ARTIST	REV	REASON FOR CHANGE	DATE
S. Greene		New	01/21/05
S. Greene	A	Text Changes	01/31/05
S. Greene	B	Text Changes	05/10/05
S. Greene	C	Text Changes	10/11/05

Alcon GLOBAL GRAPHICS

FILE NAME: 9000171-0805 Trav Pat Broch

ARTIST APPROVAL: CONCURRER:

PRINTING COLORS

CYAN MAGENTA YELLOW BLACK

08/30/04	

MDH APPROVAL:

Z00100B-

PKG/DATE: BEL 08/30/04

PKG/DATE: MHE 08/31/04

For questions or additional information, ask your eye care professional or call **1-800-333-8981.**

Alcon®

ALCON LABORATORIES, INC
Fort Worth, Texas 76134
www.alconlabs.com

TRAVATAN™ DOSING AID

©2005 Alcon, Inc. 1/05 9000171-0805 Printed in U.S.A.

TRAVATAN™ DOSING AID

Instructions

Alcon®

1. TEXT, COLOR & COATING AREA.
2. COLOR & COATING AREA, NO TEXT ALLOWED.
3. GUTTER AREA- NO TEXT ALLOWED

08/30/04

MDH APPROVAL:

Z00100B-

PKG/DATE: BEL 08/30/04

PKG/DATE: MHE 08/31/04

Welcome

The TRAVATAN™ dosing aid is designed to help remind you to take your TRAVATAN® Eye Drops and also help you put drops in your eyes. Please read the following instructions so you can become familiar with how it works.

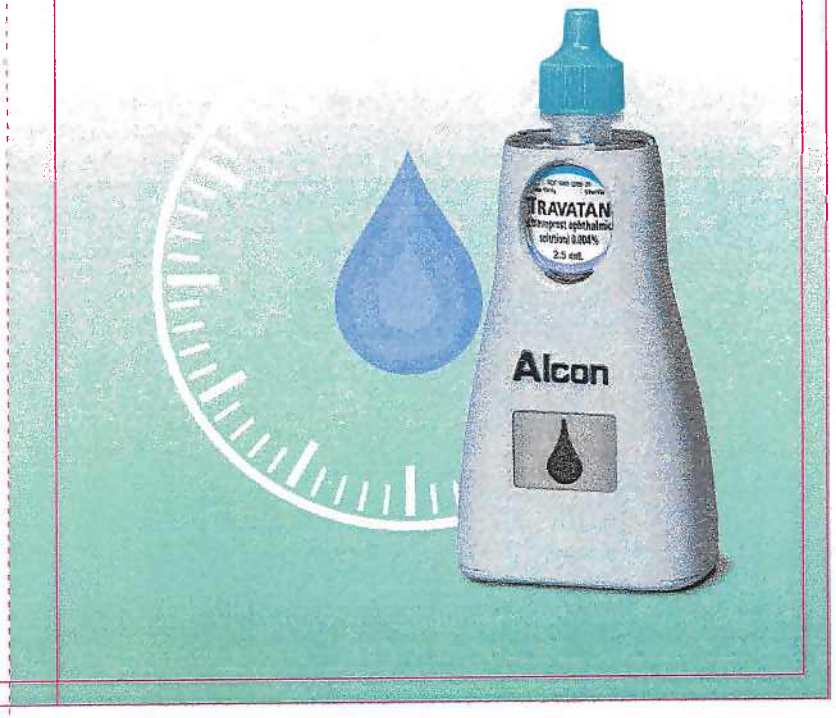
Your doctor has requested that you receive the TRAVATAN™ dosing aid, at no cost to you.

We hope you find it helpful and easy to use. Make sure you always bring it with you to your doctor visits. Please give your eye care professional any comments you may have.

Your eye care professional has already programmed the TRAVATAN™ dosing aid unit with your recommended dosing schedule. The rest is up to you.

Patient kit contains:

- TRAVATAN™ dosing aid
- Dosing aid instructions
- 2.5 mL and 5 mL medication bottle baskets
- Drop guider attachment



1. TEXT, COLOR & COATING AREA.
2. COLOR & COATING AREA, NO TEXT ALLOWED.
3 GUTTER AREA- NO TEXT ALLOWED

08/30/04

MDH APPROVAL:

Z00100B-

PKG/DATE: BEL 08/30/04

PKG/DATE: MHE 08/31/04

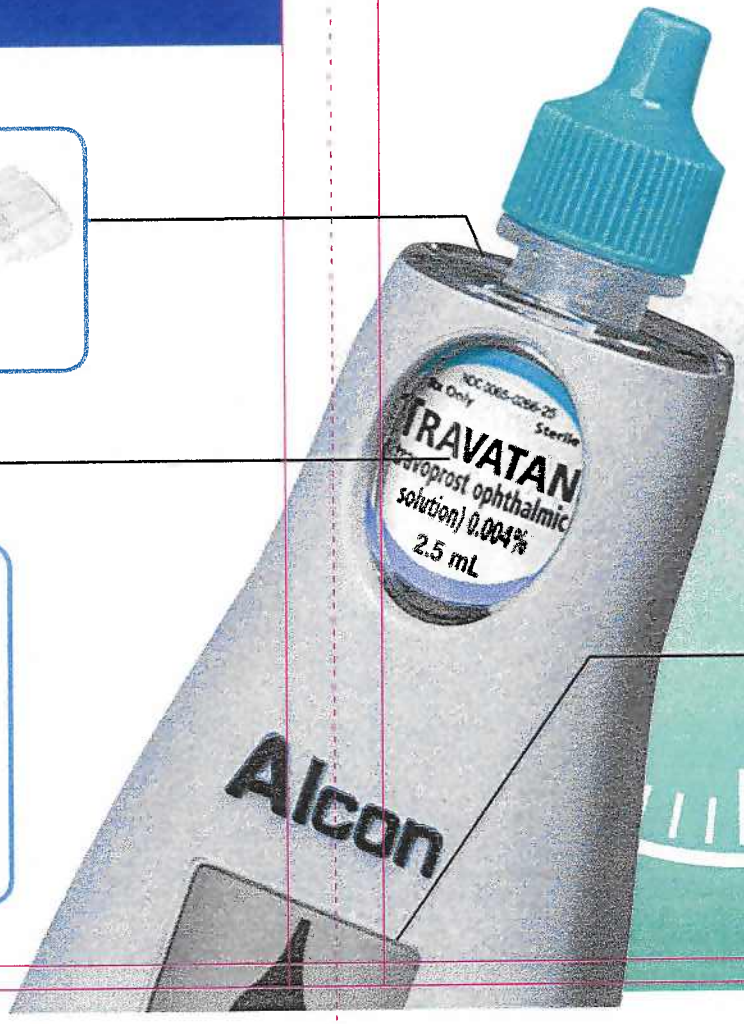
Your TRAVATAN™ dosing aid

- Medication bottle basket

- Bottle of TRAVATAN® (travoprost ophthalmic solution) 0.004%

  Medication is not included.

- Drop lever
- Battery compartment in rear



- Drop guider attachment

- LCD screen

1. TEXT, COLOR & COATING AREA.
2. COLOR & COATING AREA, NO TEXT ALLOWED.
3 GUTTER AREA- NO TEXT ALLOWED

08/30/04

MDH APPROVAL:

Z06100B-

PKG/DATE: BEL 08/30/04

PKG/DATE: MHE 08/31/04

Your TRAVATAN™ dosing aid can help remind you to take your TRAVATAN® Eye Drops

Reminder "flash"

You and your doctor will agree on a scheduled daily dosing time for your medication. Every day, a drop symbol (shown here) will appear on the LCD screen to remind you to take your medication. The drop will appear before your programmed dosing time, and will begin flashing at your dosing time. The drop will remain flashing for a period of time after your scheduled dosing time. Once you take your medication, the drop symbol will disappear until the following day.

Reminder "beep"

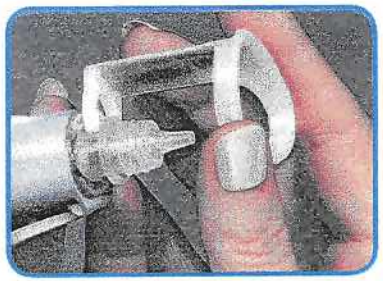
If your doctor has activated the audible reminder on your unit, 3 short beeps will sound at each of the following time-points: before your scheduled dosing time, at your dosing time, and after your dosing time. Once dosed, the reminder "beep" will remain off until the next day.

For example, if your dosing time is 9:00 PM, 3 short beeps will sound at 8:30 PM, again at 9:00 PM, and once again at 9:30 PM. Your doctor can modify this time window to meet your preferences.

Your TRAVATAN™ dosing aid can make it easier to take your drops

Optional drop guider

The drop guider can easily be snapped onto the TRAVATAN® Eye Drops bottleneck. Once attached, this can help you line up your dosing aid with your eye for simple, accurate dosing.



1. TEXT, COLOR & COATING AREA.
2. COLOR & COATING AREA, NO TEXT ALLOWED.
3. GUTTER AREA- NO TEXT ALLOWED

08/30/04

MDH APPROVAL:

Z001008-

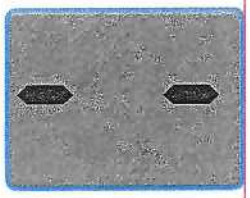
PKG/DATE: BEL 08/30/04

PKG/DATE: MHE 08/31/04

Important symbols on your TRAVATAN™ dosing aid LCD Screen

Sleep mode

This symbol on the LCD screen means that your TRAVATAN™ dosing aid is "resting." There is no need to dose at this time.

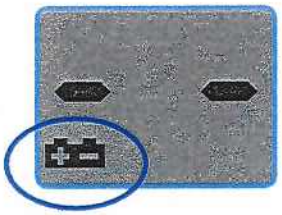


Dosing mode

When it is time for you to take your medicine, an eye drop symbol (shown here) will flash on the LCD screen. Once you take your medication, the symbol will disappear until the next day.

Low battery indicator

A low battery symbol (shown here) will be visible on the LCD screen when your battery needs to be replaced. When this appears, replace the battery in the unit with a new battery as quickly as possible.



Replacing the battery on your TRAVATAN™ dosing aid

- This unit requires a CR2032, 3-volt battery. The old battery should be removed and the new battery should be immediately inserted. When inserting, remove the back cover and place the battery in the unit with the writing side face up. If the battery completely dies, please return the unit to your eye care professional for reprogramming.

1. TEXT, COLOR & COATING AREA.
2. COLOR & COATING AREA, NO TEXT ALLOWED.
3 GUTTER AREA- NO TEXT ALLOWED

08/30/04

MDH APPROVAL:

Z00100B-

PKG/DATE: BEL 08/30/04

PKG/DATE: MHE 08/31/04

Instructions for use

Step 1: Loading your medication

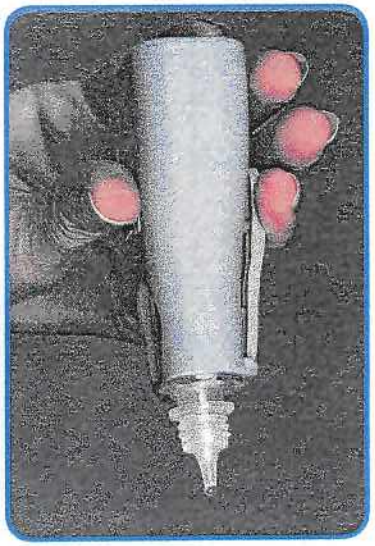
Before you administer the eye drops, wash your hands thoroughly with soap and water. The TRAVATAN™ dosing aid is designed to work only with TRAVATAN® Eye Drops. The TRAVATAN® bottle slides into the oval opening of a plastic basket. There are two baskets — one for the 2.5 mL TRAVATAN® Eye Drops and one for the 5 mL. The basket for the 2.5 mL is already in the unit. If you need to change the basket for the 5 mL size, remove the unwanted basket by gently using your thumb to press inward and up on the front oval-shaped window. Keep this basket in case you need it in the future. The new basket can then be inserted.

Step 2: Preparing for use

When it's time to take your medication, an eye drop symbol on the LCD screen will begin flashing. Pick up the unit and unscrew the cap. Place the cap on its side.

Step 3: Taking your drops

Invert the TRAVATAN™ dosing aid over your eye. Do not let the tip of the bottle touch your eye or the surrounding area because this could contaminate the solution. Fully depress the lever until one drop is dispensed, and release. Then check the LCD screen to ensure that the drop symbol has been replaced by sleep mode (--). If you keep the lever depressed for too long, the dosing aid will continue to dispense drops. Repeat for the other eye, if instructed by your physician. After dosing the second eye there will be no change in the LCD display. Replace the cap without touching the tip of the bottle or the inside of the cap.



1. TEXT, COLOR & COATING AREA.
2. COLOR & COATING AREA, NO TEXT ALLOWED.
3 GUTTER AREA- NO TEXT ALLOWED

08/30/04

MDH APPROVAL:

Z001008-

PKG/DATE: BEL 08/30/04

PKG/DATE: MHE 08/31/04

Replacing your medication

Pull the TRAVATAN® Eye Drops bottle straight up to remove it from the plastic basket and unit. Insert your new bottle as in Step 1. Be sure to push the bottle all the way down so that only the cap is exposed.

Cleaning

Your TRAVATAN™ dosing aid can be cleaned with a cloth lightly moistened with water and a nonabrasive cleaner on the outer casing. Wipe dry with another soft cloth. Never immerse the unit in liquid.

Frequently asked questions

Q: What if I miss a dose?

A: Return to your normal schedule the next day. The unit will not be affected in any way.

Q: Where should I keep my TRAVATAN™ dosing aid?

A: The unit is designed to be a pleasant reminder of your dosing schedule. Keep it where you normally dose your medicine and you can see and/or hear the reminders.

Q: Will other medications fit into my TRAVATAN™ dosing aid?

A: This unit is specifically designed to contain TRAVATAN® Eye Drops. Other medications should not be used with this dosing aid.

For questions or additional information, ask your eye care professional or call **1-800-333-8981.**

1. TEXT, COLOR & COATING AREA.
2. COLOR & COATING AREA, NO TEXT ALLOWED.
3. GUTTER AREA- NO TEXT ALLOWED

08/30/04

MDR APPROVAL:

Z00100B-

PKG/DATE: BEL 08/30/04

PKG/DATE: MHE 08/31/04

Manufacturer's Declaration and Guidance

The TRAVATAN™ Dosing Aid has been tested and complies with the international standard IEC 60601-1-2: 2001.

The TRAVATAN™ Dosing Aid does not contain RF transmitter.

- It uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment (e.g. TV).
- The Model TRAVATAN™ Dosing Aid is suitable for use in all establishments, including home environment.

The TRAVATAN™ Dosing Aid is also designed to be immune to electromagnetic disturbances.

- For protection against damage due to electrostatic discharge, if the floors are covered with synthetic material, relative humidity higher than 30% is preferred.
- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. The user of the TRAVATAN™ Dosing Aid can help prevent electromagnetic interference by maintaining a distance of 7 feet (2.2 m) between portable and mobile RF communications equipment (transmitters with a rated maximum output power up to 10 W). If abnormal performance is observed, additional measures may be necessary, such as re-orienting or moving the Model TRAVATAN™ Dosing Aid farther away from these transmitters.

The TRAVATAN™ Dosing Aid cradle complies with the international standard IEC 60601-1-1:2000. For its continued compliance, it should be connected to a computer that meets IEC 60950 or equivalent standard (e.g. UL 60950 in the U.S). Please refer to your computer's operators manual for its compliance with standard equivalent to IEC 60950.

1. TEXT, COLOR & COATING AREA.
2. COLOR & COATING AREA, NO TEXT ALLOWED.
3. GUTTER AREA- NO TEXT ALLOWED

TRAVATAN™ DOSING AID

Physician Instructions

TABLE OF CONTENTS

CRADLE AND SOFTWARE INSTALLATION 4
Cradle Installation *4*
Software Installation *4*
CREATING THE FIRST USER 6
LOGIN AND PASSWORDS 7
ADMINISTRATIVE FEATURES 7
Additional Users *7*
Updating Users *8*
Security Reports *8*
SETTING UP A NEW PATIENT 8
TRAVATAN™ DOSING AID PARAMETERS 9
RETRIEVING DATA 10
DISPLAYING DATA 11
Drop Log Report *11*
Calendar Report *12*
ACCESSING DATA OFF-LINE 14
UPDATE **TRAVATAN™ DOSING AID** ID 15
DATABASE MANAGEMENT 15
MANUFACTURER'S DECLARATION AND GUIDANCE 16

WELCOME

We hope you find the **TRAVATAN™ Dosing Aid** easy to use. The small cradle can fit just about anywhere in your office, as long as it is located near your computer. For any questions or concerns, contact your Alcon representative.

COMPUTER REQUIREMENTS

The minimum computer requirements needed to efficiently use the **TRAVATAN™ Dosing Aid** are

- Pentium II
- Windows® 2000 or Windows® XP*
- Available 9-pin serial port
- 10 MB of free disk space
- 256 MB of RAM
- Minimum 800 x 600 pixel display with 16 bit color
- Printer

CRADLE AND SOFTWARE INSTALLATION

CRADLE INSTALLATION

Turn the computer off and plug in the serial cable to a serial port on the back. Plug in the other end of the serial cable to the cradle. Ensure that the cable has all pins fully connected. Turn the computer back on.

If you do not have an available serial port, you may acquire a USB-to-serial adaptor to connect the serial cable through a USB port.

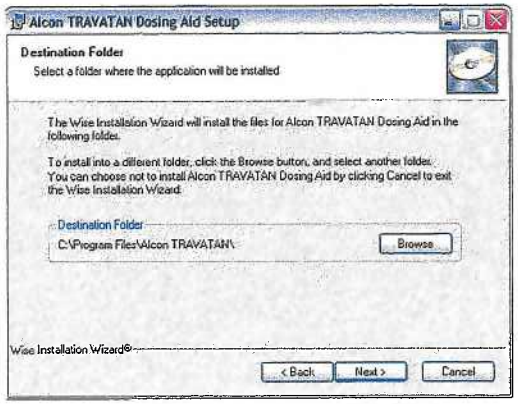
SOFTWARE INSTALLATION

Log in to a Windows® account that has administrative privileges. Place the **TRAVATAN™ Dosing Aid** Software Installation CD in the CD drive.

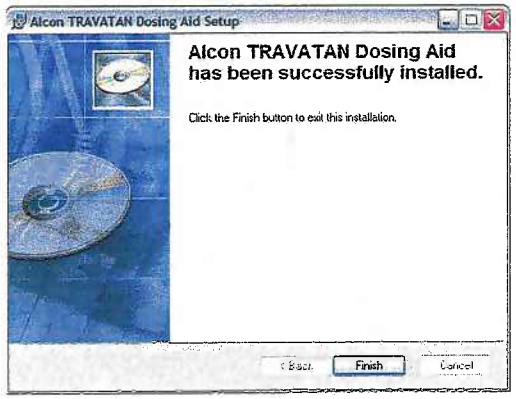
If the software does not automatically start, follow these steps:

- Double-click the "My Computer" icon and select the CD drive where the software is located.
- Double-click the "Travatan.exe" file.

Follow the directions on the screen.



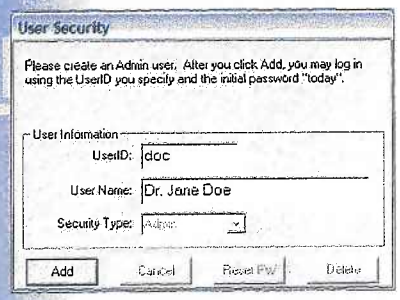
When the installation is complete, a message will indicate that the setup was successful.



CREATING THE FIRST USER

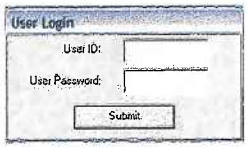
To begin, open the software by double-clicking the Alcon **TRAVATAN™ Dosing Aid** icon on the desktop. This will take you to a "User Security" screen. Type in a UserID and enter your name as the User Name. Click the Add button.

This first login you create will be the first Admin.



You will be reminded of your initial password and then you will see the User Login screen.

LOGIN AND PASSWORDS



Log in using your User ID. If this is your first login, you will be instructed to change the default password.

Please note: User Passwords ARE case sensitive, i.e., they remember upper and lower case letters. User IDs and User Passwords cannot exceed 10 characters.

After you log in, you may see an error saying that the software could not communicate with the cradle. If you would like to use the cradle, then make sure that the cradle is properly connected. Then go to > Settings > Program Settings. Select the serial port that the cradle is connected to and then click the Test Connection button. Follow the instructions.

ADMINISTRATIVE FEATURES

Admin users may access the following three features.

ADDITIONAL USERS

To create additional users, such as an assistant, select menu option > Security > Enter New User. Enter a new User ID and User Name and select a Security Type. Additional users are limited to the Security menu only, if necessary, to change their passwords.

For all new users, the default password is "today." To use a different User log in, you will need to exit the software and restart the program.

UPDATING USERS

To modify an existing user, go to > Security > Update User and select a user name. Click Select. On this screen you may modify the User ID, User Name and Security Type. There must always be at least one user with the Admin Security Type. Click Update to commit the changes or Cancel to continue without changes.

Use the "ResetPW" button to reset the user's password to "today."

Click Delete to remove the user from the **TRAVATAN™ Dosing Aid** system.

SECURITY REPORTS

To view an accounting of changes to user logins, changes to patient info and dosage data downloads, go to > Security > Security Reports.

SETTING UP A NEW PATIENT

Place the **TRAVATAN™ Dosing Aid** in the cradle, making sure it is secure and the cradle is properly attached to the PC.

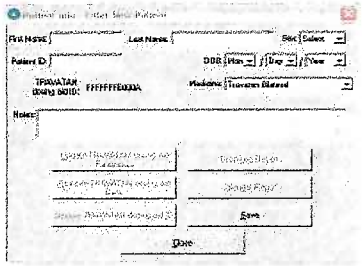
Ensure that the time set on your computer is correct. The **TRAVATAN™ Dosing Aid** will be set using the time from your PC.

From the Main screen, select > File > Connect to **TRAVATAN™ Dosing Aid**. You must enter the patient's first and last name. Entering the patient's sex, patient ID, DOB and notes is optional.

The medicine will be defaulted to TRAVATAN bilateral. It can be changed to TRAVATAN unilateral as needed. Once all data is entered, click "Save."

When finished, click "Close" to return to the Main screen.

When you use the "Connect to **TRAVATAN™ Dosing Aid**" feature, the **TRAVATAN™ Dosing Aid** unit's clock will be synchronized automatically with your PC clock.



Note: After placing a new unit in the cradle for the first time, all icons on the unit will flash continuously until you open the patient info screen, which sets the unit's clock.

Patients may also see the flashing icons if the battery is dead or improperly installed.To correct this, place the unit in the cradle and select > File > Connect to **TRAVATAN™ Dosing Aid**. If necessary, close the Patient Info screen and choose > Settings > Reset Factory Defaults.

TRAVATAN™ DOSING AID PARAMETERS

To change the default **TRAVATAN™ Dosing Aid** parameters, put a **TRAVATAN™ Dosing Aid** in the cradle and select > File > Connect to **TRAVATAN™ Dosing Aid**. The "Patient Info" screen will appear. Click on "Update **TRAVATAN™ Dosing Aid** Parameters."

This screen allows the user to change the **TRAVATAN™ Dosing Aid** parameters according to your preferences. *See screen print on next page.*

Enter the Dosage Time, which is the time that the user is expected to take his or her medication in 24-hour time, hours and minutes. You may only track one dose per day. **(The default is 21:00.)**

Enter the Visual Reminder Interval, which is the amount of time before and after the Dosage Time. A tear drop icon will display on the **TRAVATAN™ Dosing Aid** until a dose is taken. This also establishes the time period when a dose will be considered compliant. The parameter is entered in hours and minutes. **(The default is 3:00... 3 hours before the set dosage time and 3 hours after the set dosage time.)**

The **TRAVATAN™ Dosing Aid** features an audible reminder that is automatically activated by default. To disable the audible reminder, click (uncheck) the Audible Reminder Box. To change the interval of the audible reminder, enter the time interval before and after the dosage time for the audible reminder to sound if a dose has not been taken. **(The default is 00:30.)**

The audible reminder will sound 30 minutes before dosing time, at dosing time and 30 minutes after dosing time.

To save your changes, click the Update button. Click the "Exit" button to continue using the software.

RETRIEVING DATA

To retrieve the patient's dosage data from the **TRAVATAN™ Dosing Aid**, place the unit securely in the cradle and make sure the cradle is properly attached to the PC.

From the Main screen, select > File > Connect to **TRAVATAN™ Dosing Aid**. The "Patient Info" screen will display the information for this unit. Click "Retrieve **TRAVATAN™ Dosing Aid** Data." Once the data has been downloaded, the data is deleted from the unit.

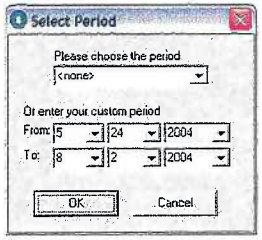
If you receive an error message, try to reseat the unit in the cradle and initiate the download again. After downloading, if there was data, a message will appear informing you that the data has been retrieved. Click "OK" to return to the "Patient Info" screen.

DISPLAYING DATA

There are two options for displaying **TRAVATAN™ Dosing Aid** data: the Drop Log Report and the Calendar Report.

DROP LOG REPORT

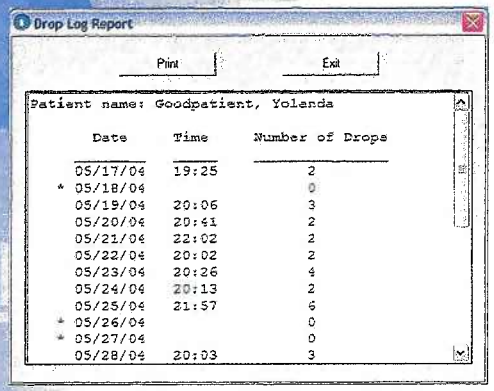
From the "Patient Info" screen, click on "Drop Log Report." The "Select Period" screen will display.



Whenever data is retrieved from the **TRAVATAN™ Dosing Aid**, the new time period is stored and added to the list. A drop-down menu will contain all of these stored time periods for the patient.

You can select one of the time periods or you can enter custom "From" and "To" dates. Only records that fall on or between these two dates will be retrieved. By default, the custom date range will select all available data for the patient, so you can simply click OK to view all the data.

Clicking "OK" will route the user to the "Drop Log Report" screen. Date, Time, and Number of Drops will be displayed. If the patient missed a day, a "0" will be shown for the number of drops on that day. Days on which the patient is noncompliant will be marked with an asterisk. *See screen print on next page.*



To print the report, select "Print." A printer dialog box will appear. Select the appropriate settings and click "Print."

CALENDAR REPORT

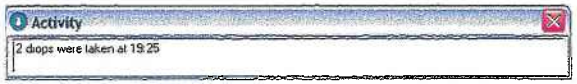
From the "Patient Info" screen, click "Calendar Report." The "Select Period" screen will display. Choose the time period desired as explained previously.

The "Calendar" option displays a monthly format with a numeric value in the upper left-hand corner of the day indicating the number of drops recorded for that day.

The number in the upper left corner will be blank if that day was not in the selected time period. The number will be blue if the patient was compliant. The number will be red if too few drops were recorded or if the drops were not taken during the proper time interval.

At the bottom of the "Calendar" screen, there are two calculated fields. The first field shows the number of noncompliant days in the report. The second field shows the percentage of days in the report which the patient was compliant.

To investigate a single day's activity, click on the day on the calendar, and an "Activity" screen is displayed, as shown below. Close the screen by clicking the ☒ in the upper right corner.

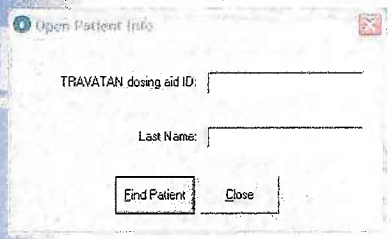


You can also print out the calendar report one month at a time. It will contain all the days and number of drops listed just as in the "Calendar" screen. Instead of showing the numbers in color, if the patient was compliant for that day, the word "Compliant" will be printed under the date.

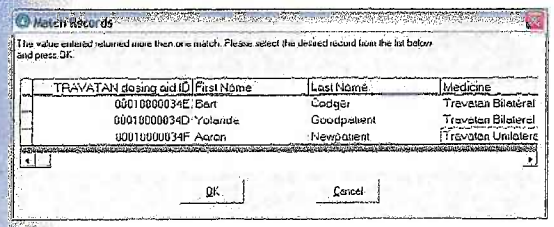
To print the report, select "Print." A printer dialog box will appear. Select the appropriate settings and click "Print."

ACCESSING DATA OFF-LINE

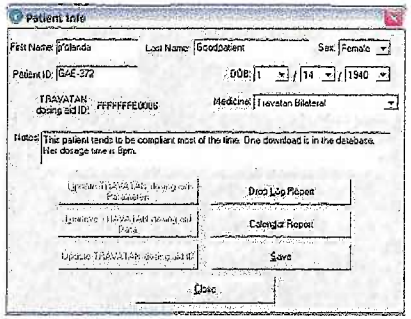
If you do not have access to the **TRAVATAN™ Dosing Aid** unit, you can still view a patient's existing information by selecting File > Open Patient Info Off-Line from the Main screen. The following screen will appear.



You can type in the **TRAVATAN™ Dosing Aid** ID or Patient Last Name, then click "Find Patient." If you don't enter any search criteria, then all patients will be listed. If the program finds a single patient matching the search criteria, the "Patient Info" screen will appear. Otherwise, all patients matching the criteria entered on the "Match Records" screen will be displayed.



Simply click on the patient and click "OK," or double-click that patient's name to bring up the "Patient Information" screen.



You may modify the patient data and click "Save" to save the changes. If you put the patient's **TRAVATAN™ Dosing Aid** in the cradle you may use the "Update TRAVATAN™ Dosing Aid Parameters" and the "Retrieve TRAVATAN™ Dosing Aid Data" buttons.

UPDATE TRAVATAN™ DOSING AID ID

To assign a new **TRAVATAN™ Dosing Aid** to a current Delivery Aid patient, open the "Patient Info" screen for this patient. Make sure the new **TRAVATAN™ Dosing Aid** is plugged into the cradle and that it is not already assigned to a patient. Select "Update TRAVATAN™ Dosing Aid ID" from the "Patient Info" screen. The patient's stored information will be updated using the new ID from the new unit.

DATABASE MANAGEMENT

All data is saved in a file located at "c:\Program Files\Alcon TRAVATAN™ Dosing Aid\alcon.mdb" if you use the default installation folder. Otherwise, you may search for the file "alcon.mdb." Make sure to back up this file regularly.

To move the cradle to a different computer, first complete the installation procedure on the new computer. Then copy the database file "alcon.mdb" from the old computer to the "Alcon TRAVATAN™ Dosing Aid" folder on the new computer. This procedure should be performed by a qualified system administrator.

Do not use databases on more than one computer at a time or patient data will be irretrievably split between the two.

MANUFACTURER'S DECLARATION AND GUIDANCE

The **TRAVATAN™ Dosing Aid** has been tested and complies with the international standard IEC 60601-1-2: 2001.

The **TRAVATAN™ Dosing Aid** does not contain RF transmitter.

- It uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment (e.g. TV).
- The Model **TRAVATAN™ Dosing Aid** is suitable for use in all establishments, including home environment.

The **TRAVATAN™ Dosing Aid** is also designed to be immune to electromagnetic disturbances.

- For protection against damage due to electrostatic discharge, if the floors are covered with synthetic material, relative humidity higher than 30% is preferred.
- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. The user of the **TRAVATAN™ Dosing Aid** can help prevent electromagnetic interference by maintaining a distance of 7 feet (2.2 m) between portable and mobile RF communications equipment (transmitters with a rated maximum output power up to 10 W). If abnormal performance is observed, additional measures may be necessary, such as re-orienting or moving the Model **TRAVATAN™ Dosing Aid** farther away from these transmitters.

The **TRAVATAN™ Dosing Aid** cradle complies with the international standard IEC 60601-1-1:2000. For its continued compliance, it should be connected to a computer that meets IEC 60950 or equivalent standard (e.g. UL 60950 in the U.S). Please refer to your computer's operators manual for its compliance with standard equivalent to IEC 60950.

NOTES

NOTES

NOTES

Once again, thank you

for including the

TRAVATAN™ Dosing Aid and

TRAVATAN® (travoprost ophthalmic solution) 0.004%

in your therapy regimen.

For help or assistance,

please call

(800) 695-1998

or contact your

Alcon Representative

Alcon®

ALCON LABORATORIES, INC.
Fort Worth, Texas 76134

www.alconlabs.com

©2005 Alcon, Inc. 08/05 9000170-0805 Printed in the U.S.A.
*Windows® 2000 and Windows® XP are registered trademarks of Microsoft Inc.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Linda Ng
1/23/2006 09:47:00 AM