The Choice for Precision and Accuracy ***TM***

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FMD User Guide

Contains Proprietary Information

Please Read Carefully

Before using the FMD device it is mandatory that you read and understand the entire **User Manual.** Falck Medical, Inc., makes no warranty, express or implied regarding the fitness or merchantability of any of the products for any application. As a condition of use, you freely assume and agree to use the products at your own risk, accept full responsibility for any injury that may occur and agree to indemnify and hold harmless Falck Medical, Inc., its directors, officers, employees, agents, licensees, successors and assigns from and against any and all damages, claims, costs, judgements, penalties and expenses of any kind.

CAUTION: US Federal Law restricts this device to sale by or on the order of a practitioner.

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Introduction

This document details the operation and clinical use of the Falck Medical, Inc., Multi-function Device (FMD_{TM}).

Operation and Indications for Use

The FMD is used as an accessory with the slit-lamp microscope. It attaches to a slit lamp microscope with the FMD pivot mount and the standard tonometer arm. It is designed for examination of the human eye.

The FMD device is used to measure Conventional Outflow Facility-Tonography. Perfusion Pressure-Ophthalmodynamometry, Intraocular Pressure, and Ocular Pulse Amplitude.

Contraindications

- Force application on eyes with a penetrating or perforating injury, ulceration, surgery, trauma and / or compromised blood flow should be avoided.

Brief Description of the Device

- The instrument takes serial measurements of intra-ocular pressure during systole and diastole.
- The device compensates for wetness, capillary and corneal elasticity forces.
- Recording digital tonography measures the outflow resistance of the trabecular meshwork (conventional outflow facility).
- Central Retinal Artery Force is measured.
- Before each measurement an automated self-check routine is completed.
- The single use disposable prism blocks transmission of infectious agents.
- User measurement error is reduced by using a microprocessor coupled optical system to measure applanation, indentation, pulsation, wetness and force.
- Multiple measurements are taken during each test and statistically analyzed for precision and accuracy.
- Measurement data can be saved to a USB flash stick.

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1.0 Safe Operation

1.1 Necessary Warnings / Precautions

WARNING: The disposable prism must be changed between each patient. The instruments will not allow a measurement to be taken on another patient without first changing the prism. The instrument will also not allow the user to alter the prism and use it on a different patient.

PRECAUTIONS

1. The prism must be disinfected before use. **See Section 7.1**
2. The prism is only to be handled by grasping the top and bottom of the longitudinal surface. This surface is grasped between the first and second digit. **See Figure 5**.
3. Do not touch the light emitting diode or the detector located on the internal surface of the prism holder.
4. An error message will be displayed if there is a failure in the self-check routine. If this should occur, refer to the error message list in **Section 5.0** and take the action listed.

1.2 Shipping, Storage and Operating Temperature, Pressure and Humidity.

The FMD device may be transported and stored in the original sealed packing material for a maximum of 26 weeks under the following conditions:

1. Storage ambient temperature range of + 10 to + 50 °C.
2. Storage Barometric pressure range 380 to 760 mmHg.
3. Storage in non-condensing relative humidity range of 10% to 75%.
4. Operating ambient temperature range of + 15 to + 35 ^{0} C.

Once the equipment arrives at the installation site, it should remain in the original packing material for four hours to prevent the formation of condensation. Before use the prisms must be stored at a minimum temperature of +20^{0} C.

1.3 Usage / Warnings

Only qualified, trained personnel who have studied this manual should operate the device. The device is not to be used for any other purpose other than its designated indications.

The FMD is a screening device and should not be used alone to assess the risk of disease.

Failure to use the instruments properly may result in a corneal abrasion. If the device is unintentionally dropped or the prism arm hit forcefully, it should be returned to the manufacturer for inspection and repair.

Touch screen input method is finger nail. Do not use sharp objects.
Repairs and upgrades to the device must only be performed by Falck Medical, Inc., or service technicians approved by Falck Medical, Inc. Falck Medical, Inc. will disclaim all liability for damage, loss and / or injury resulting from the unauthorized repair, improper use of, and/or the use of prisms not supplied by Falck Medical, Inc.

Do not open any of the enclosures. Do not open the power supply enclosure. Do not use any other power supply. Do not use any other power supply cord. Always keep the power supply outlet accessible. Unplug the power supply cord from the electrical outlet before moving or cleaning the equipment. Do not put anything other than a USB flash stick into the USB port on the Controller Display Unit.

Do not use the device in the presence of flammable agents. The device should be only be connected to an approved outlet. ***At the end of each workday turn off the power supply to the device.*** Unplug the device from the wall outlet when it is not being used for extended periods. ***Failure to observe these warnings can result in damage to the instrument and serious personal injury. When the FMD is mounted on a slit lamp microscope it should be left in place. Moving it from one slit lamp microscope to another slit lamp microscope can damage the connector cable and connector ports resulting in a" Communication Error" message.***

1.4 Maintenance

On a regular basis check the cables for a secure fit and for signs of wear. Replace worn or poorly fitting cables.

The case on the controller display unit and the tonometer body may be cleaned using a soft micro-fiber cloth. Unplug the unit before cleaning. Use only approved LCD cleaning pads for wiping the touch screen.

1.5 Regulatory and Statutory Specifications

The device and disposable prisms are designated as an FDA Class II medical device with specific indications for use.

1.6 Components

The following items are shipped from the manufacturer in the box:

1. Main FMD Device Body
2. Touch screen Controller Display Unit.
3. Interface communication cable to connect the FMD Main Body and Controller Display Unit.
4. Power Supply – 230/115 volts 50/60 HZ, IEC 60601.
5. Power Supply Cord, Three Prong, Hospital Grade, IEC 60320.
6. Prism Container.

2.0 Instrument Description

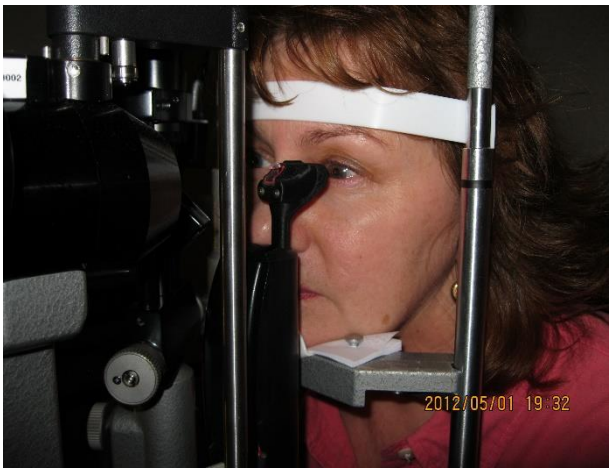


Figure 1 - Falck Medical Multi-Function Device (FMD).

Figure 2 – FMD Main Menu Touch Screen Display (CDU).

2.1 General information

The FMD Main Body connects to the CDU with the supplied cable using the ports labeled CON1. The 90-degree angle end plugs into the main body. The straight connector plugs into the CDU. ***Before plugging the straight connector into the CDU port be certain you have the correct connecter orientation. Forcing it in upside down will damage the port resulting in a "Communication Error".*** The medical grade transformer power output cord plugs into the power supply port on the CDU.

2.2 Slit-Lamp Microscope Mounting

For slit lamp microscope mounting, the FMD uses a pivot mount which attaches to the top of the slit-lamp. There are different pivot mounts for each slit lamp model. The standard tonometer arm attaches to the plate on the bottom of the main body.

The FMD sits on the pivot mount and is rotated into the measurement position in front of the left ocular from the right side. In this position, the prism applanation surface is viewed through the left ocular. On limited slit lamp models, alignment and viewing is through the right ocular. When not in use, it is rotated back to the rest position on the right side. See Figure 3.

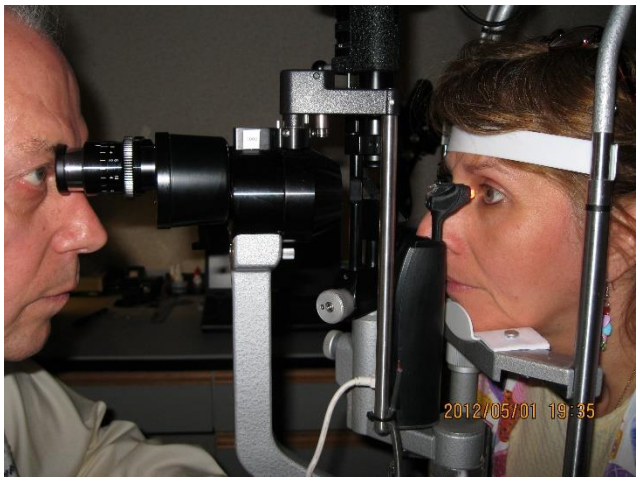


Figure 3 - Falck Medical Multi-Function Device ™
Slit Lamp Mounting

3.0 Instrument Operation

3.1 Measurement Overview

The Slit Lamp Microscope light is turned off before activating the device and for all measurements. The FMD optical prism is a single use disposable. The prism applanation surface is round and flat with a diameter of 6 mm. On the back side of the prism applanation surface is a cross-hair with a center circle. The cross-hair is used

for contact alignment with the cornea. Prism 'B' is used with the device to perform TNG, ODM, OPA, TEAR and IOP.

Figure 4 - Prism Cross Hair View

The prism is inserted into the prism holder by grasping the top and bottom longitudinal surface. ***Push the prism all the way in with one single motion.*** When properly seated the guide tab will protrude out of the back of the prism holder. To remove the prism press down and forward on the tab. Grasp the top and bottom surface and pull it straight out. ***Do not touch the applanation or optical surfaces.***

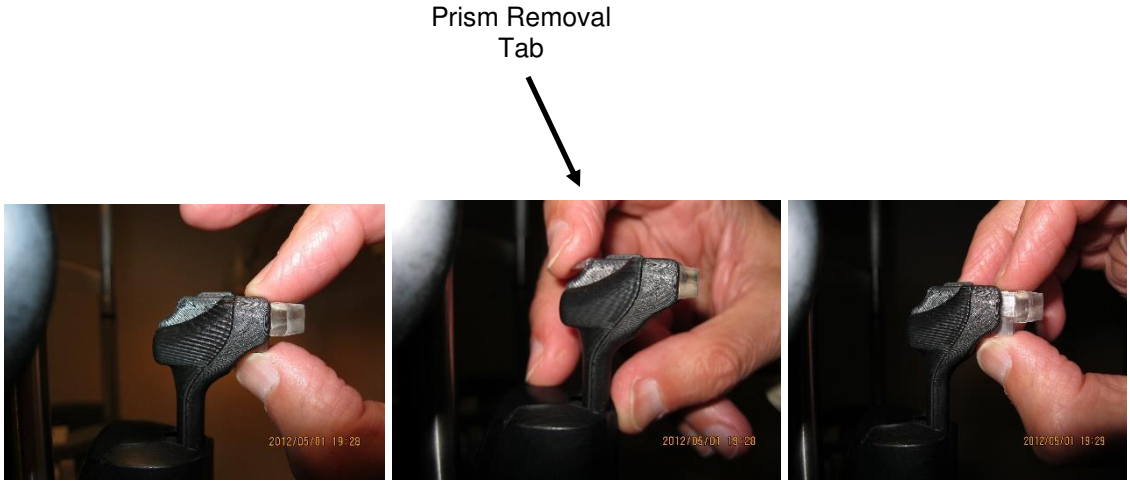


Figure 5 – Prism Insertion and Removal.

When the device is activated, the initial check is for prism replacement. The prism must be replaced before the device will allow a measurement on a different patient, or if more than 150 seconds has elapsed since the device has been used on the same patient. ***The background on the Controller Display Unit will appear red if the prism needs replacement. If the prism is not replaced and a measurement attempt is made, "Replace Prism" will appear. The background will turn blue once an acceptable unused prism has been inserted. This system eliminates the risk of infectious disease transmission.***

Do Not Reuse

Used prisms are to be treated as a biohazard and must be disposed of in accordance with local, state and federal regulations.

To perform a measurement, a drop of ***proparacaine*** or ***tetracaine*** is placed in the eye to anesthetize the cornea.

CAUTION: *Fluorescein or rose bengal or topical anesthetic agents containing fluorescein or rose bengal are not to be used. Their use will cause inaccurate measurements.*

To activate the device and display the main menu, touch the screen on the Controller Display Unit. With an unused prism "B" inserted the display will be blue and have the following active buttons:"TNG", "ODM", "TEAR" and "IOP ".

Intraocular Pressure / Ocular Pulse Amplitude:

Turn the slit lamp microscope light off before activating the device and during all measurements.

IOP is displayed with Tonography (TNG) and Ophthalmodynamometry (ODM). If multiple tests are to be performed on the same eye and you want to perform serial IOP as a separate measurement, do serial IOP first. Repeated applanation can decrease IOP. It is recommended to wait at least 5 minutes before repeating a measurement.

With some patients, it will not be possible to obtain an accurate measurement due to blepharospasm, movement, etc. If the measurement variation is greater than 10%, the variation is displayed in red. The measurement should be repeated. It is recommended that testing be abandoned after two failed attempts.

If the device is in sleep mode (dim screen), touch the center of the LCD screen. Select "IOP". The device will perform a self-check routine and when completed, the prism will glow red. The "OD" active button will be high-lighted. To select the left eye tap on "OS". If the device has **"AutoStart", "AutoStart Enabled"** will be displayed. Instruct the patient to blink several times. ***Adjust the ocular so that the applanation surface and crosshair of the prism are in focus***. Use the joy stick to place the prism in central contact with the cornea. ***Once contact is made, stop forward movement.*** When looking through the ocular, the contact area with the cornea will appear dark against the red background. Use the joystick to center the contact area in

the center of the crosshair. ***It is important to keep the contact area centered on the prism during the measurement process.*** On the touch screen the crosshair and center circle is also displayed. When contact with the cornea occurs, the center circle will appear green. Once you have contact stop moving the prism forward.

If the contact area is green but outside the center circle, the prism has been pushed in too far. Pull the prism off the eye, check alignment and proceed. If the contact area is red, the ocular surface is dry. Pull the prism off the eye, have the patient blink several times to wet the ocular surface and proceed. If the contact area is blue, the ocular surface is too wet for optical coupling. Remove the prism from the eye have the patient blink several times to clear the tears and proceed.

With "Autostart Enabled" displayed, the measurement automatically proceeds if central contact is maintained.

Without "Autostart Enabled", once central contact is present, tap on the touch Screen to initiate the measurement.

During the measurement process, serial samples of IOP during Systole and Diastole are obtained.

When the red prism light goes off, pull the slit lamp back away from the eye. The data is statistically analyzed and the results displayed.

If "***Check Patient / Prism Alignment***" is displayed, central corneal contact was lost. Check the patient for proper positioning and alignment. Provide the patient a fixation target to look at. Have the patient blink to clear the tears before the measurement. Select the test eye icon. Proceed with the measurement. Keep the prism in central contact with the cornea. See **Section 3.8** for sources of measurement errors.

IOP, OPA and % Variation results are displayed. ***If the measurement variation is greater than 10%, variation is displayed in red. To repeat the measurement, select the test eye icon.*** To save the data, insert a Micro-USB Flash Stick and select "***Save***". Select "***Edit ID".*** Enter a numeric file code. Select "***Ent***" and "***Save***" again. Data is saved in the numeric code file by date and time and can be transferred from the Micro-USB flash stick into an Excel file.

After two in-complete measurement attempts on the test eye, the device will default to the results screen.

If you want to change the test selection, select the "**Home"** icon.

Ophthalmodynamometry (ODM):

To perform an Ophthalmodynamometry measurement, on the main menu select "ODM". Enter the upright measured ***brachial*** systolic and diastolic blood pressure for

the right and left side using the plus / minus keys. ***Do not use a wrist cuff.*** After entering ***both*** blood pressures press the arrow on the bottom of the screen. Ask the patient to blink. When the prism glows red, use the joy stick to place it in central contact with the cornea. If "**Autostart Enabled"** is displayed the measurement is automatic if central cornea contact is maintained. If "**Autostart Enabled"** is not displayed, maintain central cornea contact and tap on the center of the touch screen to initiate a measurement. Mean arterial pressure (**MAP),** mean central retinal pressure (**MCRAP),** ocular pulse amplitude (**OPA**), and ocular perfusion pressure (**OPP)** results are displayed.

If "***Check Patient / Prism alignment***" is displayed central corneal contact was lost. Check patient positioning. Provide the patient a fixation target to look at. With the joy stick keep the prism in central contact with cornea. Have patient blink. Select the test eye icon. Proceed with measurement.

If "***Repeat – Verify Results"*** is displayed, select the test eye and proceed with remeasurement.

If the measurement variation is greater than 10%, the variation is displayed in red. To repeat the measurement, select the test eye icon and proceed.

To save the data to the Micro-USB flash stick, select "***Save***" and "***Edit ID"***. Enter a numeric file code. Select "***Ent"*** and "***Save".*** To test the opposite eye, select it at the bottom of the screen. To change the test election, select the "**HOME**" Icon.

After two in-complete measurement attempts on the test eye, the device will default to the results screen.

Tonography (TNG):

To perform a tonography measurement, on the main menu select "TNG". When the prism glows red, ask the patient to blink. The test eye is highlighted. Place the prism in central contact with the cornea. ***Use the joy stick to keep the contact area centered***. If "**Autostart Enabled"** is displayed and central cornea contact is maintained the measurement is automatic. If "**Autostart Enabled"** is not displayed, maintain central cornea contact and tap on the touch screen to initiate the measurement. When the red light goes off, remove the prism from contact with the cornea.

If "***Check Patient / Prism Alignment***" appears on the screen, central contact was lost. Check patient positioning. After making corrections repeat the test.

If "***Repeat - Verify Results"*** appears, repeat the test. ***After two in-complete measurement attempts on the test eye, the device will default to the results screen.***

Outflow Facility (C), Initial IOP (Po), Po / C and % Variation results are displayed.

To repeat the measurement on the test eye, select the test eye icon. To save the data to the USB flash stick, select "***Save***" and "***Edit id".*** Enter the numeric file code, select "***Ent***" and "***Save***". To measure the opposite eye, select it at the bottom of the screen.

After two in-complete measurement attempts on the test eye, the device will default to the results screen.

If you want to change the test selection, select the "**HOME**" Icon.

TEAR / WETNESS

Select "TEAR**"** on the main menu screen. After the Self Check routine is completed the prism will glow red. Ask the patient to blink several times. Place the prism in central contact with the cornea. ***Use the joy stick to keep the contact area centered.*** If "**Autostart Enabled"** is displayed and central cornea contact is maintained the Measurement is automatic. If "**Autostart Enabled"** is not displayed and central cornea contact is maintained tap on the touch screen to initiate a measurement. When the red light goes off, remove the prism from contact with the cornea.

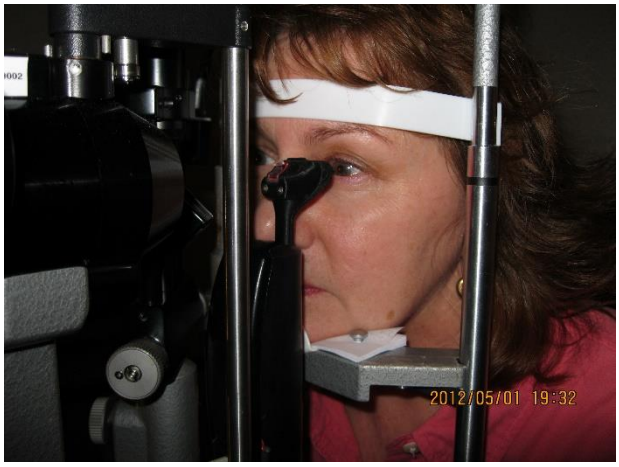
If ***"Check Patient / Prism Alignment"*** appears on the screen, central cornea contact was Lost. Check patient positioning. Make corrections and repeat the test.

The results are displayed as a color scale: red–dry eye, green–in range and blue-wet eye.

3.2 Patient Preparation

1. One drop of Tetracaine or Proparacaine is placed in both eyes. ***Do not use fluorescein or rose bengal or topical anesthetic agents containing fluorescein or rose bengal***. Fluorescein and / or rose bengal will interfere with the measurements.

2. ***The patients chin is comfortably placed down on and in the chin rest with the forehead firmly against the forehead rest. See Figure 6.***



Canthal Angle Mark

Figure 6 – Proper Patient Position.

3.3 Instrument Preparation

1. ***Turn off the microscope light. It will interfere with the measurement***. It is not needed.

2. Swing the slit-lamp illumination unit to the left. Rotate the FMD from the right into the measurement position located by a notch.

3. ***Look through the ocular and adjust it so that the prism applanation and cross hairs are in focus.***

3.4 Patient Instructions

1. ***The patient's head should be adjusted so that the lateral canthal angle is aligned at the same height as the black ring (canthal angle mark) on the chin and forehead rest vertical support bar. See Figure 6.***

2. ***The patient's head should be firmly against the forehead rest and the chin down and in the chin rest. Instruct the patient to keep the head in this position.***

3. Place the microscope fixation target in front of the opposite eye. Instruct the patient to focus on it. ***Steady fixation is important***.

4. ***Instruct the patient to blink twice just before the measurement and then keep both eyes wide open.*** It is helpful to tell the patient the measurement is brief. Instruct the patient to breathe normally. Breathe holding artificially raises eye pressure.

5. The lids maybe held open with the fingers. Do not press on the eye.

3.5 Intra-ocular Pressure/Ocular Pulse Amplitude, Tonometry

1. Touch the LCD screen.

2. Press "IOP" on the main menu screen. "IOP" and "OD" for the right eye is highlighted. To select the left eye press "OS".

3. ***When the red light comes on ask the patient to blink twice and then keep both eyes wide open***.

4. ***Remind the patient to keep the head firmly against the forehead and chin rest, to focus on the fixation target with the opposite eye and breathe normally***.

5. Move the slit lamp forward toward the test eye until contact with the cornea is made. Once contact is made, stop moving forward.

6. Look through the ocular. Use the joystick to place the contact area in the center of the prism crosshairs. The contact area appears dark against the bright red background. ***A small green circle will appear in the center of the cross hairs on the touch screen display.***

7. If "**Autostart Enabled "**is displayed and central cornea contact is maintained, the measurement is automatic. If "**Autostart Enabled"** is not displayed, tap on the touch screen. Do not look away from the ocular. Use the joy stick to keep the contact area centered. When the red light goes off, remove the prism from contact with the cornea.

8 Serial measurements of IOP during diastole and systole are captured, averaged and displayed. The variation of IOP during diastole and systole, the ocular pulse amplitude (OPA), is also displayed. This is a unique feature of the FMD and is the only device cleared at this time by the FDA to measure OPA.

9. ***Use the joy stick to keep the contact area centered in the cross hairs***. If central contact is lost "***Check Patient /Prism Alignment***" will appear in the display. Press the test eye icon and proceed from Step 3.

10. If "***Repeat - Verify Results***" appears the instrument will default to the test eye. Press the test eye icon and proceed from Step 3.

11. Measurement results on the test eye are numerically displayed for review. ***If the measurement variation is greater than 10%, the variation is displayed in red.*** To repeat the measurement, press the test eye icon and proceed from Step 3.To save a measurement result, insert a Micro-USB, press **"Save**" and **"Edit id**". Enter a numeric file code and press **"Ent**" and **"Save**". To measure the opposite eye, select it from the bottom of the screen and proceed from Step 3 above.

12. Measurement results from both eyes are numerically displayed for review.

13. The measurements maybe repeated at the discretion of the user by pressing "OD" or "OS" twice and proceeding from step 3 above.

14. Without further instruction, the instrument will go into "Sleep Mode" after 150 seconds.

3.6 Conventional Outflow Facility, Tonography

1. Touch the LCD screen.

2. Select "TNG" on the main menu screen. "TNG", "OD" will be highlighted. To measure the left eye, select "OS". Ask the patient to blink twice.

3. When the red light comes on place the prism surface in central contact with the cornea. ***Keep the area of contact centered within the crosshairs during the measurement using the joy stick. A green circle will appear in the display.***

4. If "**Autostart Enabled"** is displayed and central cornea contact is maintained, the measurement is automatic. If "**Autostart Enabled"** is not displayed, tap on the screen to initiate the measurement. When the red light goes off remove the prism from contact with the cornea.

5. If "***Check Patient / Prism Alignment or Repeat - Verify Results"*** is displayed, select the eye and proceed from Step 3.

6. ***If the test cannot be completed after two attempts, the device will default back to the results screen.***

7. Measurement results on the test eye are displayed numerically. ***If the measurement variation is greater than 10%, variation is displayed in red***. To repeat the measurement, press the test eye icon. To save a measurement, insert a Micro-USB, press "***Save"*** and "***Edit id*** ". Enter a numeric file code and press "***Ent***" and "***Save***". To measure the opposite eye, select it at the bottom of the screen.

8. Conventional outflow facility results for both eyes are numerically displayed for review.

9. Measurements maybe repeated by pressing "OD" or "OS" twice and proceeding from Step 3 above.

3.7 Ophthalmodynamometry Force Measurement

1. Touch the LCD screen.

2. Press "ODM" on the main menu screen. The screen will prompt for input of the right and left systolic and diastolic upright brachial (arm) blood pressure. ***Do not use a wrist cuff.*** Both sides must be entered. ***Do not use default BP data. Measure the BP right before testing.*** Input the data using the + / - display keys.

3. Press the arrow on the bottom of the screen. "ODM" and "OD" are highlighted. To select left eye press "OS". Ask the patient to blink twice. When the red light comes on place the prism surface in central contact with the cornea. If "***Autostart Enabled"*** is displayed and central cornea contact is maintained, the measurement is automatic. If " ***Autostart Enabled"*** is not displayed, and central cornea is maintained, tap on the center of the touch screen to initiate a measurement. ***Use the joy stick to maintain central contact.***

4. When the red light goes off remove prism from contact with cornea.

5. If "***Repeat - Check Patient / Prism Alignment***" is displayed press the ***test eye Icon*** and the device will default to the test eye. Check patient alignment. Repeat the test. If "***Repeat – Confirm Blood Pressure*****"** is displayed, re-measure and re-enter the correct blood pressure. Repeat the ODM measurement. If "***Repeat – Verify Results"*** is displayed, press the ***test eye Icon*** and repeat the test.

6. Results on the test eye are displayed numerically and graphically for review. ***If the measurement variation is greater than 10%, variation is displayed in red***. To repeat the measurement, press the test eye icon twice. To save a measurement, insert a Micro-USB, press "***Save***" and "***Edit id*** ". Enter a numeric code and press "***Ent***" and "***Save***" again. To measure the opposite eye, select it from the bottom of the screen and proceed from Step 3 above.

7. Results for both eyes are numerically and graphically displayed for review.

8. Measurements maybe repeated by pressing "OD" or "OS" twice and proceeding from Step 3 above.

3.8 Tear / Wetness

1. Place the anesthetic drop in the eye. Before proceeding wait for burning to subside.

2. Have the patient blink multiple times.

3. Touch the LCD Screen. Select Tear

4. When red light comes on place the prism in central cornea contact using the joy stick.

5. If **"Autostart Enabled"** is displayed and central cornea contact is maintained, the measurement is automatic. If "**Autostart Enabled"** is not displayed and central cornea contact is maintained, tap on the touch screen to initiate a measurement.

6. If "**Repeat-Check Patient/Prism Alignment**" is displayed, central cornea contact was lost. Select the test eye to repeat.

7. Completed test results are displayed as a color scale.

3.9 Sources of Measurement Error

1. Patient head not against chin and forehead rest. Not aligned with canthal angle mark.

2. Patient holding breathe during measurement. Common in patients with short thick neck or large chest.

3. Patient squeezing so that the prism is touching the eyelid.

4. Patient backing away from forehead or chin rest during measurement.

5. Patient moving forward toward prism during measurement.

6. Eye movement.

7. Eye blinking.

8. User pushing slit lamp to far forward after contact with cornea.

9. User pushing slit lamp forward into cornea during measurement.

10. Placing fluorescein or rose bengal in the eye.

11. Excessive tearing after topical anesthetic placed. Wait at least one minute before proceeding with a measurement. Ask patient to blink several times to clear the tears.

12. User not keeping contact area centered on prism face.

13. Artificial decrease in IOP due to repeated measurement.

14. Incorrect blood pressure data entered.

4.0 Data Display

4.1 Intraocular Pressure / Ocular Pulse Amplitude Data

IOP is higher during systole and lower during diastole. The amplitude varies with the cardiac cycle. The FMD measures the amplitude of the IOP variation (OPA). The FMD displays the mean IOP (systolic and diastolic IOP), % Variation , and the OPA. N is the number of serial IOP measurements obtained. The mean IOP represents the actual intraocular pressure. The serial measurement of IOP during systole and diastole is a unique feature of the FMD.

The Goldmann Applanation Tonometer (GAT) ***does not*** measure the Ocular Pulse Amplitude (OPA). The GAT only measures the diastolic IOP.

The FMD device compensates for wetness, capillary and corneal elasticity forces. The GAT ***does not*** compensate for wetness, capillary and corneal elasticity forces.

The GAT reading cannot be analyzed for repeatability and accuracy. It only obtains one subjective sample. The FMD captures serial samples which are analyzed for repeatability and accuracy.

For these reasons the FMD and GAT readings are not equivalent.

4.2 Conventional Outflow Facility (Tonography) Data

The underlying cause of glaucoma is impaired aqueous outflow Tonography is a measurement of aqueous humor outflow through the trabecular meshwork.

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If the outflow is not measured on one eye, or the outflow was not detectable, or the measurement was not completed, "***Outflow Not Detected"*** is displayed.

If resistance is increased, outflow is decreased. Decreased outflow results in

increased IOP. It is generally accepted that all forms of glaucoma except Normal Tension result from impaired outflow. Current medical and surgical treatment of glaucoma is directed at improving outflow to decrease IOP (See Reference 1). Displayed is the initial IOP-Po, % variation, outflow-C and Po/C.

The concept that increasing IOP may decrease aqueous humor production is called pseudo-facility. This may be a potential source of error in estimating outflow facility. However, the validity of the pseudo-facility concept has been questioned (See Reference 3, page 55).

Thin sclera (high myopia) may cause an underestimation and thick sclera (high hyperopia) may cause an overestimation of outflow facility (See Reference 3).

4.3 Ophthalmodynamometry

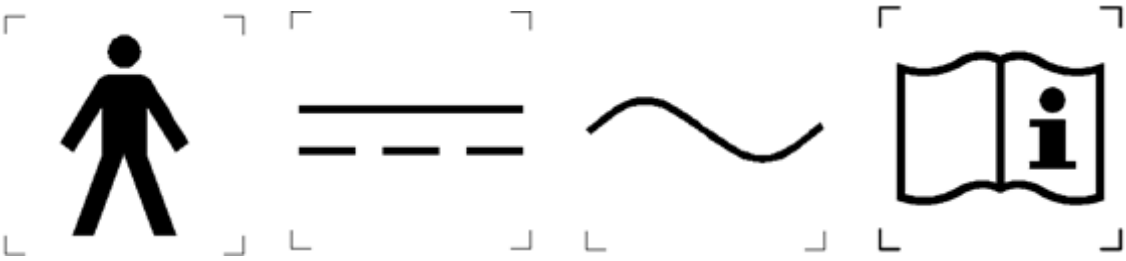
Displayed is the force in mmHg required to observe pulsation of the central retinal artery. Graphically displayed is the pulsatile change recorded by the optical detector. (See Reference 4). Also displayed is the ocular perfusion pressure (OPP). OPP is the net force that provides ocular blood flow.

5.0 Error Messages

Message	Action
Red CDU Background	Replace Prism.
Repeat - Check Patient / Prism Alignment. Repeat - Verify Results.	Loss of central prism contact. Check patient alignment. Increased tearing. Blink to clear tears. See Section 3.8 for sources of measurement errors.
Repeat – Confirm Blood Pressure	Re-measure and Re-enter correct blood pressure values. Do not use wrist cuff.
Replace Prism	Replace prism.
Communication Error	Check Connection Cable and Connection Ports.

Note: If the touch screen is not responding to input, follow the instructions in Section 7.3, Touch Screen Calibration.

6.0 Electrical Specifications



Input: 100-240Vac, 50/60 Hz, 28VA
Output: 7.5Vdc, 1.1 A
IEC 60601-1, 60601-1-2, 60950-1, Level B FCC CFR 47 Part 15, EN55011, 55022, 61000-6-3, 6100-3-2.

Input: Detachable Power Supply Cord, Male Plug 3 Conductor to C13 Female Connector, Hospital Grade, IEC 60320.

7.0 Appendices

7.1 Prism Disinfection:

1. Prism is supplied non-sterile and must be disinfected before use.
2. Read and Follow the Directions for Use and Warnings included with CIDEX OPA (Johnson and Johnson) to disinfect the prism.
3. Soak the prism in CIDEX OPA (Johnson&Johnson) for 12 minutes.
4. Rinse with three separate one-minute sterile water rinses.
5. Air dry.

7.2 Technical Specifications:

Light Source	LED
Prism Material	Clear Medical Grade Plastic
Force Unit	Linear Induction Motor
Case Material	High Impact Nylon Polymer
IOP Measurement Range	10 mmHg to 60mmHg
Display Unit	LCD

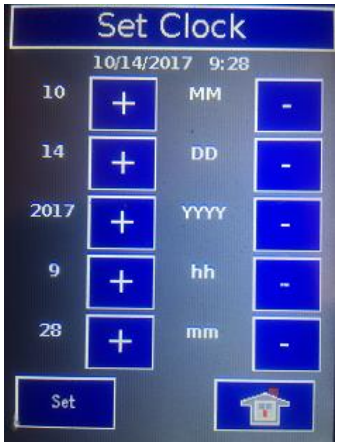
7.3 Touch Screen Calibration

1.0 Unplug the power supply from the wall.
2.0 Place your finger in the center of the Touch Screen and hold it there.
3.0 Plug power supply back into wall outlet.

4.0 Follow the on-screen prompts.

7.4 Setting the Date and Time

1.0 Go to the main menu screen and press the **"?" icon**.
2.0 Press the **"Clock" icon** located on the maintenance menu.
3.0 The screen image shown below will appear. Start by setting the Month - MM, Day-DD and Year-YYYY using the +/- keys. Next, set the time which uses a 24-hour format, 0 to 23 as the hour and 0 -59 as the minutes. The hour is represented as hh and minutes as mm. Once the desired date and time is entered press the **"SET"** key and the Real Time Clock is updated. The date and time settings are retained by the battery. Accurate date and time settings are necessary for record storage on the USB.
4.0 Press the **Home** key to return to the main menu.



7.5 Clinical Trials and Laboratory Studies

Clinical Tonometry Trial Summary:

In a clinical trial comparing the Falck Medical Applanation Tonometer to a reference Goldmann Applanation Tonometer for IOP measurement in 205 eyes, the following results were obtained:

- Average Mean Difference between Falck Applanation Tonometer and the Goldmann Applanation Tonometer: 0.7 mmHg, r^2=0.93, (9 to 56 mmHg).

- No statistical relationship found between Falck Applanation Tonometer readings and corneal curvature or thickness, $r^2 < 0.05$.

Manometric Study Summary:

In a comparative study of the Falck Medical Applanation Tonometer readings to a reference u-tube mercury manometer using human eye bank eyes, the following results were obtained:

- Average Coefficient of Variation: 2.6% +/- 0.10 (5 to 50mmHg).
- Average Standard Deviation: 0.7 mmHg +/- 0.4 (5 to 50mmHg).

Clinical Tonography Trial Summary:

In a clinical trial comparing the FAT1 to a reference indentation tonographer for the measurement of conventional outflow facility in 91 eyes from 91 subjects the following results were obtained:

- The mean conventional outflow facility (C) difference between the FAT1 and the reference Indentation Tonographer over a range of 0.01 to 0.70 ul/min/mmHg was 0.0043 ul/min/mmHg (95% CI, 0.001 to 0.0076), n= 182.
- Average FAT1 conventional outflow facility measurement in the glaucoma group was 0.09 +/- 0.05 and in the non-glaucoma group was 0.31 +/- 0.12 ul/min/mmHg, $p < 0.0001$, n = 182.
- Average FAT1 IOP measurement in the glaucoma group was 20.02 +/- 5.5 and in the non-glaucoma group was 18.6 +/- 2.4, $p = 0.01$, n = 182.
- In the High outflow facility group ($C \geq 0.18$) (non-glaucoma, 28/30 eyes) 93.3% of the paired differences were within +/- 1.96 standard deviations of the mean difference between the FAT1 and the reference Indentation Tonographer, n=60.
- In the Medium outflow facility group ($C > 0.09 < 0.18$) (glaucoma, 29/31 eyes) 95.2% of the paired differences were within +/- 1.96 standard deviations of the mean difference, n=62.
- In the Low outflow facility group ($C \leq 0.09$) (glaucoma, 30/30 eyes) 96.7% of the paired differences were within +/- 1.96 standard deviations of the mean difference, n=60.

Tonographic Laboratory Study Summary:

In a comparative tonographic laboratory study using freshly enucleated preserved eye bank eyes, the following results were obtained:

- For every 10 mmHg change in IOP average anterior chamber fluid volume change was 3.22 ul/minute, for a 20 mmHg change in IOP average anterior fluid volume

change was 7.027 ul/minute and for 30 mmHg change in IOP average anterior fluid volume change was 11.75 ul/minute, $r^2 = 0.99$.

- The correlation coefficient for volume decrease and corneal indentation was 0.999.
- The correlation coefficient for volume decrease and applanation diameter was 0.997.

Clinical Ophthalmodynamometry (ODM) Study Summary:

In a clinical trial involving 42 adult eyes where ipsi-lateral OPH force, brachial artery blood pressure and IOP were recorded, the following results were obtained:

- The average OPH estimated force was 59.73 +/- 11.10 mmHg.
- The Mean Brachial Artery Blood Pressure (MBAP) was 93.16 +/- 8.32 mmHg.
- The average IOP was 15.72 +/- 3.04 mmHg.

7.6 REFERENCES:

1. Epstein DL et al. Chandler and Grant's Glaucoma, Fourth Edition. Williams & Wilkins. 1999. pp 45-48, 183-198.
2. Drews RC. Manual of Tonography. CV Mosby.1971.
3. Becker-Shaffer's Diagnosis and Therapy of the Glaucomas. Sixth Edition. C. V. Mosby.1989. pp18, 41-55.
4. Kaufman PL et al. Adlers Physiology of the Eye. Tenth Edition. 2003. pp 764-767.

7.7 DEFINITIONS

Intraocular Pressure (IOP): Pressure inside the eye.

Tonography (TNG): Measurement of aqueous humor outflow.

Conventional Outflow Facility: Measure of trabecular meshwork resistance. IOP is directly related to resistance. Increased resistance, increased IOP. Decreased resistance, decreased IOP.

Ophthalmodynamometry (ODM): Force required to observe pulsation of the central retinal artery.

Ocular Pulse Amplitude (OPA): Variation of the IOP with the cardiac cycle.

Ocular Perfusion Pressure: Net force driving blood flow into the eye. (MCRAP – IOP)

Imbert-Fick Law: The pressure inside a thin dry walled sphere is equal to the force required to flatten a fixed area (Pressure = Force / Area).

Capillary Force: Force resulting from the adhesive, cohesive and surface tension of the tear layer acting on the flat applanation surface of the prism.

FMD Disposable Optical Prism System: Fixed use blocks transmission of infectious agents.

7.8 Glossary of Symbols


Type B Applied Part


Direct Current


Alternating Current


See Instructions


Do Not Reuse

Patents: US and Foreign Patents Issued and Pending.

For additional information please go to falckmedical.com or contact Falck Medical, Inc at 860-536-9000.

REVISION 1.1