#### WELLDOC BLUESTAR OR WELLDOC DIABETESMANAGER SYSTEM AND DIABETESMANAGER RX SYSTEM- accessories, pump, infusion WellDoc, Inc

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**Prescription Medical Device** 

**User Guide** 



#### <u>WellDoc BlueStar or WellDoc Diabetes Manager® System and Diabetes Manager®-RxSystem</u> <u>Registration and Listing</u>

WellDoc BlueStar (NDC/NHRIC #89129-0100-01) is an FDA cleared prescription product for adults with type 2 diabetes and their healthcare providers. BlueStar is registered in the FDA "Establishment Registration & Device Listing" database of FDA cleared products. For clarity, the product was originally cleared under the trade name DiabetesManager® System and DiabetesManager®-RxSystem [Premarket Notification Numbers K100066, K112370, K120314]. Subsequently to the original clearance and prior to commercial launch, the BlueStar name was added to the device listing [as

#### evidenced by the image below]



#### **Product Description**

#### The World's First Mobile Prescription Therapy

# BlueStar<sup>TM</sup> is an FDA Cleared product for type 2 diabetes. It is only available with a prescription from your healthcare provider.

#### **IS BLUESTAR RIGHT FOR YOU?**

Are you struggling to manage your diabetes? Is it overwhelming and confusing? We know that trying to remember your doctor's

advice about medications, diet, and exercise isn't easy, but diabetes doesn't have to take over your life. Talk to your doctor about

getting a prescription for BlueStar.

#### **DIABETES SUPPORT, ANYTIME ANYWHERE™**

BlueStar is not a pill or a shot — it's a completely new kind of approach to support you and help you manage your type 2 diabetes. BlueStar's real-time coaching fits into your daily life helping you stay on track with your diabetes self-care. It works with you, struggles with you, achieves with you, and celebrates with you. It can help make living with diabetes easier which makes for a healthier, happier you. BlueStar is accessible from your mobile phone, tablet, or computer, and supports your healthcare provider's instructions while providing you with diabetes education and motivational support.

#### **COORDINATE YOUR CARE WITH YOUR DOCTOR**

Before your next diabetes check-up, you can use BlueStar to send your information to your doctor. This helps your healthcare provider understand the challenges that you face between appointments so that during your office visit you can discuss a treatment plan that is just right for you.

#### **INDICATION FOR USE**

BlueStar is indicated for use by healthcare providers and their adult patients, aged 21 years and older, who have type 2 diabetes. BlueStar provides secure capture, storage, and transmission of diabetes data, as well as, motivational, behavioral, and educational coaching messages to aid in diabetes self-management. BlueStar is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

**CONTRAINDICATIONS:** Type 1 diabetes, patients on insulin pumps, patients less than 21 years of age, and women who are pregnant.

**IMPORTANT SAFETY INFORMATION:** For medical questions, please contact your healthcare provider. If you are experiencing an emergency, please dial 911.

Caution: Federal law restricts this device to sale by or on the order of a physician.

#### For more information visit www.bluestardiabetes.com

#### **BlueStar Customer Care**

Available to Answer Your Questions

BlueStar<sup>TM</sup> Customer Care can assist you with the following:

- How to use BlueStar
- Reporting of errors when trying to use BlueStar
- Technical questions related to BlueStar on web and/or mobile
- Questions about your prescription or health insurance reimbursement

Available: Monday-Friday, 9:00 a.m.-5:00 p.m. (ET) Phone: (888) 611-4794

#### **Getting Started**

If you are new to BlueStar<sup>™</sup>, select the Sign Up button to begin the registration process or Log In with your username and password.



#### **Getting Started...Continued**

Enter your Prescription Number, BlueStar<sup>™</sup> ID, and personal information to create your BlueStar account.

ueStar	Already have Account? Log I
	Please complete below information to create Your BlueStar Account.
	Prescription Number
	Healmea
3	BlueStar ID
Real-Time Coaching	Required
	Choose username
	6 Characters millinum
	Create a password
Holistic Diabetes Self-Management	8 Characters minimum
	Confirm your paramont
	Fie-Enter Ressword
	Email
Medication Management and Adherence	example@example.com
٠	Please answer security question below to identify and help you to reset your password in future.
Positive Behavioral Reinforcement	Annuar
	Prequired
3	Do you take any medications for Ves No your diabetes?
Personalized Support	I am 21 years of age or older diagnosied with Type 2 Diabetes. I am also not pregnant and using any insulin pump.
	I agree to Terms of Use
	Create Account
	9:00 AM - 5:00 PM EST

## <u>Using BlueStar on your phone</u>

BlueStar<sup>™</sup> on mobile is recommended for use on phones with iOS 6 and greater or Android OS 2.2 and greater

#### <u>BlueStar Mobile</u>



Log In a. Enter Username. b. Enter Password. c. Tap Log In.

Trouble logging in?

d. Tap Forgot Password? to retrieve your BlueStar<sup>™</sup> password.

e. Tap Forgot Username? to retrieve your BlueStar username.

New to BlueStar?

f. Tap Sign Up to register for BlueStar. This will prompt you to complete your registration via the registration form.

#### Home Screen (Mobile)



The BlueStar<sup>TM</sup> carousel displays important information to help you manage your diabetes.

a. BG Spotlight. Your BG entries are reviewed on a daily basis. When BlueStar sees something worth noting, it delivers a message to your carousel. The message also appears in your logbook for that day.

b. Motivational Message. This provides support for your general health and well-being. A new motivational message is displayed daily.

c. Educational Video. The educational videos are designed to provide "need to know" information about diabetes in a way that fits into your busy schedule. The videos are short (2-5 minutes) and cover various aspects of diabetes. Each video is available for 48 hours before it is replaced by the next video in the carousel.

#### **Entering Information**



- a. Click on New Entry.
- b. Enter any of the following:
- Blood Glucose readings (BG)
- Number of Carbs in your meal

Medication - Medications are displayed as "Scheduled" or "Other". Daily medications are displayed under "Scheduled" if their administration time is within 60 minutes of the current time. Weekly and Monthly medications are displayed under "Scheduled" if their administration time is within 8 hours of the current time. Medications that are not scheduled for the current time are displayed under "Other".
Notes - Tap Notes to enter important information related to your BG entry.

c. Activity Type - The Activity Type defaults according to your Daily Schedule presets on the web application. Scroll through to select your current Activity Type.

d. Date and Time - The current Date and Time is displayed. You may also adjust this portion to view or edit entries from an earlier date.

#### **Recording Medications**



a. Medication Administration Display:

• Your medications are displayed grouping your doses by the time of day you are scheduled to take them.

• Full prescription information for metabolic meds (those for BG, BP, or cholesterol) is only displayed once your provider confirms the dose (e.g. number of pills, units of insulin, etc.). If the dose is not yet confirmed, or there is a conflict between the information entered and your provider's records, the name of the med will be displayed without the dose.

Note: Always continue your medications as prescribed and confirm your prescription information with your healthcare provider at your earliest convenience.

• For non-metabolic medications, we do not request that your provider confirm that information, so the total prescribed dose is never displayed.

b. Recording Your Medication Dose:

• Simply choose the medication you wish to record and enter the dose (number of pills, units of insulin, etc.) that you took.

#### **Coaching Messages**



BlueStar<sup>TM</sup> provides you with coaching messages about BGs within 120 minutes of the blood glucose entry (within 30 minutes if the blood glucose is less that 70 mg/dL). These messages provide you with several different types of information:

- Immediate coaching on your BG value
- Information on nutrition
- Education about diabetes related health issues like blood pressure and cholesterol

• Messages of motivation and inspiration, or personal stories from other people with diabetes All BGs entered are included in the BG Spotlight message if the BG shows something important that

you should pay attention to.

#### Messages



The number displayed over the Messages Icon indicates the number of unread messages in your Inbox.

#### a. Tap on Messages.

b. Tap on the message you wish to view. Tap the Back Arrow to return to the list of messages or Delete to remove the message from your Inbox.

Note: Your BlueStar<sup>™</sup> messaging system is a read-only system. You cannot send or forward messages from it.

#### Logbook



Logbook is a record of all your BG readings and related information such as carbs, meds, and notes entered into the BlueStar<sup>TM</sup> system.

a. Tap on the Logbook icon.

b. Select a date and Add New Entry to enter current or earlier information. You can also tap to view the BG Spotlight for that day if available.

c. Tap the Graph icon to view a trend chart of your entries.

Note: Only the last thirty (30) days of data will appear in the logbook on your phone. You can edit any logbook entry, simply by clicking on it, making changes and saving it. To view your complete logbook display or to print, please Log In to the BlueStar website.

#### Health Info: (Medications)



This is where you can review all your medication information. To add or change medications, please log into www.bluestardiabetes.com

- a. Tap on Health Info.
- b. Enter your PIN. If you have not created a PIN, BlueStar<sup>™</sup> will prompt you to create one.
- c. Tap on Medications to view the medications you have entered into BlueStar.

Note: Health Information cannot be added or edited on your phone. To edit your Health Information log on to www.bluestardiabetes.com

IMPORTANT SAFETY INFORMATION:

For medical questions, please contact your healthcare provider. If you are experiencing an emergency, please dial 911.

Health Info: (Medical History)



This is where you can review your medical history, lab results and preventive health information. To add or change medical history, please log in at www.bluestardiabetes.com

- a. Tap on Health Info.
- b. Enter your PIN. If you have not created a PIN, BlueStar<sup>™</sup> will prompt you to create one.
- c. Tap the Medical History tab to view information that you have entered into BlueStar.

Note: Health Information cannot be added or edited on your phone. To edit your Health Information log on to www.bluestardiabetes.com

#### Health Info: (My Team)



This is where you can review your healthcare provider information and send a SMART Visit to your healthcare provider. To make changes to your healthcare provider information, you must call BlueStar<sup>TM</sup> Customer Care at (888) 611-4794. Available: Monday-Friday, 9:00 a.m.-5:00 p.m. (ET).

- a. Tap on Health Info.
- b. Enter your PIN. If you have not created a PIN, BlueStar will prompt you to create one.
- c. Tap the My Team tab to view your provider information.

Note: SMART Visit is a report containing your lab results, dates of screening exams and vaccinations, logbook entries, and medication list. It is suggested that you send SMART Visit 1-2 days prior to an office visit so that your healthcare provider will have it to review with you at that time.

#### Settings



1. PIN Settings

Use PIN Settings to change your PIN number or lock BlueStar<sup>™</sup>. A PIN is required to access your Health Info.

- Tap on the Cog icon.
- 2. Change PIN
- Tap on Change PIN.
- Enter your current PIN and then your new PIN number.

3. Lock Blue Star

• Move the Lock BlueStar slider control to the right to lock your application.

Tips



a. Tap on Tips.

b. Tap on each Tips category to view information to help you understand and manage your diabetes better.

Help



There are two ways to access helpful information about BlueStar<sup>TM</sup> from your phone:

a. Tap on the Help icon.

b. BlueStar Help

• Tap on BlueStar Tour to take a tour of BlueStar.

• Tap the Help categories to view helpful information.

• Tap the Customer Care number to speak with a BlueStar customer care representative. Available: Monday-Friday, 9:00 a.m.-5:00 p.m. (ET).

c. BlueStar Tour

#### Using BlueStar on the Web

Note: BlueStar<sup>TM</sup> on web is recommended for use on computers with Internet Explorer 10 and 11 and Mozilla Firefox 25 and 26 and Chrome 32

#### Log In



Log In a. Enter Username. b. Enter Password. c. Click Log In.

Trouble logging in? d. Click Forgot Password to retrieve your BlueStar™ password. e. Click Forgot Username to retrieve your BlueStar username.

New to BlueStar? a. Click Sign Up to register for BlueStar.

Home Screen (Web)



The BlueStar<sup>TM</sup> carousel displays important information to help you manage your diabetes.

• BG Spotlight. Your BG entries are reviewed on a daily basis. When BlueStar sees something worth noting, it delivers a message to your carousel. The message also appears in your logbook for that day.

• Motivational Message. This provides support for your general health and well-being. A new motivational message is displayed daily.

• Educational Video. The educational videos are designed to provide "need to know" information about diabetes in a way that fits into your busy schedule. The videos are short (2-5 minutes) and cover various aspects of diabetes. Each video is available for 48 hours before it is replaced by the next video in the carousel.

#### Home Screen (web) Continued



1. Profile Complete: This is a display of the status of the completion of your overall Health Info profile and each individual section. Clicking on any of the links will directly take you to the respective section. Alternatively you can click on Health Info to complete your profile.

Note: Entering Clinical Results, Preventive Health, Medical History, and Lifestyle information will help customize BlueStar<sup>™</sup> for you.

2. Download the BlueStar app: Click on the link to receive an SMS to download BlueStar. You can also download the BlueStar app via Google Play or the iTunes App Store.

Making Entries (Web)

BlueStar	Home Lo	S C ogbook Health Info	C Messages (1)	LAST BG ENTRY	100 mg/dL 09/21/2013 08:00 AM EDT Breakfast	New En
New Entry	<i>a</i> ,	<del>س</del> م	i i last	(00 mg/dL_08/21/201		8
DATE, TIME & ACTI	VITY	Sun, Sep 22, 2	013 02:08 PM	Just checkir	ig 🔄	
BLOOD GLUCOSE		mg/dL				
CARBS		gram(s)	)			
ENTER MEDICATIO	N	SCHEDULED	NOW	SCHEDULED AT O	THER TIMES	
▶ NOTES						
				-	(	
	_	90000			Cancel Save	

- 1. Click on New Entry.
- 2. Enter your data.

a. Select the Date and Time. Note: Will default to current date and time.

b. Select the Activity (Breakfast, Fasting, Bedtime, etc.) Note: Will default to an activity based on the Daily Schedule.

c. Enter your Blood Glucose reading (BG).

d. Enter your Carbs (if applicable).

e. Medication - Medications are displayed as "Scheduled Now" or "Scheduled at Other Times". Daily medications are displayed under "Scheduled Now" if their administration time is within 60 minutes of the current time. Weekly and Monthly medications are displayed under "Scheduled Now" if their administration time is within 8 hours of the current time. Medications that are not scheduled for the current time are displayed under "Scheduled at Other Times".

f. Notes - Enter any applicable notes. (Up to 6 multiple choice items or type in your own).

3. Click on Save.

#### **Recording Medications (Web)**

DATE, TIME & ACTIVITY	Wed,	Oct 2, 2013 10:03	PM	seatime	2
BLOOD GLUCOSE	200	mg/dL			
CARBS	10	gram(s)			
ENTER MEDICATION	() sc	HEDULED NOW	() SCHE	DULED AT OTHE	R TIMES
Medication	Prescribed Dose		I took:	Last Entry	1
metformin 500 mg	Daily, 7:00 AM Brea	skfast	tablet(s)	1 tablet(s) 10/01/201	) 13 8:12 PM
Apidra View Prescription	7 unit(s) Dally Breakfast		unit(s)	(2)	
Humalog	Daily, Lunch		unit(s)		
NOTES					

1. Medication Administration Display:

a. Your medications will be displayed grouping your doses by the time of day you are scheduled to take them.

b. For metabolic medications (those for blood glucose, blood pressure, or cholesterol), the

full prescription information will be displayed once your provider confirms the dose. If the information has not yet been confirmed, or if there is a conflict between the information you

entered and your provider's records, the name of the medication will be displayed without the prescribed dose (e.g. number of pills, units of insulin, etc.)

c. For non-metabolic medications, we do not request that your provider confirm that information, so the total prescribed dose is never displayed.

Note: Always continue to take your medications as prescribed and confirm your

prescription information with your healthcare provider at your earliest convenience.

2. Recording your Medication Dose:

a. Simply choose the medication you wish to record and enter the dose (number of pills, units of insulin, etc.) that you took.

#### Coaching Messages (Web)



BlueStar<sup>™</sup> provides you with coaching messages about BGs within 120 minutes of the blood glucose entry (within 30 minutes if the blood glucose is less that 70 mg/dL). These messages provide you with several different types of information:

- Immediate coaching on your BG value
- Information on nutrition
- Education about diabetes related health issues like blood pressure and cholesterol
- Messages of motivation and inspiration, or personal stories from other people with diabetes

All BGs entered are in the BG Spotlight message if the BG shows something important that you should pay attention to.

#### Messages (Web)

Your Message	e Inbox		Delete
Status	From	Subject	Received
C Read	BlueStar	BlueStar Maintenance	Mon Jan 27 2014 03:29 PM
From: BlueSt Subject Blue	ar Star Maintenance		

- 1. Click on Messages.
- 2. Review the list of messages.
- 3. Click on the message you wish to read.4. Click on Back to return to the list of messages or Delete to remove the message from your Inbox.

Note: Your BlueStar<sup>™</sup> messaging system is a read-only system. You cannot send or forward messages fromit

#### Logbook (Web)

BlueStar Home Logbook	ealth Info Messages(24)	150 mg/dL 02/12/2014 04.41 PM Alter both	New Entry
Dates 02/06/2014 to 02/13/2014	(2)	View By: Activity Type	
Filters: Select a Option  FreakfastTasting After Breakfast	Lunch After Lunch Dinner	After Dinner Bedtime	Other*
Feb 13 Thursday	5		
Feb 12 Wednesday 150 mg/st.	150 mg/dL 6		180 mg/dL
	2-45 PM 69 mg/sL	<u> </u>	150 mptr.
BG Spotlight	We noticed you had a low B/G value	44	

Logbook is a record of all your BG readings and related information (carbs, meds, notes,) entered into the BlueStar<sup>TM</sup> system.

- 1. Click on Logbook.
- 2. Click on the Calendar icon to customize the date range.
- 3. Click on View By dropdown to change the view to view by time.
- 4. Click on the Graph icon to view Logbook as a graph.
- 5. You can edit any Logbook entry by clicking on it, making changes and saving it.
- 6. You can also add historical entries to the Logbook by clicking inside of a cell.
- 7. Click on Arrow to view BG Spotlight.

#### Health Info (Medications) (Web)

lueStar	Home Logboot	Health Info Mess	) lages	AST 250 mg/dL 01 K9 02:06 AM Just checking	/31/2014	New Entry
Medications M	edical History	Clinical Results	Preventive Heal	th Lifestyle	Provide	
Show:  Currently	r Taking (4) 🛛 🔿 S	Suspended (0)	Discontinued (5)			🗞 New Meds
Ine purpose of this p provider to make sure correct If you see a message a chance to speak with	age is to anow you to e BlueStar has the se that states there is a h your healthcare prov	reep a record or all yo ime information. Your h conflict 1, please con ider.	w medicasons, when ealthcare provider will tinue to take the medic	tins list is updated, fax a response bac ation as you believe	it in be paxe k to let BlueS it to be prescr	o to your nearncare tar know if the list is ibed until you've had
metformin 500 m	ng extended release 2	4 hr, Daily		Edit	Suspend	Discontinue
7:00 PM Dinner	2 tablet(s)			<u> </u>		
Victoza 3-Pak	0.6 mg/0 1 mL (18 mg the skin) Pen inject	y'3 mL) or, Daily		Edit	Suspend	Discontinue
8:00 AM Breakfast	1.8 mg					
lisinopril 40 mg Oral (By mouth) tablet	. Daily			Edit	Suspend	Discontinue
8:00 AM	1 tablet(s)					
Lipitor 20 mg Oral (By mouth) tablet	, Daily			Edit	Suspend	Discontinue

1. Medications: This is where you can manage your medications in BlueStar<sup>TM</sup>.

2. Complete prescription information is displayed including:

a. Name, Strength, Dose Time, associated Activity and Dose Amount

Note: For medications that need to be taken with food such as short-acting insulin's (including those in combination with other types of insulin), and certain oral medications such as sulfonylureas and metaglinides, only the associated meal type is displayed with the dose and not a time.

3. Click on New Meds to add a medication.

- 4. Edit/Suspend/Discontinue.
- a. Click Edit to change a medication dose or time.
- b. Click Suspend to temporarily stop a medication.
- c. Click Discontinue to permanently stop a medication.

#### IMPORTANT SAFETY INFORMATION:

For medical questions, please contact your healthcare provider. If you are experiencing an emergency, please dial 911.

#### **<u>IHealth Info (Medications) (Web) (continued)</u>**

<ol> <li>Select your medication</li> </ol>	2 When do you take it?
Search for medication metformin	Daily O Weesly O Monthly O As Needed      How many times a day do you take this medication? 1
tablet	1st time Time Activity 1 8 • 00 • AM • Breakfast • 1 tablet(s)
500 mg 🔹	

Adding New Meds: Once you have selected New Meds from the medication display screen (Step 3 on the previous page), you can enter new medication information.

1. Select the medication name, how it is taken (i.e. tablet, injection, etc.) and prescribed strength (i.e. how many mg or units).

2. Select whether you take it daily, weekly, monthly, or as needed. Then select how many times per day, week, month, etc. you take it.

3. Select the time that you take your medication and the associated activity (e.g. 8:00 A.M., breakfast). Enter your dose (number of pills, units, etc.) at each administration time. If you take the medication more than once per day, week, month, etc., the appropriate

number of times will appear.

4. Click Save.

#### Health Info (Medical History, Clinical Results etc.) (Web)

	LAST BG ENTRY	257 mg/dL ( 02.09 PM After lunch	1/27/2014	New Entry
There ingrane another methodies				**
Medications Medical History Clinical Results Preventive He	alth	ifestyle	Provider	r]
Ceneral				
General				
Duration of Diabetes		On: 05	/2010	
Duration of Diabetes		On: 05	/2010	
Duration of Diabetes High Blood Pressure		On: D5	/2010	
Duration of Diabetes High Blood Pressure Cholesterol		On. D5	/2010 T	
Duration of Diabetes High Blood Pressure Cholesterol		On: D5	/2010	
Duration of Diabetes High Blood Pressure Cholesterol Cardiovascular Disease (CVD)		On: DS	/2010 T	

Use this section to record your important health information into BlueStar<sup>™</sup>, incuding:

- 1. Medical History (other medical problems that can affect your diabetes management).
- 2. Clinical Results (A1C, cholesterol, kidney function tests, etc.).
- 3. Preventive Health (vaccinations, foot exam, eye exam, etc.).
- 4. Lifestyle information (height, weight, smoking history).

Note: If you're not sure of the answer to some of the questions, be sure to discuss it with your healthcare provider. Remember to update your information periodically.

#### Health Info (Provider) (Web)

uestar	Home Logboo	ok Health info Mess	ages 🛄	Just checking	
Medications	Medical History	Clinical Results	Preventive Healt	h    Lifestyle    Provi	der
					1
Provider	r Name. Ethan Susai E. Sinai				
2525 Yo Towson	rk Road, Maryland				
United S	states, 21030				
Fax 200	LLOLLLL				
128 3	124 (2 A) (0 C) (2 C)				
Prescrit	bing provider.Yes				
Prescrit The pro	oing provider:Yes vider has agreed to recei	ve SMART Visit and Medic	ation faxes.		
Prescrit The pro Call Blu	oing provider.Yes vider has agreed to recein eStar Customer Care at	ve SMART Visit and Medic 1(888)611-4794 to change	ation faxes. Your healthcare provid	27.	
Prescrit The pro Call Blu SMART	oing provider.Yes vider has agreed to recei eStar Customer Care at Visit	ve SMART Visit and Medic 1(888)611-4794 to change	ation faxes. 9 your healthcare provid	ər.	
Prescrit The pro Call Blu SMART Please	oing provider.Yes vider has agreed to recein eStar Customer Care at Visit click on send SMART Vis	ve SMART Visit and Medic 1(888)611-4794 to change it button to send SMART \	ation faxes. 9 your healthcare provid Jisit report to your provid	er.	

This is where you can review your healthcare provider information and send a SMART Visit to your healthcare provider.

To make changes to your healthcare provider information, you must call BlueStar<sup>™</sup> Customer Care at (888) 611-4794. Available: Monday-Friday, 9:00 a.m.-5:00 p.m. (ET).

Note: SMART Visit is a report containing your Logbook entries, Medication list, and a summary of your Medical History. It is suggested that you send SMART Visit 1-2 days prior to an office visit so that your healthcare provider will have it to review with you at that time.

#### Settings (Web)



Click on the Cog icon to make updates to your settings.

• My Profile: Email Address

Note: No changes can be made after registration to basic profile information. If you have changed your name due to marriage, divorce or other legal means, please call customer care.

- Security and Password: User Name, Password, Security Questions
- Daily Schedule: Breakfast, Lunch, Dinner, Bedtime Schedules
- Delivery Preferences: Feedback Messaging, Email Reminders



This is where you can download PDF information for using BlueStar<sup>™</sup> and access contact information.

# WELLDOC BLUESTAR OR WELLDOC DIABETESMANAGER SYSTEM AND DIABETESMANAGER RX SYSTEM

accessories, pump, infusion

#### Help (Web)

Product Information	on			
Product T ype	MEDICAL DEVICE	Item Code (Sou	ırce)	NHRIC:89129-100
Packaging				
# Item Code	Package Description	Marketi	ng Start Date	Marketing End Date
<b>1</b> NHRIC:89129-100-01	1 in 1 PACKAGE			
<b>Marketing Info</b>	rmation			
Marketing Category	Application Number or Mono	graph Citation	Marketing Start D	ate Marketing End Date
premarket notification	K120314		02/24/2014	

# Labeler - WellDoc, Inc (021217115)

### Establishment

Name	Address	ID/FEI	Business Operations
WellDoc, Inc		021217115	manufacture

Revised: 3/2014

WellDoc, Inc