates the plan.

Prevention Against Illegal Access of an Unattended Machine

OrthoView is intended to be used for a short term pre-operative planning session and the program terminates after. Please make sure that the use environment has one of the following group policy in place:

- The workstation should be automatically locked after a configured idle time, or
- The workstation should automatically logs the user off after a configured idle time

We do not recommend using a computer with a commonly known centralised username and password as it may breach the IT standards and/or the local IT policy. However, there can be certain situations when the patient safety may overwrite the general rules e.g. a machine in an operating room which access should not be blocked in case of an emergency. For those situations we recommend running the local corresponding cybersecurity measures for addressing any potential illegal access to an unattended workstation.

Audit Log

OrthoView traces any access to the software together with lifecycle events involving any type of Protected Health Information. The log is file based and its location is defined in the [Software Data](#) chapter.

The logged actions:

- LOGIN:
- OPEN_EXAM:
- OPEN_IMAGE:
- IMPORT_IMAGE:
- IMPORT_EXAM:
- EXPORT_EXAM:
- EXPORT_IMAGE
- PRINT_EXAM:
- RECEIVE_DICOM:
- RETRIEVE_DICOM:
- SEND_DICOM:
- ARCHIVE_EXAM:

The software provides a flexible way of defining the log message granularity when a PHI has been accessed. It is recommended to choose the smallest set of PHI to be displayed in the audit log entry which still provides adequate traceability related to the action. The values which the administrator can select on the GUI:

- Patient ID
- Patient name
- Accession Number
- Examination ID
- File name (as it is on the disk)

Maintenance

Software Data

Local Machine

The following table summarizes the workstation folders which contain OrthoView controlled data if the selected storage type was “Local Machine” during the installation.

Data folder type	Default location	Configurable	Estimated Working Size	Frequency of change
Software binaries	<OS Program Files>/OrthoView/<build ID>	Yes ¹	~250 MB	None
Software configuration	<OS Program Files>/OrthoView/<build ID>/Config	No	~2-5 kB	None
System configuration	<OS program data folder>/OrthoView/<build ID>/*.xml	No	~30-250 kB	Infrequent
XRays folders (if not stored in PACS)	<OS Program Files>/OrthoView/<Build ID>/XRays_*	Yes ²	Depends on the number of examinations stored there	Frequent
Prosthesis templates (from template delivery server)	<OS program data folder>/OrthoView/Templates	No	8kb-450MB	Infrequent
Workstation application data	<OS program data folder>/OrthoView/<build ID>	Yes ³	100-200 kB	Infrequent
System log (technical)	<OS program data folder>/OrthoView/<build ID>/Logs/OV_<username>_*.txt	No	Max. 20 MB, rolling	Frequent
Audit Log	<OS program data folder>/OrthoView/<build ID>/Logs/audit.txt	No	Depends on the logged operation meta data	Frequent

¹Configurable only during the installation

²Configurable on a GUI for administrators if the “Local Machine” storage type was selected during the installation

³Configurable only by special config file

Workstation Data - Network File Share Data Storage

During the Installation, the administrator can choose the desired storage type. If the “Network Shared Folder” was selected, a corresponding network path has been

configured. In this way workstation installations on multiple machines can be connected and unified under one central configuration and data folder.

The following table contains the data folder locations:

Type	Default location	Configurable	Estimated Working Size	Frequency of change
Software binaries	<OS Program Files>/OrthoView/<build ID>	Yes ¹	~250 MB	None
Software configuration	<OS Program Files>/OrthoView/<build ID>/Config	No	~2-5 kB	None
System configuration	<Network Share Path>/<Build ID>	No	~30-200 kB	Infrequent
Prosthesis templates (NFS prothesis templates)	<Network Share Path>/TemplateShare	Yes ³	8kb-450MB	Infrequent
Prosthesis templates (from template delivery server)	<OS program data folder>/OrthoView/Templates	No	8kb-450MB	Infrequent
XRays folders (if not stored in PACS)	<OS Program Files>/OrthoView/<build ID>/XRays_*	Yes ²	Depends on the number of examinations stored there	Frequent
System log (technical)	<Network Share Path>/Logs/OV_<username>_*.txt	No	Max. 20 MB, rolling	Frequent
Audit Log	<Network Share Path>/Logs/audit.txt	No	Depends on the logged operation meta data	Frequent
Local workstation application data	<OS program data folder>/OrthoView/<build ID>	No	30-200 kB	Infrequent
NFS workstation application data	<Network Share Path>/	Yes ³	30kB-450MB	Infrequent

¹ Configurable only during installation

² Configurable on a GUI for administrators if the “Network Shared Folder” storage type was selected during installation

³ Configurable only by special config file

PACS Data

The recommended way of storing patient data and the pre-operative plans is the PACS. Please refer to the PACS provider documentation to establish the necessary storage policy.

Backup

The [Software Data](#) chapter describes the application folder which are the targeted backup sources.

Backup the Software Binaries (for local and NFS)

For backing up the software binaries we recommend creating a computer image after the installation. This is necessary because the software installation procedure creates registry entries besides the folder data.

The installer must be also preserved to support an alternative restore procedure via clean installation.

Backup the Application Folders (everything except the software binaries, for NFS only)

A file system backup is required for the folders listed in the [Software Data](#) chapter (except Software binaries). The table in the chapter summarizes the average size and the expected frequency of change.

The backup of infrequent data can be a decision of local strategy and configuration.

Folder backup of frequently changing data is recommended on a daily basis, but this can be less strict if the local policy allows.

Restore

Restore from a Computer Image

If the latest computer image is available, the restore procedure is the following:

1. Restore the computer from the latest system backup image
2. Restore the application data folders listed in [Software Data](#) chapter from the backup archive

Restore with Installation

If there is no complete computer image available and the software binaries are damaged, the following steps can be performed:

1. Uninstall the software via the standard operating system provided mechanism
2. Install the software according to the [Installation](#) chapter
3. Restore the data folders described in the [Software Data](#) chapter from the backup archive

Restore without Installation (data only)

If the software binaries were not harmed but the application data was damaged, the restore procedure is the following:

1. Restore the data folders described in the [Software Data](#) chapter from the backup source

Emergency Plan

This chapter provides guidance about restoring the software from an unforeseen disaster or other damage (like a cybersecurity threat) which may cause major disruption, and which needs to be resolved immediately in order to restore at least the minimal software functionality and while avoiding further risks.

Restore OrthoView with Full Functionality and Previous Data

For an immediate restore of the previous fully functional working state, please perform the following steps:

1. Repair or replace the hardware components to a level which complies at least with the minimum hardware configuration written in the [Minimum Hardware Specification](#) chapter
2. Restore the software as written in the Restore section

Restore Minimal Functionality

The minimal functionality of OrthoView involves the functionality covering the intended use of the software. The main difference that it does not support connectivity to any external entities, it is intended to work even on isolated hardware and can provide a resilient way for maintaining the functionality right after a serious disaster ending in sever damages in the IT networks. The nature of the medical device (software) still requires a minimum hardware level. The steps are the following:

1. Repair or replace the hardware components to a level which complies at least with the minimum hardware configuration written in the [Minimum Hardware Specification](#) chapter
2. Install the software as written in the [Installation](#) chapter and select “Local Machine” as storage

Obtain an image for planning

1. Locate and export the image(s) of the related study from the PACS system. This is a PACS specific step; please refer the related vendor provided documentation.
2. Transfer or copy the image into the machine where OrthoView is installed
3. Run OrthoView, use the Import functionality to open the image from the local folder and perform the intended planning

Open a previously created plan

1. If the plan was previously stored:
 - a. In the PACS: locate the study and the related series in the PACS and export the previously saved plan. This is a PACS specific step; please refer the related vendor provided documentation.
 - b. In a folder: restore the desired plan from the backup source. The folder location is written in the [Software Data](#) chapter.
2. Transfer or copy the plan into the machine where OrthoView is installed

3. Run OrthoView, use the Import functionality to open the plan from the local folder, and the software will automatically recognise and display the plan.

Patching Policy

Microsoft OS

The policy and best practice for Microsoft OS patches and service packs on a system where OrthoView is installed is as follows:

There are no known issues with any Microsoft patches or service packs and we recommend continuing the default update policy of the local IT on site.

Java (prior to OrthoView 6.6.x)

OrthoView is a Java based application and each release is tested with, and validated to work up to the currently available version of Java. We don't recommend updating Java beyond the current recommended maximum tested version for the installed version of OrthoView. The OrthoView application will display a warning on start-up if it detects a newer version of Java than it knows about.

Java (OrthoView 6.6.x +)

OrthoView contains an option to use an embedded version of Java that is completely separate from any other version of Java installed on the system. Any updates to the system Java will not affect the OrthoView embedded Java.

Declaration of Conformity and Regulatory Standards

Declaration of Conformity

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



Declaration of Conformity – OrthoView

Legal manufacturer/ manufacturing site:
Meridian Technique Ltd
Southampton Science Park
Southampton, SO16 7QJ

EU Rep:
Materialise N.V.
Technologielaan 15
3001 Leuven, Belgium

This declaration is based on certificate no. 1434-MDD-118/2019, delivered by Notified Body PCBC, 23a Klobucka Street, 02-699 Warsaw, Poland

The legal manufacturer/ manufacturing site declare under his sole responsibility that the product to which this declaration relates,

OrthoView 7.x

- Is a class IIa medical devices according to Annex IX of the Council Directive 93/42/EEC (MDD 93/42/EEC);
- Is in conformity with the Essential Requirements (Annex II) and fulfill the applicable provisions of the Council Directive 93/42/EEC concerning medical devices.
- Is Compliant with harmonized standards, see attached annex.

Signed by Dawn Vear,
Quality Manager
Person responsible for regulatory compliance

Southampton, UK
27/09/2021

Regulatory Standards

Annex: list of Standards Applied

The following standards have been adhered to by Meridian Technique Ltd in order to demonstrate compliance of the **OrthoView™** device with the Essential Requirements of EC Council Directive 93/42/EEC, incorporating the requirements of Directive 2007/47/EC.

Standard Reference	Standard Title	EN Standard Reference or Other
ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes	EN ISO 13485:2016
MDSAP	Medical Device Single Audit Program	
CAN/CSA-ISO 13485-16	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes	
FDA 21 CFR Part 820	Quality System Regulation (United States)	
ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices	EN ISO 14971:2019
ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information, Part 1 general requirements	EN ISO 15223-1:2016
BS EN 62304:2007+A1:2015	Medical device software – Software life cycle	BS EN 62304:2007+A1:2015
BS EN 62366-1:2015	Medical devices – Application of usability engineering to medical devices	BS EN 62366:2015
ISO 20417:2021	Information supplied by the manufacturer of medical devices	BS EN ISO 20417:2021
NEMA PS 3.1-3.20	Digital Imaging & Communications in Medicine (DICOM)	
	Commission Regulation (EU) on Electronic Instructions for Use of Medical Devices	No: 207/2012
	ANVISA	Resolution RDC no. 185, of October 22nd, 2001
	Therapeutic Goods Administration (Australia)	Medical Devices Regulations 2002

USA – Prescription Statement (21 CFR 801.109/b/1)

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

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.

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

Request a Printed User Guide

To receive a printed copy of this user guide, please fill out this form. You will need your OrthoView OR number and version. Alternatively, you can launch OrthoView and select **<Request printed User Guide>** on the Help menu, which will automatically fill in your OR number and version on the form.

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 workstation 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.

Operators must verify that the displayed user details are those for which the plan is required. Stored plans must be controlled (reliably stored, backed up) by the operator or technician. This is particularly important where plans are saved to disk rather than direct to a PACS system.

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.

The device is not to be used for mammography.

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