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BIONIME

USER'S MANUAL MANUAL DEL USUARIO

Diabetes Management Software Software de gestión de la diabetes V1.2

Rightest[®]

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Introduction

The **Rightest**[®] Diabetes Management System is designed to help its users manage, view, and analyze blood glucose readings. It is intended for use by healthcare professionals as well as patients with diabetes.

The software included in the *Rightest*[®] Diabetes Management System features multiple user profiles. Each user must create a profile to login. Once logged in, users can import data from a *Rightest*[®] Blood Glucose Meter, view and analyze these blood glucose readings, and print blood glucose reports directly from the PC. Additionally, users can backup and recover profiles.

The *Rightest*[®] Diabetes Management Software is designed to help you pick out patterns in your blood glucose values. It will not provide a diagnosis or suggest treatment. Your healthcare provider may help you to find patterns and will help you make decisions about therapy based upon your blood glucose values. You should not make decisions about therapy without their help and approval. Changing your medicines without medical supervision may be dangerous.

Contents included in the *Rightest*[®] Diabetes Management System Kit:

- 1. Installation CD Setup files for the *Rightest* Diabetes Management Software and *Rightest* PC Link Adapter Driver (PL2303).
- 2. **Rightest**[®] Diabetes Management Software User's Manual.
- 3. *Rightest*[®] PC Link Device.
- 4. *Rightest*[®] PC Link Instruction.

Before installing the *Rightest*[®] Diabetes Management Software, please make sure your system meets the following requirements:

Microsoft Windows PC
CPU: 550 MHz Intel Pentium 3 or above
DRAM: 512 MB or more
HD: 600 MB or more
OS: Windows XP (SP3 or above), Windows Vista, or Windows 7
Internet Explorer 7.0 or above
USB 2.0 or above
LCD screen with resolution of 1024*768 or above, and 65536 colors or more
CD-ROM or DVD-ROM Drive
Mouse and Keyboard
Printer

Installation

To install the *Rightest*® Diabetes Management Software, please complete the following steps.

1. Turn on your PC.

2. Insert the *Rightest*[®] Diabetes Management Software Installation CD.

3. Double-click on 'My Computer'.

4. Find and double-click on your CD-Drive. By default, it should be labeled (D:) drive.

- 5. Double click on the "*Rightest*[®] DMS CD v1.2 ", and then double click on the "*Rightest*[®] DMS Setup v1.2.msi ". This will run *Rightest*[®] Diabetes Management Software Setup Wizard (shown on page 5). Follow the prompts to complete the installation. Once installation is complete, a shortcut named "*Rightest*[®] Diabetes Management Software" will appear on your desktop.
- 6. Apply the following steps ONLY when your PC Link Device which is a wired adapter, but NOT if the device uses Bluetooth technology: Go back to "My Computer" CD-Drive (D). Double click on "PL2303_Prolific_DriverInstaller_v1417.exe" setup file. This will install the *Rightest*[®] PC Link Adapter Driver (PL2303). Follow the prompts to complete the installation. No shortcut will appear on your desktop for "PL2303".
- 7. Find the "*Rightest*® Diabetes Management Software" shortcut created on your desktop, and double-click it each time you wish to use the *Rightest*® Diabetes Management Software.

Software Setur) Wizard				20
The installer will guide you Software on your compute		eps required to in	stall Rightest Diabe	tes Managemen	t
WARNING: This compute	er program is pro	tected by copyrig	ght law and internal	ional treaties.	اندىزە م
WARNING: This compute Unauthorized duplication or criminal penalties, and	or distribution of	this program, or	any portion of it, ma	ay result in sever	e civil



The screenshots in this User's Manual were taken from a PC using Windows 7. Appearance may vary slightly depending on the operating system of your PC.

Language Setting

After installation, when you launch the *Rightest*[®] Diabetes Management Software for the first time, you will be asked to select between two different language settings: English and Spanish. Select the language you need and click on "OK" to finish the setting.



If you clicked on "OK" without selecting any language, a pop-up screen will appear that says "Please Select Language". Click on "Yes" to return to the Language Setting.

Rightest DMS	23
Please Select Language. Favor de selecionar el idioma	
	No

// NOTE

If you have chosen an unfamiliar language and wish to select another, please uninstall the software (refer to "Un-installation" instructions on Page 29) and reinstall the software.

Creating User Profiles

The *Rightest*[®] Diabetes Management Software can be used by one or more users. To create a user profile, please complete the following steps.

After double-clicking on the *Rightest*[®] Diabetes Management Software shortcut, a welcome screen will appear.
 Click on "Add user" Add User to create your user profile. Enter your personal information, meal time schedule, and blood glucose information.

3. User Profile Settings: Enter your last name, first name, date of birth, and sex.

4. Daily Meal Time Setting: You can choose from different daily meal time slots. Make sure to set the Meal Times based on your normal daily eating schedule. This allows the data analysis to accurately track the blood glucose variation between each of your meals.

 • Before Bfast.: BEFORE BREAKFAST
 • Before L.: BEFORE LUNCH
 • Before Din.: BEFORE DINNER

 • After Bfast.: AFTER BREAKFAST
 • After L.: AFTER LUNCH
 • After Din.: AFTER DINNER

5. Blood Glucose Limits and Ranges Setting:

The choice of values for hyperglycemia and hypoglycemia is personal and you may want to consult your health care provider to help you decide. Many people with diabetes consider hyperglycemia to be values above 180 mg/dL. For tight blood glucose control, some consider a value of 140 or even lower. Hypoglycemia is generally values less than 70, but if you do not feel symptoms of hypoglycemia, you may want to select a higher value.

6. Click on "Next" ______ to finish and exit the profile setup.

7. Click on "Login" Login next to your user name to login.

Rightest DMS					
Welcome to	Rightest Diabetes Managen	nent Software. Plea	ase Select the l	Jser you want t	o Log In.
		Backup All	Recover	Add User	Exit
No. Last	name First name	Last update	Login	Delete	Backup
test DMS					
User profile	Last Name:				
Daily Meal Time Setting	First Name:				
+	First Name:				
BG Limits and Ranges	Birthday: 1/ 1/1950				
¥					
ОК	Sex: Male Female				
	Next	Cancel			
	140%	II. Cancor			

// NOTE

- 1. When entering your information, DO NOT leave any fields blank. You will not be able to proceed to the next step if a field is blank.
- 2. To ensure that all of your blood glucose readings from the meter appear in their respective meal time slots, it is extremely important that the meal schedule you entered matches your actual daily meal schedule.
- 3. According to the AACC (The American Association for Clinical Chemistry):
- Hyperglycemia is any value higher than 126mg/dL.
- The normal range for those without diabetes should have a blood glucose reading within 70~99 mg/dL.
- 4 Please discuss with a healthcare professional or physician on what values to enter for your blood glucose ranges and limits. For more information please visit :

http://www.labtestsonline.org/understanding/analytes/glucose/test.html

To connect the *Rightest*[®] Blood Glucose Meter to your PC, please refer to the attached "*Rightest*[®] PC Link Instruction ".

NOTE

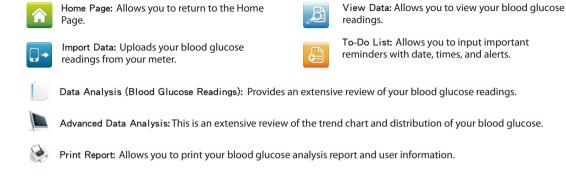
If your PC link device is a wired adapter, before connecting the meter to your PC, please make sure the *Rightest* PC link adapter driver (PL2303) is installed. If not, please refer to the "instructions" (on Page 4) to install the driver. If the device is a Bluetooth PC Link, please make sure the connection between the Bluetooth PC Link and PC is established.

Main Features

Main Features

Once you log in, the "Home Page" (pictured below) will appear on your screen. The home page will display your 10 latest blood glucose readings and your To-Do List (with the 5 most recent "To-Dos"). It will also display icons for all of the main features. The following are descriptions of each main feature.





User Settings: Allows you to change your profile information.



💽 🖂 : This allows you to access BIONIME's services via the web or email.

Phelp: This goes directly to the online user manual.

Importing Data

Importing Data

All blood glucose readings from your meter, including the date and time of the readings, will be transferred to your PC. During or after the data transfer, your readings cannot be altered or deleted. To import data, please complete the following steps.

1. Click on "Import Data" 🖵 to start transferring the data.

- 2. While data transfer is in progress, you should see its percentage of completion.
- 3. Once transfer is complete (shown on page 15), a pop-up screen will appear that says "Import success. Total (# of data)".
- Click "OK" to close the pop-up screen.
- 4. Click on "Close" Close to finish and exit.

ΝΟΤΕ

To import your data successfully, the symbol "PcL" needs to appear on the meter's screen BEFORE you click "Import Data". If "PcL" is not showing up on the screen, please refer to the attached "**Rightest**® PC Link Instruction".

11/30/2012 1:36:00 PM	148			Notes
11/20/2012 2.40.00 014	140	After L.	-	
11/30/2012 3:49:00 PM	98	After L.	-	
12/4/2012 10:38:00 AM	111	After Bfast.	-	
12/4/2012 6:18:00 PM	97	Before Din.	-	
12/7/2012 10:54:00 AM	109	After Bfast.	•	
12/10/2012 11:36:00 AM	134	Before L.	•	
12/11/2012 8:44:00 AM	100	Before Bfast.	•	
12/13/2012 6:11:00 PM	101	Before Din.	•	
1	12/7/2012 10:54:00 AM 12/10/2012 11:36:00 AM 12/11/2012 8:44:00 AM 12/13/2012 6:11:00 PM on Test Result. was tested outside of the norma	12/7/2012 10:54:00 AM 109 12/10/2012 11:36:00 AM 134 12/11/2012 8:44:00 AM 100 12/13/2012 6:11:00 PM 101	12/7/2012 10:54:00 AM 109 After Bfast. 12/10/2012 11:36:00 AM 134 Before L. 12/11/2012 8:44:00 AM 100 Before Bfast. 12/13/2012 6:11:00 PM 101 Before Din.	12/7/2012 10:54:00 AM 109 After Bfast. • 12/10/2012 11:36:00 AM 134 Before L. • 12/11/2012 8:44:00 AM 100 Before Bfast. • 12/13/2012 6:11:00 PM 101 Before Din. • on Test Result. was tested outside of the normal temperature range. •

Viewing Your Data

Viewing Your Data

The **Rightest**[®] Diabetes Management Software allows you to review your blood glucose readings for the previous 90 days. The data table and trend chart will be displayed on the Home Page.

The data table will provide measurement dates, time stamps, and meal times. You can choose from six different preset time periods to view your data.

On the trend chart, there will be two lines that represent the hyperglycemia and hypoglycemia limits. The normal blood glucose range lies between these two values. The limits and range can help you better understand your blood glucose readings. To view your data, please complete the following steps.

Click on "View Data" 2. The software will automatically display blood glucose readings from the 30-day time period.
 You may select a different preset time period, located to the left of the data table.

1 Day	No.	Date/Time	Blood glucose	Before/after meal	*		- Blood Glucose - Hyperalycemia Value - Hypoglycemia Value
	1	12/7/2012 10:54:00 AM	109 mg/dL	After Bfast.		(Jb/gi	10 The second se
7 Days	2	12/10/2012 11:36:00 AM	134 mg/dL	Before L.		5	8
11.0	3	12/11/2012 8:44:00 AM	100 mg/dL	Before Bfast.	Ξ	ding	
14 Days	4	12/13/2012 6:11:00 PM	101 mg/dL	Before Din.		Rea 1	
30 Days	5	12/17/2012 2:58:00 PM	107 mg/dL	After L.		80	
	6	12/17/2012 5:39:00 PM	98 mg/dL	Before Din.		Gluo	•
60 Days	7	12/18/2012 6:05:00 PM	101 mg/dL	Before Din.		D DO	
	8	1/8/2013 5:19:00 PM	97 mg/dL	Before Din.		B	12/05 12/12 12/19 12/26 01/02 01/09 01/16 01/23 01/30 02/06 02/13 02/20 02/27
90 Days	9	1/16/2013 11:03:00 AM	120 mg/dL	After Bfast.	-		Date (M/D)

\square	1. Click on 🔎 to enlarge the trend chart. To exit zoom view, simply close the window.
G	2. Make sure to consult with a healthcare professional or your physician before entering the hyperglycemia and
	hypoglycemia limits, as well as the normal blood glucose range.
	3. On the Trend Chart:
	The gray area in between the limits indicates the normal blood glucose range.
	- The purple line is the hyperglycemia value.
	- The blue line is the hypoglycemia value.

If you move your mouse cursor over the Trending Line, you can see your Blood Glucose Readings.

Data Analysis (Blood Glucose Readings)

Click on the "Blood Glucose Readings" icon to view and analyze your blood glucose readings.

Instructions for Data Analysis:

- 1. You can choose from seven different time periods: 1 day, 7 days, 14 days, 21 days, 30 days, 60 days, or 90 days. You may also enter a customized time period.
- 2. You can choose from nine different meal times: Before/After Breakfast, Before/After Lunch, Before/After Dinner, Before/After Meal, or View All Data.
- 3. Your blood glucose readings will be represented by different colors:
- [Red] This blood glucose reading is higher than the hyperglycemia value
- [Orange] This blood glucose reading is considered to be a high outlier
- [Green] This blood glucose reading is within the normal range
- [Blue] This blood glucose reading is considered to be a low outlier
- **[Indigo]** This blood glucose reading is lower than the hypoglycemia value
- [White] An ERROR has occurred in the data
- 4. The software has five different methods to view your data with statistical analysis: View All Data, Total Analysis Data, Average Value, Standard Deviation, and Coefficient of Variation. In the table, you can view the percentage of each blood glucose reading.
- 5. When analyzing your data, you can select particular readings to view. Keep in mind that unselected readings will be excluded from ALL calculations and reports in Data Analysis and Advanced Data Analysis.

Customias	Refore/:	after meal		Hyperglycemia Value	0	0.0 %	All Data	33
Customize				High Outlier	13	86.7 %	Data to be analysed	15
From: 12/	5/2012 💽 🗸 🔍		st. 🔿 After Bfast.	Normal Value	2	13.3 %	Data excluded	0
_		re Meal 🔘 Before L.	O After L.	Low Outlier	0	0.0 %	Average	119.5mg/d
To: 3/	4/2013 📑 🔿 Afte	r Meal 💿 Before Din	. 🔘 After Din.	📕 🗹 Hypoglycemia Value	0	0.0 %	Standard deviation	21.87
				Erroneous data	18		Coefficient of variation	0.18
				Any Data with Errors will NOT be a	nalyzed.	You	can Select specific Data th	at you want to anal
No.	Date/Time	Blood glucose	Before/After mea	1	Note	es		Analysis 🔽
	12/7/2012 10:54:00 AM	109 mg/dL	After Bfast.					V
2	12/10/2012 11:36:00 AM	134 mg/dL	Before L.					V
3	12/11/2012 8:44:00 AM	100 mg/dL	Before Bfast.					
4	12/13/2012 6:11:00 PM	101 mg/dL	Before Din.					
5	12/17/2012 2:58:00 PM	107 mg/dL	After L.					
6	12/17/2012 5:39:00 PM	98 mg/dL	Before Din.					
7	12/18/2012 6:05:00 PM	101 mg/dL	Before Din.					
8	1/8/2013 5:19:00 PM	97 mg/dL	Before Din.					
9	1/16/2013 11:03:00 AM	120 mg/dL	After Bfast.					
10	2/1/2013 2:02:00 PM	142 mg/dL	After L.					
11	2/4/2013 4:14:00 PM	108 mg/dL	After L.					
12	2/25/2013 9:28:00 AM	151 mg/dL	After Bfast.					
13	2/26/2013 9:02:00 AM	174 mg/dL	After Bfast.					
14	2/27/2013 9:54:00 AM	124 mg/dL	After Bfast.					V
15	3/4/2013 2:24:00 PM	126 mg/dL	After L.					



Data in the meter with an ERROR will be transferred to the database, but will be excluded from all calculations and analysis.

Advanced Data Analysis

Click on the "Advanced Data Analysis" icon 🐚 to view the Advanced Data Analysis Report. Select either "Trend Chart" or "Distribution of Blood Glucose Readings".

Instructions for Blood Glucose Trend Chart:

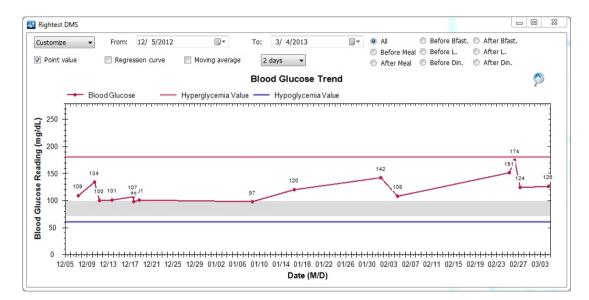
- 1. You can view data based on different time periods: 1 day, 7 days, 14 days, 21 days, 30 days, 60 days, and 90 days. You can also input a customized time period.
- 2. You can view data based on different meal times: Before/After Breakfast, Before/After Lunch, Before/After Dinner, Before/After Meal, or View All Data.
- 3. The trend chart can display either a regression curve or a move average line. The regression curve lets you see the longterm patterns of the selected time period. The move average line allows you to view short-term changes within the selected time period.

// NOTE

- 1. You can uncheck "Point Value" from your readings if you do not wish them to be displayed. If so, only the minimum and maximum point values will be shown. When you move your mouse cursor along the trend line, it will show the date, time, and point value of that particular reading.
- 2. If you only select one day to view your readings, then the regression curve and moving average line will NOT be displayed.
- 3. Click on 🔎 to enlarge the trend chart. To exit zoom view, simply close the window.

4. On the trend chart:

- The gray area in between the limits indicates the normal blood glucose range.
- The purple line is the hyperglycemia value.
- The blue line is hypoglycemia value.

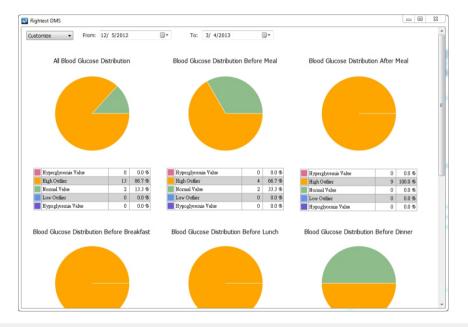


Advanced Data Analysis (continued)

The **Rightest**[®] Diabetes Management Software allows you to view your blood glucose readings in different formats, including pie chart. However, the percentage of each blood glucose reading is not available in the pie chart.

Instructions for Pie Chart:

- 1. You can display certain blood glucose readings by selecting the different time periods: 1 day, 7 days, 14 days, 21 days,
- 30 days, 60 days, or 90 days. You may also input a customized time period.
- 2. In the pie chart, your blood glucose readings will be represented by different colors. The following is a COLOR KEY for the values.
- [Red] The blood glucose reading is higher than the hyperglycemia value.
- [Orange] The blood glucose reading is considered to be a high outlier.
- [Green] The blood glucose reading is within the normal range.
- [Blue] The blood glucose reading is considered to be a low outlier.
- Indigo] The blood glucose reading is lower than the hypoglycemia value.



NOTE Any errors within the data will NOT be included in the pie chart.

Printing Reports

The *Rightest*[®] Diabetes Management Software allows you to print your blood glucose readings and reports.

Printing Steps:

Click on "Print Report" to enter the printing settings.
 Select the desired time period for the readings and reports you wish to print.
 You can click on 'Advanced Print' for more options.

After you log in, you can update or change your user profile information using the following step:

1. Click on "User Settings" 👗 to access your user profile.

You can modify your personal information (except name), meal time schedules, and blood glucose limits and ranges.
 Click on "Save and Close" Save and Close to save your settings.

NOTE

- 1. It is important that the meal time schedule you set up in the *Rightest*® Diabetes Management Software is the same as your daily meal schedules.
- If any fields are left blank or entered incorrectly, the software will not allow you to continue. If you are unsure, click "Recommended Setting".
- 3. According to the AACC (The American Association for Clinical Chemistry), the suggested hyperglycemia maximum is any reading higher than 126mg/dL, and the normal blood glucose range is any reading within 70~99 mg/dL.
- 4. Be sure to consult with a healthcare professional or your physician BEFORE entering in your blood glucose limits and ranges. For more information please visit:
- http://www.labtestsonline.org/understanding/analytes/glucose/test.htm

NOTE

- 1. If you wish to print the regression curve and the moving average line, use the "Advanced Print" function.
- 2. If you select data from one specific day, the regression curve and the moving average line in the trend chart will NOT be available for printing.

Backup and Recovery

. 0 .

You can back up one or more user profiles at the welcome screen before you login. To backup and recover, please complete the following steps.

Backup Steps:

1. Click on "Backup" Backup to backup your individual user profile, or click on "Backup All" Backup All to backup all user profiles.

2. Select the folder you wish to save the backup in.

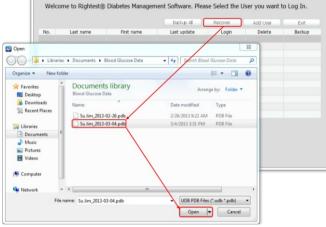
3. Click on "OK" OK to finish backing up.

			Backup All	Recover	Add User	Exit
0.	Last name	First name	Last update	Login	Delete	Backup
1	Su	Jim	2/26/2013	Login	Delete	Backup
Brows	e For Folder		22		-	
		/				
		/				
	P Favorites	/				
	🗽 Links		1			
	🗽 Links					
	 Links My Documents 		E			
	 Links My Documents Application Blood Glucos 		-			
	Links Difference My Documents Difference Dif					
	 Links My Documents Application Blood Glucos 		E			

Recovery Steps:

Click on "Recover" Recover to retrieve your previously saved data.
 Select the file you wish to recover.
 Click on "Open" Open to finish the recover.



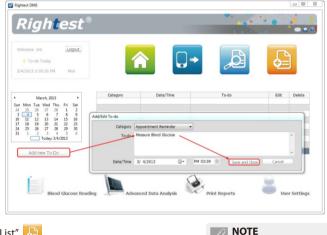




Once you recover data, your current profile will be replaced with the backup profile you selected.

Rightest DMS

With the *Rightest*® Diabetes Management Software, you can set up reminders of upcoming events, medicine dosage or important comments and alerts. To create a To-Do list, please complete the following steps.



to create a

1. In each event, the maximum number of

appointed time.

characters in a note is 255. If you exceed this

amount, an ERROR message will pop up.

2. All reminder messages will alert you at their

- 1. Click on "To-Do List"
- 2. Click on "Add new To-Do" new event.
- 3. Input the time, select the category of the reminder, and enter in any notes about the event.
- 4. Click on "Save and Close" Save and Close to finish and save.

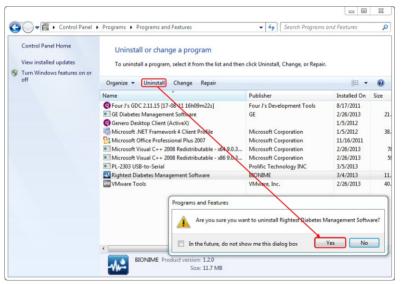
Add new To-Do

To un-install the *Rightest*[®] Diabetes Management Software, please complete the following steps.

1. Go to the "Control Panel" and select "Uninstall a program".

2. Find and select "Rightest® Diabetes Management Software".

3. Click on "Uninstall", then confirm by clicking "Yes" to un-install the program.



Customer Service

Please be sure to read and review ALL instructions of this User's Manual prior to using the *Rightest*[®] Diabetes Management System.

At BIONIME, our number one goal is to provide our customers with complete and high quality service. We will do everything we can to provide you with satisfactory customer service.

If you have any questions or concerns, please call the BIONIME Technical Service Department at 1-(888) 481-8485, toll free. Or, you may contact us via email at <u>technicalsupport@bionime.com</u>. Alternatively, click on the internet icon at the home page of the **Rightest**[®] Diabetes Management Software. It will link you to the User's Manual providing all the latest information.

If you have any health-related questions or concerns, be sure to contact a healthcare professional or physician.

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