



MDS 3300 HD / MDS 3300

DIGITAL VIDEO COLPOSCOPE

User Manual

ALARIS MEDİKAL ve ELEKTRONİK SİSTEMLER SAN.TİC.

www.alaris.com.tr

Table Of Content

| | page |
|----------------------------------------------------------------------|------|
| Preface | 3-4 |
| General Information and The Characteristic of Our Colposcope | 5 |
| Structure Of The Unit | 5 |
| Power Requirements | 5 |
| Section 1 MDS-3300HD / MDS-3000 System Operation Manuel | 5 |
| 1.1 System Installation Buttons | 5 |
| 1. ON/OFF Button | 5 |
| 2. Fuse | 5 |
| 3. 110V/220V AC Input | 5 |
| 4. BNC Video Output | 5 |
| 5. S-Video Output | 5 |
| 1.2 Control Buttons | 6 |
| 1. Power Led Indicator | 6 |
| 2. Auto / Manuel Focusing (AF / MF) | 6 |
| 3. White | 6 |
| 4. Green | 6 |
| 5. Freeze | 6 |
| 6. Wide | 6 |
| 7. Tele | 6 |
| 8. Time | 6 |
| 9. One Push Automatic Focusing | 6 |
| 1.3 Camera Adjustment | |
| 1. Hand Grip | 8 |
| 2. Fixing Handle | 8 |
| 3. Camera Horizontal Rotation Control Block | 8 |
| 4. Camera Tilting Rotation Control Button | 8 |
| 5. Floor Stand Height Adjustment Button | 8 |
| 1.4 Operation Before Examination | 9 |
| 1.4.1 Adjust Camera Height | 9 |
| 1.4.2 Enter Software Interface | 9 |
| 1.4.3 Focusing | 9 |

page

| | | |
|------------------|---------------------------------------------------|-----------|
| 1.4.4 | Image Freeze | 9 |
| 1.5 | Clinical Observation | 10 |
| 1.5.1 | Preparation | 10 |
| 1.5.2 | Speculum Placement | 10 |
| 1.5.3 | Direct Observation | 11 |
| 1.5.4 | Detailed Observation | 11 |
| 1.5.5 | Acetic Acid Solution Test | 11 |
| 1.5.6 | Iodine Solution Test | 12 |
| 1.5.7 | Trichloroacetic Acid Solution Test | 13 |
| 1.5.8 | Reagent | 13 |
| 1.5.8.1 | 3 % or 5 % Acetic Acid Soltion | 13 |
| 1.5.8.2 | Iodine Solution | 14 |
| 1.5.8.3 | 40 % Trichloroacetic Acid | 14 |
| 1.6 | Technical Features Of MDS-3000HD / MDS-3300 | 14 |
| Section 2 | Maintenance and Trouble Shooting | 15 |
| 2.1 | Video Colposcope Cleaning | 15 |
| 2.2 | Service | 15 |
| 2.3 | Service Responsibility | 15 |
| 2.4 | Service Information | 16 |
| 2.5 | Trouble Shootings | 16 |

P R E F A C E

Introduction To Colposcope

Colposcope which was invented in 1924 is a device which is deemed to be the “golden standard” in the diagnosis of cancer and pre-cancer diseases of woman external genital organs today. The Procedure carried out with a colposcope is called “colposcopy”.

Colposcope is essentially a depth-sensing (stereoscopic) microscope and assists in diagnosing cancer of covering membranes (epithelium) of external genital organs and more importantly those diseases which may turn to cancer in the future by magnifying 4 to 60 times.

The physician who shall perform colposcopy must have been specifically trained in this subject. Some of pre-cancer diseases turn to cancer 10-15 years later on the average. Only part of those women who have genital cancer can be saved by such difficult and expensive treatments which have a great many side effects. Those “pre-cancer diseases” which are diagnosed by colposcopy are such diseases which can be eradicated at a rate close to 100% by out-patient treatment methods. The “pre-cancer diseases” which are diagnosed at this stage are usually treated by minor surgical interventions under local anaesthesia without causing any loss of organs.

Thus fecundity may be maintained and the research carried out show that pregnancy rates and course of pregnancy are within normal limits following treatment at this stage.

Colposcopic procedure may be performed within a period of 2-3 minutes which shall be added to the gynaecological examination. While the patient lies on the gynaecological examination table in the same position, the gynaecologist examines the vagina by externally smearing it with physiologic serum (saline water) and/or 3% acetic acid (vinegar acid) up to the cervix. Following this procedure, the epithelium (covering membranes) may coated with an iodine coating called Lugol.

At the end of the examination, part(s) a few millimetres in size is/are taken from abnormal tissues using special instruments and forwarded to the pathology laboratory. The tissue is examined in detail at the pathology laboratory and diagnosed finally. Then if there is any pre-cancer disease which must be treated, colposcopy is performed in its treatment so that the disease can be completely removed and is prevented from recurring or in order not to unnecessarily dissect excess tissue.

As seen, in cervix cancer, colposcope has a great importance in cervix examinations. It is particularly an important diagnostic device in the diagnosis of cervix cancer which is the most widespread type of cancer in our country. The device which is most widely used at present is the conventional type just like MDS-3000HD and MDS-3300 Digital Video Colposcope.

Advantages of this device over the other conventional colposcopes are :

- Capability to transfer the image to a monitor or computer
- Archiving of the image transferred to computer
- Printing of the image so obtained as a patient's report
- Capability of obtaining a 800.000 pixels perfect image by a 1/4 type Super HAD CCD camera for MDS-3000 and 2.000.000 pixels for MDS-3300HD
- Capability to optically zoom in the image by 26 times (x20 for MDS3300HD)
- Capability to digitally zoom in the image by 12 times
- Capability of showing the image to the patient by means of an external monitor to be connected

General Information and The Characteristic of Our Colposcope :

The ultimate is in convenience on our digital video colposcope system. The ergonomic design arrangement of the controls allows convenient single-hand operation of the Video Colposcope MDS-3300HD / MDS-3000. The excellent CCD camera and high-end features settings for low to high magnifications ensure reliable diagnosis and treatment.

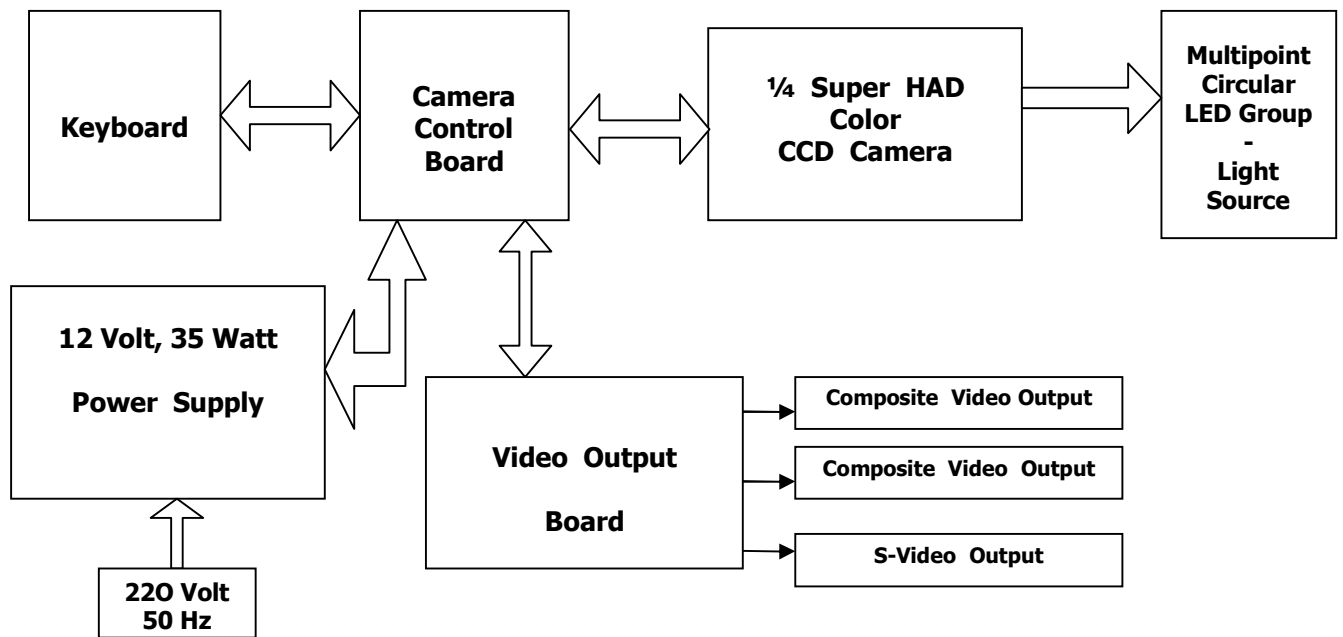
ALARIS MEDICAL MDS-3300HD and MDS-3000 series digital video colposcope imaging system is a new video colposcope. It is high-resolution electronic imaging technology and many advancements. This technique is different from traditional colposcopy. It does not have an eyepieces. Without the limitation of traditional colposcopy, it does not have an eyepieces. Without the limitation of traditional colposcopy, doctors only need to observe the lesion on the monitor. The high quality light source and highly magnified image provide very subtle details. In addition, it is easy to operate, so conventional system can be used in the process of both diagnosis and treatment. Therefore, such innovative technique creates a more advanced method for education and research as well as clinical colposcopy diagnosis and treatment.

Intended Use :

- To confirm and remove the precancerous lesion on cervix to prevent it form cancerization.
- To select abnormal lesion, perform coloscope guided biopsy and improve the positive rate of biopsy
- To determine the degree of abnormalities, especially the degree of the lesion in the cervical canal
- To confirm the normal and abnormal columnar and squamous cells junctional and metastatic region.
- To eliminate infiltrating cancer.

Structure Of The Unit :

The block diagram of video colposcope systems MDS-3300HD / MDS-3000 and the main unit operation principle are shown as Figure A.



Block Diagram Of MDS-3300HD / MDS-3000 Figure A

Power Requirements :

The power requirements for the unit are as specified as below. Never use this unit when power supply does not meet the requirements, or the unit may possibly be damaged.

- **Power Voltage For The Main Unit :**

The power voltage for the main unit should be in accordance with the specification or the rear panel of the unit. The voltage fluctuation of power supply to the unit should be within the limits of $\pm 10\%$. Otherwise, the unit is likely to be damaged.

- Power Voltage : 110V ~ 220V
- Frequency of the Power Supply : 50Hz / 60Hz
- Apparent Impedance of Power Supply : 0.5 Ω or less
- Grounding

Connect the power supply after the additional protective ground connector is connected to the special ground device.

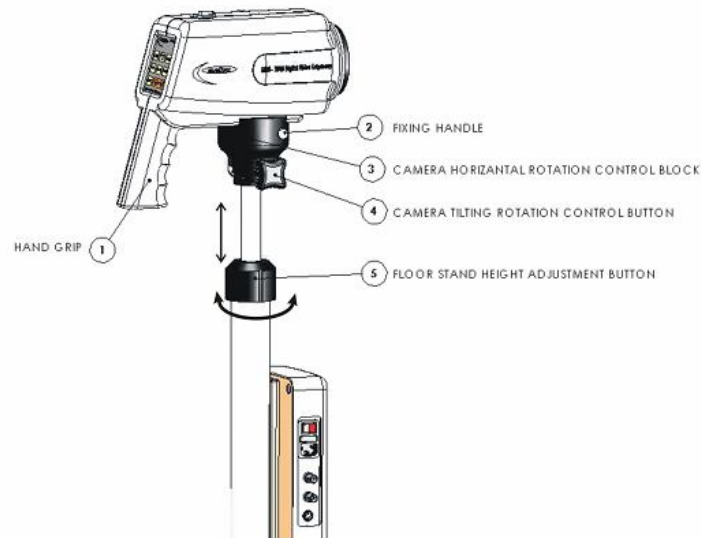
WARNING : The user should wait for at least 5 seconds before switching the unit on again after power off.

Section 1 MDS-3300HD / MDS-3000 System Operation Manuel

1.1 System Installation Buttons

The system installation buttons applies for MDS-3300HD / MDS-3000 camera has five buttons.

- 1.) ON / OFF Button : When you select " 0 " position of button that indicates the system is OFF position. When you select " I " position of button that indicates the system is ON position
- 2.) Fuse : It provides prevention aganist for any abnormal irregular voltage artefacts.
- 3.) 110V / 220V AC Input : The system can be installed both 110V and 220V automatically
- 4.) BNC Video Output : You may connect this output for convenient optional LCD Monitor or CRT monitor and Color Video Printer as well.
- 5.) S-Video Output : You may connect this features for convenient optional LCD Monitor or CRT monitor and Color Video Printer as well.



MDS-3300 / MDS-3000 System's Installation Buttons Are Shown As Figure 1

1.2 Control Buttons

This manual applies for MDS-3300HD / MDS-3000 camera has 9 buttons

1.) Power LED Indicator

When the LED appear in RED color means that the system is ON mode. When the LED does not appear RED color means that the system is in OFF mode.

2.) Auto/Manual Focusing (AF/MF) :

When you run the system, system open itself in AF (x 6 Magnification) mode. When the system in AF mode the camera searches the objects, auto focusing function will automatically adjust the image clarity in accordance with the distance between the colposcope and the object. When the camera is in manual focus mode direct camera towards to object, press button 2 the camera will manually adjust the distance between camera and the object must be within 300 – 400 mm.

3.) White : Press it once, switch green filter mode return to normal mode.

4.) Green : Electronic green filter key. Press this key, the system will automatically filter the red tissue in the image being observed and highlight the enhanced vessel image and the vascular morphology.

5.) Freeze : Image " freeze " control key. First time press the key, image will be frozen. Press the key again, image will be unfrozen and dynamic image will be restored.

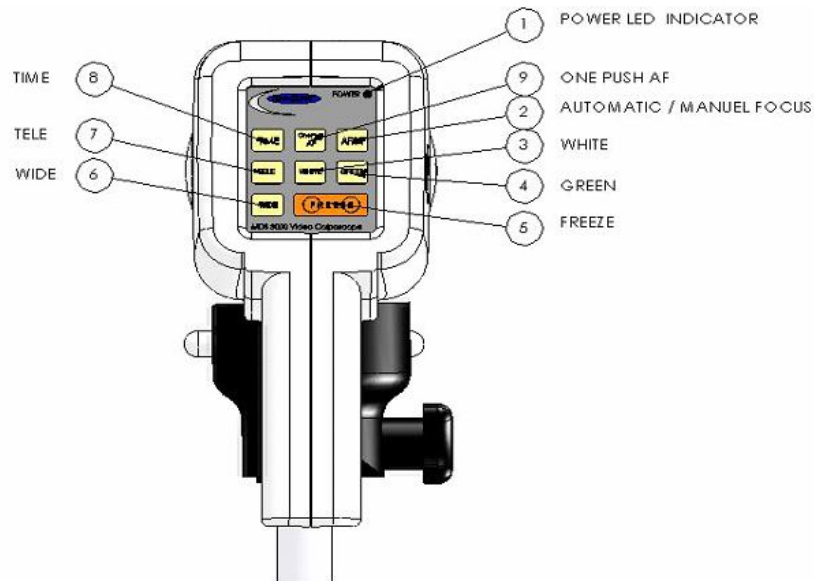
6.) Wide : Image observation window for magnification control, equivalent to local reduction.

7.) Tele : Image observation window for reduction control, equivalent to local magnification.

8.) Time : Press this button the first time, magnification and time will display on monitor. It also appear on the screen which mode system opened itself such as AF (Automatic Focusing) or MF (Manuel Focusing) mode . Press again, then all information will be erased automaticly.

9.) One Push Automatic Focusing :

When the camera is in manuel focusing mode, this button in order to adjust clarity to the clearest . MDS-3000HD and MDS-3300 has this features.

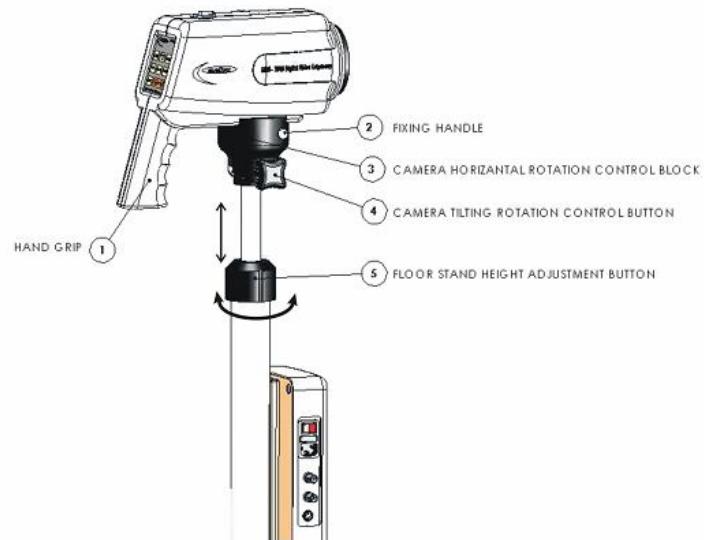


MDS-3300HD / MDS-3000 Control Buttons Are Shown As Figure 2

1.3 Camera Adjustment

MDS-3300 / MDS-3000 camera fixing and movements are shown in Figure 3.

- 1.) Hand Grip : You may hold the unit by using hand grip and can move in twin axis.
- 2.) Fixing Handle : Remove the camera by pulling it *or* fix the camera by pushing it.
- 3.) Camera Horizontal Rotation Control Block :
- 4.) Camera Tilting Rotation Control Button : When you release the button upside then you may arrange the camera horizontal rotation. When you release the button down then you fix the camera.
- 5.) Floor Stand Height Adjustment Button : Release the button towards to lefthand side to adjust the height. After adjustment, lock it to fix the height.



MDS-3300 / MDS-3000 Camera Fixing and Movements Are Shown As Figure 3

1.4 Operation Before Examination

1.4.1 Adjust Camera Height

Adjust the height of the colposcope, remove camera cover and turn on the power switch off the camera.

1.4.2 Enter Software Interface

We give MDS-3300HD / MDS-3000's software as free for all customer, so system may enter image capture interface on PC easily. Observed dynamic image can be displayed by using this interface. It is better to get professional assistance from any computer company / technician in your area for the installation of software and transmitting the observed image from colposcope to PC. Thus the customer can use the software more activately.

1.4.3 Focusing

a.) Place the colposcope at a proper distance from the speculum (30 – 40 cm) , until the image on the monitor is clear (Note : When " AF / MF " zoom switch is in " AF " position, camera will automatically adjust the image clarity).

b.) When local lesion is to be observed, under " AF " mode, use " Wide " or " Tele " to magnify the part of the image to be observed and obtain the clear images of the endocervix or vaginal vault.

1.4.4 Image Freeze

(1) After selecting the optimal image observation effect, the operator should freeze the current image promptly. If the images of other positions are to be acquired, repeat the above operations. If not, advise the patient to leave the exam table.

(2) To active " freeze " function, press FREEZE key on the colposcope to freeze the current image. To unfreeze the image, press FREEZE key again to restore dynamic image. Then another patient or another lesion can be examined.

(3) When vessel image enhancement function is activated, in order to obtain a clear vascular image (angiography) and contraction function image of the cervix, observer may stabilize the cervix image and press " green " button. Now the light source turns green and the image turns dark blue. Observer can obtain clear vascular shape and contraction image under the green light source after red is filtered out.

Note :

Colposcope is used to observe the abnormal changes in the epithelium and vascular morphology of the lesion, so before examination stimulation and interference to the region to be examined. For example, within 24 hours before examination of the vagina or cervix, sexual intercourse, pelvic exam, local biopsy or treatment shall be avoided. For concurrent acute infection, such as trichomonal vaginitis, colpomycosis, first infection shall be controlled. And after local acute inflammation is cured, colposcopy can be done. In addition, to optimize the examination results, it is recommended to have a coloposcopy within 3 to 7 days after a period.

Note : If abnormal color is to be restored, press " white " key , then the image will return to the original color.

Special Alert :

1. Press " TELE " to magnify image, the larger the image, the smaller the depth of field. Auto focus has a special requirement on the distance between the camera and the object (only when the camera is distance around 25cm from the object, can satisfactory result be obtained).
2. The auto focus distance of the camera is within **30 to 40** cm.

1.5 Clinical Observation

1.5.1 Preperation

During colposcopy, patient should lie in a lithotomy position, lying down on the exam table, with knees bent and legs spread apart. In accordance with the height of the exam table, adjust the height of the floor stand and make it suitable for observation.

1.5.2 Speculum Placement

When placing the speculum, do not use any lubricant, such as liquid paraffin, soap water. If an elderly woman's vagina is dry, apply some normal saline or a little non-irritating lubricant. Select different speculum according to patient's age and size. If a patient is large, speculum with long and wide leaves should be used. It is recommended to use beak shape speculum as it provides a wide field of view which is convenient .for observation and surgical operation. If an elderly patient's vagina is atrophic, smaller speculum with shorter and narrower leaves should be used. When placing speculum, handle it gently, expose the cervix gradually, never insert speculum forcefully. Otherwise, it may easily get the cervix injured and result in bleeding and impact observation. Be very careful especially when placing speculum into patient with cervix cancer.

1.5.3 Direct Observation

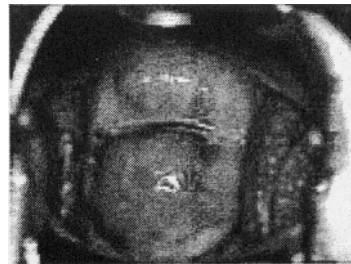
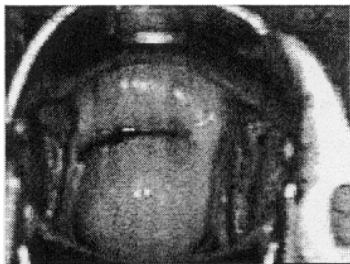
First adjust the focal length, then move the camera back and forth, until clear image is obtained on the monitor screen. Then adjust the image with " TELE " or " WIDE " to make sure the image is very clear and start observation. If cervical lesion is observed, gently wipe off the secretion on the surface of the cervix and in the vagina and then observe the lesion again. What to be paid attention to includes the size of the cervix, the size of the erosion area, and if there is any cervical mucosa eversion, or any abnormalities exist in the vessels and epithelium.

1.5.4 Detailed Observation

To further differentiate the squamous epithelium or columnar epithelium, and understand the vessel contraction reaction and judge the nature of the cervical lesion, sometimes, it is necessary to apply some drugs to enhance the image and facilitate the diagnosis. Commonly used methods are :

1.5.5 Acetic Acid Solution Test

3 % - 5 % acetic acid solution is most commonly used in colposcopy. After acetic acid is applied to the surface of the cervix, the colposcopy image will change rapidly mainly in the following aspects :



(1) After acetic acid is applied, the columnar epithelium rapidly becomes edematous and white, and presents typical "grape cluster" change. But squamous epithelium does not have such a change. Thus the squamous and columnar junction becomes very clear.

(2) After acetic acid is applied, squamous epithelium becomes white, especially the white patch area becomes prominent and white, with a clear-cut border from the surrounding normal squamous epithelium.

(3) After acetic acid is applied, vessels contract first and then dilate, stippling vessels and spiral vessels become very clear, but after several seconds, the vessels gradually become obscure.

(4) After acetic acid is applied, the squamous epithelium around the opening of the body of gland becomes white, presenting a crater form, which makes the opening easier to be recognized.

(5) After acetic acid is applied, no great changes take place in the image of true erosion, while in the pseudoerosion area, there is likely to be " grape cluster " change after acetic acid is applied. After acetic acid application, image shall be observed as soon as possible because the change will only last for several seconds. Although image can be observed again after acetic acid application, the results are not as good as that of the first time of acetic acid application.

(6) Recommended Time and Method of Acetic Acid Application

- a. First use speculum to expose the cervix, then observe the color, turbidity, and morphology of the secretion.
- b. Use a sterilized dry cotton ball to gently wipe out the mucus and observe the original cervix vessels, lesions and surface outline, color and if the border is clear and then
- c. Compare an original image with the image after acetic acid is applied.
- d. Press and hold a big cotton ball (diameter around 2cm or able to cover the cervix, see picture at left) soaked in acetic acid tightly on to the cervix and remove it after 30 seconds and start observation.
- e. Observe the epithelial morphology and color change. The color change will not happen until after 1 to 2 minutes.

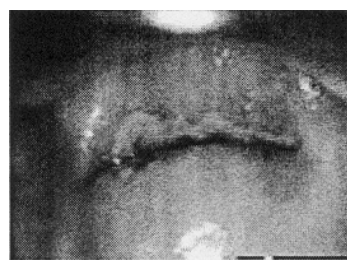
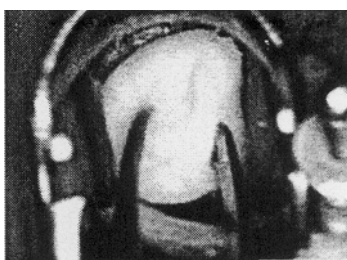
WARNING : After acetic acid is applied, if the observation period is too short, the color change will be missed, which may result in an erroneous diagnosis.

The reaction to acetic acid will disappear in 3 minutes. During image acquisition, it is recommended to take the image after the first or second application of acetic acid and compare the image with the original image. Too many times of application or too long an interval may affect the observation results.

Note : The changes in very small vessels or stippling vessels need to be observed through local magnification or under green filter.

1.5.6 Iodine Solution Test

After exposing the cervix with a speculum, use a sterilized cotton ball to gently wipe off the mucus on the surface. Then, use a small cotton ball soaked in iodine solution to evenly wipe the lesion and surrounding mucosa, and observe the pigmentation.



Observation Results : Pay attention to the lesion and its surrounding tissue pigmentation degree. The area with dark color, like dark brown or light brown is positive. The area without color change is negative. The squamous epithelium of normal cervix or vagina is rich of glycogen, so after iodine solution is applied, it will be pigmented in light or dark brown. The hue of the color depends on how much glycogen it contains. The columnar epithelium of normal cervix or lining columnar epithelium encased by the erosion surface generally do not become pigmented. When squamous epithelium has pathological change, such as atypical hyperplasia or epithelial cancerization, the glycogen content of the epithelium will obviously become less or short. Therefore, after iodine solution is applied, the lesion surface will not be pigmented or pigmented in very light color. In accordance with this principle, the lesion range is determined in clinical practice. Except for the above cases, women after menopause or very young girls, due to their low level of estrogenic hormone, thin epithelium, less content of glycogen in the cells, there can be without color change or very little color change. Therefore, iodine test is not a specific test for examining cancerization. Its clinical value is :

- (1) to distinguish normal squamous epithelium or epithelium without color change for biopsy.
- (2) to understand the range of the lesion, especially the region involved in early infiltrating cancer for providing reference for guiding surgical operation.

1.5.7 Trichloroacetic Acid Solution Test

General concentration of 40 % - 50 % of the solution is used, which has strong corrosion and fixation effect to tissues. Normal cervical or vaginal mucosa immediately turns white and thickens after trichloroacetic acid is applied but the surface is smooth. False condyloma latum (villous nympha) turns white after trichloroacetic acid is applied and the surface is obvious convex and rough. Pointed condyloma latum, after trichloroacetic acid application, immediately rise like thorns or sticks, which is easily distinguished from the normal mucosa. Trichloroacetic acid is effective in treating early pointed condyloma latum. After 2 or 3 days, the epithelium of the region where trichloroacetic acid is applied will come off. After one week, it can be applied again.

1.5.8 Reagent

During colposcopy, in order to differentiate squamous epithelium from columnar epithelium, and normal epithelium from inflammatory or malignant changes, very often 3% or 5% acetic acid and iodine solutions are used.

1.5.8.1 3 % or 5 % Acetic Acid Solution

Pure glacial acetic acid 3ml or 5ml Distilled water 97ml or 95ml Stored in well sealed brown glass bottle for use.

1.5.8.2 Iodine Solution

| | |
|------------------|--------|
| Iodine | 1 g |
| Potassium Iodide | 2 g |
| Distilled water | 100 ml |

After iodine and potassium iodide dissolve, store the solution in a brown bottle, and protect it from light and going degenerate. Generally new solution shall be made after 4 to 6 weeks.

1.5.8.3 40 % Trichloroacetic Acid

| | |
|---------------------------|-------|
| Pure trichloroacetic acid | 40 ml |
| Distilled water | 60 ml |

Trichloroacetic acid is mainly used for treating small lesion of pointed condyloma latum and the effect is even better for false condyloma lesion.

1.6 Technical Features Of MDS-3000HD / MDS-3300 :

The general system of technical features as follows ;

| Model | MDS-3300HD | MDS-3000 |
|------------------------------------------|-----------------------------------------------|-----------------------------------------------|
| Resolution | ¼ Super Had Color CCD 2.000.000 pixels | ¼ Super Had Color CCD 800.000 pixels |
| Horizontal Resolution | 1029 * 1080 pixels | 480 TV Lines |
| Image Output | YPbPr HDMI | 1 pc S-Video 2 pcs BNC |
| Working Output | 300 mm / 400 mm (Auto Zoom) | 300 mm / 400 mm (Auto Zoom) |
| Focusing Mode | Fast or Manual | Fast or Manual |
| Zooming | x 20 (Optical Zoom) x 6 (Digital Zoom) | x 26 (Optical Zoom) x 6 (Digital Zoom) |
| Magification Indicator | Yes | Yes |
| Light Source | Multipoint Circular LED Group | Multipoint Circular LED Group |
| Adjustable LED Light Source Group | Yes | Yes |
| Green Filter | CCD Electronic Green Filter | CCD Electronic Green Filter |
| Image Freeze | Control Panel | Control Panel |

Section 2 Maintenance and Trouble Shooting

2.1 Video Colposcope Cleaning

WARNING : Always turn the power switch off and unplug the power cord from the electrical outlet before cleaning.

The video colposcope housing can be wiped with a cloth dampened slightly with a mild soap water. Be careful not to allow liquid flow into the equipment. Also be careful not to allow the camera lens get wet.

CAUTION :

- * Do not attempt to sterilize any part of the equipment.
- * Do not attempt to immerse any part of the equipment in cleaning solutions.
- * There is no user serviceable parts in the equipment. Do not attempt to disassemble or repair the equipment.

2.2 Service

When any abnormality occur, shut off the power supply and inform our appointed contractor. Our service engineer or authorized dealer will visit you. More detail report of the abnormal phenomena, more help to our service. It will take shorten the service time. If it is caused by the fuse problem, the fuse 50T-T1.6AL 250V can be replaced under the instruction of service engineer. Two fuses are shipped with the unit as accessories. The same fuses can be purchased from the local market.

2.3 Service Responsibility

The video colposcope units MDS-3300HD / MDS-3000 are complicated electronic system. Except simple failure, for field service usually we or our authorized service contractor will be replaced the defective parts. We are not responsible for any failure caused by the service conducted by others.

2.4 Service Information

Please call for service, contact with. For service aid please also ask our authorized dealer in your country.



ALARIS Medikal ve Elektronik Sistemler Sanayi Ticaret

HQ Office :

Adres : 5748 Sokak No: 29 MTK Sitesi Çamdibi / İZMİR

Tel No. : 0.232.431 02 11

Faks No. : 0.232.431 02 33

www.alaris.com.tr

info@alaris.com.tr

Local Dealer / Distributor Information :

2.5 Trouble Shooting

| Phenomenon | Check Point | Solutions |
|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Camera does not work | <ol style="list-style-type: none"> 1. AC Power Socket 2. AC/DC Adapter 3. Related Wiring | <ol style="list-style-type: none"> 1. Re-connect the power cord and check if the power outlet has output. 2. Open interface box, measure the DC output. If none, replace AC/DC adapter. 3. If there is short or short circuit, rebuild the wiring. |
| Monitor does not power up | <ol style="list-style-type: none"> 1. Check the power cord connection 2. Check the video monitor power switch | <ol style="list-style-type: none"> 1. Check AC socket and the power cord connection. 2. Check if the power switch is ON. |
| No image or no color image on monitor screen. | S-Video Cable between colposcope camera and video monitor | <ol style="list-style-type: none"> 1. Check S-VIDEO connection. 2. Measure S-VIDEO cable to see if there is open or short circuit. |