

ORPHEUS



USER MANUAL

REVISION 3

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1. INTRODUCTION

1.1. ABOUT THIS MANUAL

This manual provides the information necessary to operate the Orpheus mediShow in a safe and efficient manner. **Please read and understand this manual before operating the system.** If any part of this manual is not clear, contact Orpheus Customer Support for clarification.

1.2. ORPHEUS MEDISHOW PRODUCT OVERVIEW

Orpheus mediShow is part of the **Orpheus MedicVOD** system:

- **mediCAST** – a stream decoder which is connected to a medical scope camera
- **mediShow** – this application – a viewer for real time broadcasting from a mediShow system
- **mediSearch** – a search utility application to search for and view videos and still images previously captured by mediShow.



1.3. PRODUCT FUNCTIONS

mediShow has the following capabilities:

- Automatic connection to the MedicVOD server and to display a list of active mediCAST video sessions
- User choice of up to four active mediCAST live video streams
- Zoom and Snapshot capability
- “Talk Back” feature to allow the user to have visual and audible interaction with the operating theater
- “On Screen Display” (OSD) guideline control – a layer on top of the video to create visual annotation visible to other users of the system.

1.3.1. Special messages: Warnings, Cautions and Notes

Three types of special messages appear in this User Guide:



A **warning** indicates the possibility of injury to the patient or operator.



A **caution** indicates a condition that may lead to equipment malfunction.



A **note** provides other important information.

1.4. CONDITIONS FOR USE

1.4.1. INTENDED USE

The MedicVOD system is intended as a radiological image processing system that allows for the capture, transfer, display, storage, and digital processing of medical images.

1.4.2. INTENDED USERS

mediShow is intended to be used by medical practitioners and supporting staff who have received training for the use of the system.

1.4.3. INDICATIONS

The MedicVOD system is a picture archival and communications systems (PACS) that is intended for image capturing, archiving, displaying and recording of audio/video sequences and patient data during a procedure. The system allows for capture and annotation of the surgical procedure for documentation purposes and for viewing at a later time either locally or on a secure distributed network. Information captured and stored by the system are for viewing and reference purposes and are not intended for primary diagnosis.

1.5. GLOSSARY

MEDICVOD SYSTEM:

Video On Demand application consisting of these main components:

- **MEDICAST:**
Application for **sending and archiving** a live video stream from the medical operating theater to remote viewers
- **MEDISEARCH:**
Application for browsing and **viewing archived** video streams that were created by mediShow
- **MEDI SHOW:**
Application for **viewing** and interacting with the **live** video stream created by mediShow
- **VOD SERVER:**
Software components used to broadcast, archive and retrieve video streams

OSD:

On Screen Display – picture-within-picture on the mediShow display

SESSION:

One complete session of video capture. A session may be equivalent to a single surgical operation

SESSION ID:

Unique identifier of a session. The Session ID may be entered manually, or scanned in via the built-in Bar Code reader

SNAPSHOT:

A still image of the video, captured by the mediShow user

TALK BACK:

Ability of a mediShow viewer to provide audio or graphic commentary.

2. SAFETY

2.1. GENERAL SAFETY INSTRUCTIONS



WARNING: DO NOT USE BEFORE READING AND UNDERSTANDING THIS MANUAL.



WARNING: THE SYSTEM IS RESTRICTED TO USERS WHO HAVE ATTENDED THE REQUIRED USER TRAINING COURSE FROM ORPHEUS LTD., AND WHO HAVE RECEIVED THE PROPER SYSTEM CERTIFICATION.



Caution: Changes or modifications not expressly approved by Orpheus Ltd. can affect the safety and effectiveness of the system and will void the system's warranty.



Caution: To avoid potential for electrical shock, do not operate with damaged cords or plugs. If damaged, have the cord or plug replaced immediately by a qualified service technician.



Caution: The system contains no user-serviceable components.

2.2. SPECIFIC WARNINGS AND CAUTIONS



Warning: The OSD feature is intended as a bi-directional training tool. It should not be used for diagnostic purposes.

2.3. COMPATIBILITY WITH OTHER MEDICVOD DEVICES

The mediShow System is compatible with the MedicVOD devices:

- The mediCAST system
- The mediSearch system.

3. LABELS AND SYMBOLS

3.1 SYMBOLS

Explanation of symbols:

| Symbol | Description |
|---|--|
|  | Consult instructions for use |
|  | Year of Manufacture |
|  | Special Requirements for Waste of Electrical and Electronic Equipment (WEEE Directive) |
|  | CE Compliance (Medical Device Directive) |

4. USING THE MEDISHOW SYSTEM

4.1. INSTALLATION

Installation of the MedicVOD is performed by an authorized Orpheus Medical technician. The technician installs and checks all system components prior to first use by the medical staff.

The mediShow runs on a standard PC (Windows XP and upwards) with the following minimum memory constraints:

- 1) 1GB RAM
- 2) 10 GB hard disk
- 3) 2.2Mbps network throughput

4.2. STARTUP



To start the system, double-click the mediShow icon located on the Windows desktop.

LOGIN screen

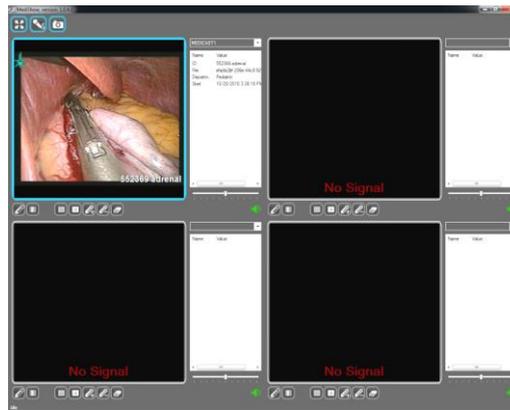
At first, the login screen appears:

- 4) Fill up the MedicVOD server IP name or address
- 5) Fill up the user name
- 6) Fill up the password
- 7) Click the "OK" button



Note: The Server IP, user name and password are provided by the system administrator of the hospital. The user name and password are either unique to the MedicVOD system or part of the hospital user name/password policy.

After a successful login procedure, the mediShow startup screen appears:



4.3. CHOOSING A SESSION

mediShow displays four Sessions, each in a separate window. Only one session is the “selected session” and has a cyan focused line on the border of the window. To select a session:

- 1) Click on or near the speaker icon, on the border of the window.
- 2) Or choose an active session from the drop-down arrow in the **Session List** that appears near the session windows. The Session List appears as follows:



| MEDICAST1 | |
|------------|-----------------------|
| Name | Value |
| ID | 552369 adrenal |
| File | efada2bf-206e-44c8-92 |
| Departm... | Pediatric |
| Start | 10/20/2010 3:38:18 PM |



In this example, the **MEDICAST1** session has been chosen. Displayed information:

- **ID** – unique Session ID assigned to this MedicVOD video stream
- **File** – File name assigned in the MedicVOD data system
- **Department** – Hospital department
- **Start** – Time and date that this Session began.



Note: If the MedicVOD server is connected to the hospital’s information system, additional values may appear, such as patient name, submission department, etc.

4.4. SUMMARY OF ACTIONS AVAILABLE WITHIN A SESSION

In the selected Session, the user can use the following controls:

| | |
|--|----------------------------------|
|  | Brightness |
|  | Audio Enable/Mute |
|  | Zoom |
|  | Snapshot |
|  | Talk Back |
|  | OSD ("On Screen Display") |

Each of these controls is described in detail below.

4.5. BRIGHTNESS



Click and drag to change the brightness of the Session window.

4.6. AUDIO ENABLE/MUTE



Use the audio control to enable or mute the audio broadcast from the session. The audio *volume* is managed by the standard Windows volume control.

4.7. ZOOM



Select a Session window and then click the Zoom icon. The Session window will zoom to full screen:



4.8. SNAPSHOT



To capture a still image ("take a snapshot"), select a Session, and then click on the Snapshot icon.

The captured image is sent automatically to the MedicVOD server to be stored on the main archive and to allow access by the mediSearch application.

4.9. TALK BACK



To activate the "Talk Back" feature, first select a Session. This is the Session that you will communicate with, using the Talk Back feature. Click on the "Talk Back" icon.

The "Talk Back" icon will flash while you are in an active Talk Back Session. When in Talk Back, the image from your web cam, and your voice audio, are sent to the mediCAST user in the operating theater. All mediShow users can also hear and see your Talk Back audio and video.

To stop "Talk Back," click on the flashing icon.



Note: When activating the Talk Back feature, the audio of the selected window should be "ON" (not muted). If the audio is muted, the people in the operating theater (and other mediShow users) can hear you, but you cannot hear them.

4.10. OSD ("ON SCREEN DISPLAY")



OSD ("On Screen Display") allows you to highlight areas of the video. The highlighting line can be any color, thin or thick, opaque or transparent.

OSD is *requested* by the mediShow user, but must be *accepted* by the mediCAST Session in the operating theater.



Note: OSD highlighting is visible to all users of the MedicVOD system.



Warning: The OSD feature is intended as a bi-directional training tool. It should not be used for diagnostic purposes.

The following sections describe each OSD button.

4.11. ACTIVATE OSD



Click to request OSD activation. The icon will flash until the OSD request is accepted by the mediCAST Session. Click again to hide all OSD highlighting.

4.12. CHANGE PAINT COLOR



The default paint color is green. To change the color, click the icon and select a new color. The paint color is shown in the box to the right – in this case, the color is red.

4.13. CHANGE TRANSPARENCY



Click to change the OSD transparency level of the highlighting.

4.14. CHANGE LINE THICKNESS



Click to change the thickness of the line drawn with OSD.

4.15. ERASE ALL OSD



Click to erase all active “On Screen Display” for this Session window.

To remove the “On Screen Display” from the window, click on the “OSD” icon again.
Click to change the thickness of the line drawn with OSD.

4.16. CLOSE THE MEDISHOW APPLICATION



To close the application, press on "X" located on the top right corner of the main window.

5. TROUBLESHOOTING

Before addressing the troubleshooting table, please check and confirm the following:

1. The Windows volume control is set to an audible level.
2. For "Talk Back", the Windows microphone is set to a medium level, and the webcam is properly installed.
3. Access is available to the network supporting the MedicVOD Server.

5.1. BASIC TROUBLESHOOTING

| Condition | Possible Cause | Recommended Action |
|---|---------------------------------------|---|
| In "Talk Back" mode, cannot hear anything from mediCAST | Audio of selected Session not enabled | Enable the Session audio (see section 4.6. Audio Enable/Mute on page 12) |
| In "Talk Back" mode, user image not in Session window | No video signal from device. | Ensure that webcam is enabled and turned on |

6. MAINTENANCE AND SERVICE

mediShow does not require maintenance or calibration on a routine basis.

6.1. OBTAINING SERVICE:

Contact the Orpheus mediShow representative:

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Fax: 972-77 437 1228

Email: <mailto:info@orpheus-medical.com>

APPENDIX A: APPLICABLE STANDARDS

The following list of standards applies to the System:

- Digital Imaging and Communications in Medicine (DICOM): PS 3.3-2004, National Electrical Manufacturers Association.
- IEC/EN 60601-1-4:1997, General Requirements for Programmable Electrical Medical System.
- IEC 62304:2006, Medical Device Software – Software Lifecycle Processes.
- IEC/EN-60601-1: 2006 (3rd. ed.), Medical Electrical Equipment; Part 1: General Requirements for Safety..
- IEC/EN 60601-1-2:2001, Medical Electrical Equipment; Part 1-2: Collateral Standard: Electromagnetic Compatibility- Requirements and Tests
- ISO 15223-1:2012, Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements