

Hospital/Trust:	Department:
Date:	Location:
OLYMPUS TRAINING FACILITATOR	DEPARTMENT CONTACT
Name:	Name:
Role:	Role:

ORBEYE

Purpose:

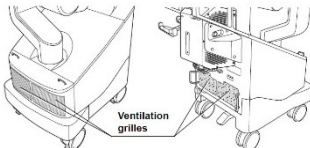
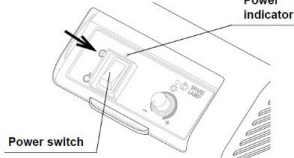
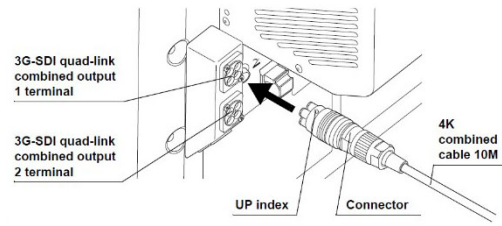
The Learning Plan is designed to highlight important points extracted from the Instructions For Use (IFU). It is NOT intended to replace the IFU.

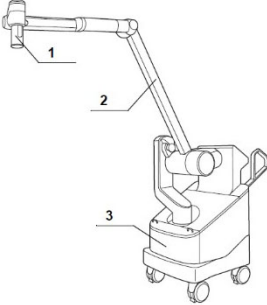
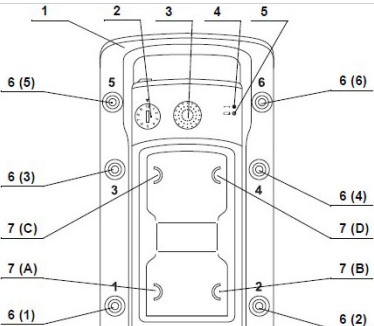
The IFU are supplied with each item of equipment and should be thoroughly read and understood before the equipment is operated.

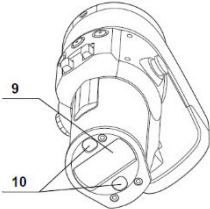
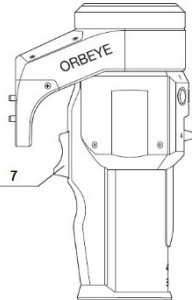

Learning objectives:

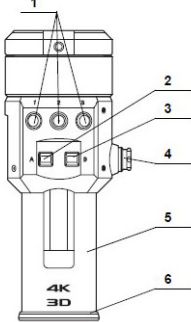
The objective of this session is for trainees to learn to set up and operate this product according to the IFU

Tasks	Tasks Covered	Training Methodology
PRE-OPERATIONAL INSPECTION AND CORRECT SET UP	(Tick as appropriate)	Input Training Method Practice/Demonstration/Discussion
<ul style="list-style-type: none"> Knows how to be sure that this is the most appropriate device for the intended use <ul style="list-style-type: none"> Acknowledges the Olympus ORBEYE 4K3D is a 2D and 3D exoscope, designed to be used during surgery, to provide magnified observation and recording of surgical sites 		
<ul style="list-style-type: none"> Knows how to check for damage/faults and serviceability 		
<ul style="list-style-type: none"> Knows how to check that both device and accessories meet Infection Control requirements 		
<ul style="list-style-type: none"> Knows how to be sure that all relevant accessories are available <ul style="list-style-type: none"> Frames and Shields ORBEYE Drapes Microscope Footswitch 		
<ul style="list-style-type: none"> Knows how to attach/set up accessories/consumables <ul style="list-style-type: none"> Knows how to remove/attach the shields to the frames Knows how to remove/attach the drape Knows how to adjust the arm Knows how to turn ON the SONY screen: <ul style="list-style-type: none"> Plugs it to an UPS (Uninterruptible Power Supply) and turn the switch ON (located under the left-hand side corner) Knows how to connect the display cable between the SONY screens and ORBEYE (one of the quad core cable per screen) Moving ORBEYE: <ul style="list-style-type: none"> Moves ORBEYE with one person pushing the manoeuvring handles from behind the equipment Uses the brake pedal to remove the brake lock 		
<ul style="list-style-type: none"> Knows how to check that power source and/or battery charge level are adequate <ul style="list-style-type: none"> Connects the power plug of the power cord to a UPS source (uninterrupted power supply) Recognises ORBEYE has no battery if the UPS source is disconnected 		
<ul style="list-style-type: none"> Footswitch <ul style="list-style-type: none"> Acknowledges the footswitch is wireless and operates with non-rechargeable LR14 batteries x 3 (size c) Check the light of the battery power indicator on the top right side of the footswitch 		

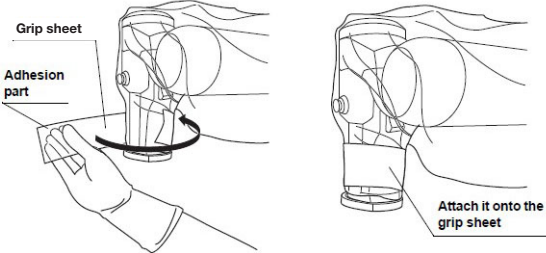
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<p>• Knows how to switch on the device</p>																				
<p>i. Checks the ventilation grilles on the front and rear of the base are not stopped by dust, a foreign object, or cloth</p>																				
<p>ii. Confirms that the power switch of the LED light source is set to on as described in the instruction manual for the LED light source</p>																				
<p>iii. Presses the power switch of this instrument to turn it on. Notices the power indicator lights green and the illumination lamp of the LED light source lights up</p>																				
<p>• Knows how to be sure all relevant accessories are available</p>																				
<p>i. Footswitch</p>																				
<p>ii. LCD monitors: Big screen (main observation monitor containing video recorder), small screen (ancillary observation monitor)</p>																				
<p>• Knows how to be sure all relevant accessories are available</p>																				
<p>i. Checks the touch panel lights up</p>																				
<p>• Completes attachment of accessories/set up consumables</p>																				
<p>• Acknowledges the footswitch has a wireless function: checks the communication status indicator: ←→ located on top of the battery power indicator is green</p>																				
<p>• Connects the main observation monitor to ORBEYE:</p> <p>i. Confirms ORBEYE and LCD monitors to be used are turned off</p> <p>ii. Confirms that the electrical contacts of the connector of the observation monitor are free of irregularities such as bending or crushing</p> <p>iii. Holds the observation monitor connector (4K quad core cable) so that the UP index comes on top and inserts it into the 3G-SDI quad link combined output 1 or 2 terminal all the way until it clicks</p>																				

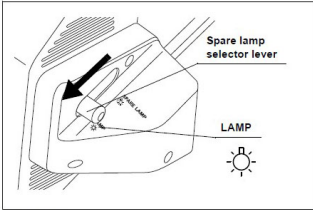
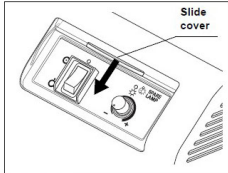
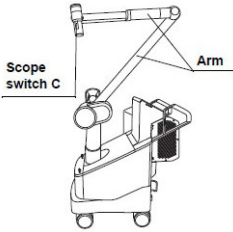
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<p>• Knows how to use all functions of the device</p> <p>i. Identifies the different parts of ORBEYE</p>  <table border="1"> <thead> <tr> <th>No.</th> <th>Name</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Microscope section</td> <td>Captures the image of the observed region.</td> </tr> <tr> <td>2</td> <td>Arm</td> <td>Used to change the positioning of the microscope section and hold it.</td> </tr> <tr> <td>3</td> <td>Base</td> <td>Used to support the entire instrument and move it.</td> </tr> </tbody> </table>	No.	Name	Description	1	Microscope section	Captures the image of the observed region.	2	Arm	Used to change the positioning of the microscope section and hold it.	3	Base	Used to support the entire instrument and move it.														
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<p>iii. Moves the base of ORBEYE</p> <p>Unlocking; pushes up the brake pedal with a foot to unlock castors</p> <p>Locking; pushes down the brake pedal and confirms it is locked the floor</p>																										
<p>iv. Identifies the main parts of the camera head section</p> <p>9. Objective lens; used to capture light of the observed region</p> <p>10. Illumination lens; used to output the illumination light</p>																										

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<p>v. Moves the ORBEYE camera head section by pressing and holding the grip and movement button (7)</p> 														
<ul style="list-style-type: none"> • Understands how to change the position of the ORBEYE to get optimal range of motion: <ul style="list-style-type: none"> ✓ Top: Arm section: the flat plastic towards the main surgeon with the black cover facing away. ✓ Bottom: Arm section: extension greater than 90 degrees. 														
<ul style="list-style-type: none"> • Selects the user: On the touch panel, select 'load user presets' according to the consultant surgeon list: • Turns the lamp ON/OFF; press and hold lamp button  <table border="1" data-bbox="397 1442 850 1697"> <thead> <tr> <th>No.</th> <th>Name</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Home button</td> <td>Tap to open the page for use during the procedure. →Refer to Chapter 7, "Operation of Function Class Screen".</td> </tr> <tr> <td>2</td> <td>Setting button</td> <td>Tap to open the page for use in the user presets, maintenance, system settings, and error history confirmations. →Refer to Chapter 4, "Function Setup".</td> </tr> <tr> <td>3</td> <td>Function buttons</td> <td>Switches the function group. The functions are classified according to their content. <ul style="list-style-type: none"> The frequently used functions. The functions related to zoom and focus. The functions related to colors and brightness. The functions related to observation, recording, and arm control. The functions related to the data display on the observation monitor. The functions used in preparation and completion of use. </td> </tr> </tbody> </table>	No.	Name	Description	1	Home button	Tap to open the page for use during the procedure. →Refer to Chapter 7, "Operation of Function Class Screen".	2	Setting button	Tap to open the page for use in the user presets, maintenance, system settings, and error history confirmations. →Refer to Chapter 4, "Function Setup".	3	Function buttons	Switches the function group. The functions are classified according to their content. <ul style="list-style-type: none"> The frequently used functions. The functions related to zoom and focus. The functions related to colors and brightness. The functions related to observation, recording, and arm control. The functions related to the data display on the observation monitor. The functions used in preparation and completion of use. 		
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<p>vi. Performs white balance</p> <ul style="list-style-type: none"> ✓ Moves camera head towards a white item ✓ Presses and holds 'Lamp' on the touch panel 														

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vii. Focus <ul style="list-style-type: none"> Adjusted by the surgeon 		
<ul style="list-style-type: none"> 1. Scopes switches 1/2/3 Used to control the functions assigned by the user: Zoom, Auto-Focus, Depth-of-field for example 2. Scope switch A Used to control the zoom or focus adjustments as assigned by the user 3. Scope switch B Used to control the zoom or focus adjustments as assigned by the user 4. Manual zoom knob Pulls out the knob and rotates it to control zoom. This knob is used in the case the motorized zoom fails 		
<ul style="list-style-type: none"> WLI (White Light Imaging) <ul style="list-style-type: none"> Standard observation using white light BL (Blue Light) <ul style="list-style-type: none"> Observation using Blue Light eg Glioma Surgery IR (Near Infrared/ICG) <ul style="list-style-type: none"> Observation using Red Light IR record and playback – acknowledges the IR does not automatically record the image Circulating nurse needs to manually record the image before the IR function is activated by the surgeon 		
viii. Record Video <ul style="list-style-type: none"> Turns on the Sony Video Recorder Presses REC via the main control panel or via remote control <ul style="list-style-type: none"> Checks a green light appears above the number of images captured to confirm it is recording Selects stop to halt recording <ul style="list-style-type: none"> Checks the green light recording symbol disappears Ends recording: Selects Menu, Endo Recording, OK, Close. Playbacks the recording on the main monitor On the right side of the main monitor, select control, PORTB With the arrows selects MENU, Recording List (will appear on the monitor) Selects the correct data to playback Selects PLAY for playback to begin Once completed, selects STOP Selects MENU Changes monitor back to live image <ul style="list-style-type: none"> Select PORT-A Select CONTROL on the monitor to remove the buttons from the main monitor 		

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ix. Takes Pictures <ul style="list-style-type: none"> • Selects CAPTURE via the main control panel or via remote control <ul style="list-style-type: none"> i. The LCD screen on the Sony Recorder shows the number of images captured 		
x. Exports files onto external storage devices		
<ul style="list-style-type: none"> • Ensures the external storage is plugged into the correct input (USB 1) and that it is displayed • Selects MENU, RECORDING LIST • Selects the correct data entry (checks date and time) <ul style="list-style-type: none"> i. At this point, status displays what formats have been recorded (2D, 2K, 3D and 4K) • Selects and ticks boxes for the files to be exported <ul style="list-style-type: none"> ii. Recommendation is to export only 2D2K files due to storage and playback ability • Selects EXECUTE • Ensures SAVE function is still set to 2D RIGHT (clicks into SAVE AS FIELD to uncheck the 2D and ticks 2D RIGHT) <ul style="list-style-type: none"> iii. Device begins exporting/writing to an external storage • Waits until the process is 100% complete • Once complete, selects CLOSE and MENU to return to the main screen 		
xi. Drapes ORBEYE		
<ul style="list-style-type: none"> • Turns the light OFF • To facilitate attaching of the drape, presses the scope control button (C) and extends the arm as shown • Opens the drape in the direction of the arrow: • With the orientation of index visible, puts holds in the folded drape and hold the lens hood • Aligns the convex shape part of the drape attaching bezel of the microscope section with the convex shape part of the lens hood and push firmly until the lens hood hits the drape attaching the bezel • Holds the lens hood and pinch the seal part, spreads the drape along the arm • Wraps the grip sheet around the grip section of the microscope section and holds own the slack of the drape <div data-bbox="446 1115 909 1792" style="text-align: center;"> </div>		

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<ul style="list-style-type: none"> Peels off the release paper at the end of the grip sheet and firmly presses the attaching bezel and attaches it onto the grip sheet  <p>The diagram consists of two line drawings. The left drawing shows a hand holding a bezel with a release paper being peeled away. Labels 'Grip sheet' and 'Adhesion part' point to the bezel. The right drawing shows the bezel being attached to a grip sheet, with a label 'Attach it onto the grip sheet'.</p>		
<p>xii. Understands any limitations or contra-indications for the use of the device</p>		
<ul style="list-style-type: none"> Acknowledges the footswitch must not be in contact with liquids due to danger of electric shock <ul style="list-style-type: none"> i. Bags the footswitch for each patient use Acknowledges ORBEYE CANNOT be used for Ophthalmic surgery or during procedures in which the illumination may make direct control with the patients eye <ul style="list-style-type: none"> i. Strong illumination can injure the retina Understands that alternating the observation of 3D images on the observation monitor and that of direct view of the observed region repeatedly promotes eye fatigue 		
<ul style="list-style-type: none"> Understands the risks of different energy, power or rates and how to choose the right setting <ul style="list-style-type: none"> i. Acknowledges the LED does not increase temperature ii. Changes the lamp intensity according to the surgical teams preferences 		
<ul style="list-style-type: none"> Knows how to check the initial/default settings & how to reset and change these if necessary 		
<ul style="list-style-type: none"> Can identify the alarms and respond appropriately 		
<ul style="list-style-type: none"> Can identify correct working distances of ORBEYE <ul style="list-style-type: none"> i. Acknowledges ORBEYE working distance from the surgical field is 220-550 mm: ii. When an object such as forceps is located near the objective microscope section, the 3D images may sometimes be hard to view. In such a case, it may be possible to improve by increasing the working distance. Otherwise, may result in fatigue. iii. Acknowledges that protection gear such as goggles or a face shield should not be used in combination with 3D eyeglasses the polarisation characteristic of the 3D eyeglasses becomes disturbed and the resulting impossibility of 3D image observation may result in fatigue or device under performance. Eye shields, however, can be worn on top of face shields and visors as detailed in scientific literature 		

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<ul style="list-style-type: none"> • Is aware of any other factors that may affect safe operation or accuracy of the device 		
<ul style="list-style-type: none"> • Can explain to the patient the purpose of the device 		
<ul style="list-style-type: none"> • Knows how to troubleshoot and solve common problems 		
<ul style="list-style-type: none"> • Failure of the lamp <ol style="list-style-type: none"> Acknowledges that each lamp has a total running time of 10,000 hours To change to the reserve lamp, select lever to SPARE LAMP Notices the spare lamp lights up and the spare lamp lighting indicator on the control panel lights amber: iii. Informs ORBEYE local representative of lamp change requirement 	 	
<ul style="list-style-type: none"> • Knows what action to take in the event of an error or failure <ol style="list-style-type: none"> Reboots ORBEYE on/off Informs ORBEYE 'account superusers' regarding performance issues for immediate response, and then local ORBEYE representative 		
<ul style="list-style-type: none"> • Understands responsibilities and procedure for cleaning and decontamination after use 		
<ul style="list-style-type: none"> • Acknowledges for official cleaning parameters to check the individual product IFU 		
<ul style="list-style-type: none"> • Knows the correct return procedure or how to store the device safely (as appropriate) 		
<ol style="list-style-type: none"> Folds the arm to store ORBEYE with a compact form Turns OFF ORBEYE and disconnects power cord from the UPS and wraps the cord away in the designated area on the rear of ORBEYE Stored the footswitch by hanging it on the footswitch hanger Ensures ORBEYE is stored with sufficient space without impacting on other equipment 		

Large empty rectangular area for notes, bounded by a blue header bar at the top and a thin black border on the sides and bottom.