

**2024, 05 revision (3rd edition)
 *2023, 03 revision (2nd edition)

* Code Number 5C9400 / 5C9500 / 5C9600

Approval Number 22800BZX00345000

Program 2. Program for Disease Treatment
Highly Controlled Medical Device Program for developing treatment plan for Peritoneal Dialysis 41049003

Sharesource

【Warnings】

Ensure that the device settings created and to be submitted are proper and match the patient's prescription. [Failure to do so may cause injuries including Increased Intraperitoneal Volume (IIPV)]

*** 【Shape, Structure and Principle】**

Outline

Sharesource is a web-based connectivity platform that performs two-way communication with Kaguya Automated Peritoneal Dialysis Device (APD device, Trade name: "Home PD system Kaguya" hereinafter referred to as "Kaguya") and with the dedicated patient mobile application (hereinafter referred to as "MyPD"), which allows authorized users (Healthcare professionals) of Shresource to remotely view, manage and monitor treatment information sent from Kaguya and MyPD (Remote monitoring). Settings and Device Program information of Kaguya can also be managed remotely (Remote device setting) and continuous ambulatory peritoneal dialysis (CAPD) therapy settings can be remotely communicated to MyPD. This product also aids in the review, analysis, and evaluation of patients' historical treatment results.

Sharesource is utilized via internet connection using a general purpose browser.

MyPD is an accessory to this product and installed into personal digital assistant devices by the patient and used under instruction by his/her doctor.

Primary Functions

APD remote management (5C9400)

| Item | Descriptions |
|-------------------|---|
| Remote Monitoring | <p>To display information obtained from Kaguya for remote monitoring.</p> <p>1. Treatment Dashboard</p> <p>Displays the list of patients that have been Treated in the last 28 days with [Patient Event] icons for previous 7 days (The user can review icons for 28 days by clicking the arrows). [Patient Event] icons show information related to:</p> <ul style="list-style-type: none"> • Treatment was completed without any problems • Treatment had at least one high priority flag※ occur • Treatment had at least one priority flag※ occur • No treatment data was received • No communication occurred between the cyclor and the dialysis center • Three or more treatments occurred on the |

| | |
|------------------------|---|
| | <p>same day</p> <ul style="list-style-type: none"> • Treatment was reviewed by an authorized user <p>※Flag = a visual indicator to clinicians that a clinician-defined event occurred during treatment.</p> <p>2. Patient Snapshot</p> <p>Provides treatment overview for the past 7 or 30 days both numerically and graphically (The user can go back 3 months using the arrows on the calendar.)</p> <p>3. Treatment Summary</p> <p>Displays the full treatment summary information about all applicable flag symbols, their descriptions, and the treatment data for the day selected.</p> <p>Information displayed includes:</p> <ul style="list-style-type: none"> • Flag symbols and their descriptions (if any) • Vitals (Weight / Pressure / Pulse / Glucose / Temperature of before and after therapy) • Prescribed Device Program (refer to "Remote Device Settings") • Actual Treatment Completion Information (Solution type / concentration / volume, Timestamp, Number of cycle (including initial drain), Fill volume, Fill time, Dwell time, Drain time, Drain volume, UF, Cycle profile, Drug survey) |
| Remote Device Settings | To remotely configure Kaguya. The setting parameters are same as Kaguya. |
| Report generation | <p>To aid in the review, analysis, and evaluation of patients' historical treatment results and generating reports, using the data obtained from Kaguya.</p> <p>Available reports are:</p> <ul style="list-style-type: none"> • Patient Clinical Data (Total UF Volume, Pre and post treatment weight / blood pressure / pulse / blood glucose / temperature) • Patient Treatment History (detailed information about the patient's treatments) • Prescribed Versus Actual (The program prescribed by a physician and the actual treatment results performed) • Treatment Flag And Events (Number, type and description of the events and flags that occurred during specified treatments) • Treatment Summary (Information about individual treatment sessions) • Clinic Treatment History |

Refer to User Guide

| | |
|---|---|
| <p>Therapy result analytics: Analytics 1.0 (Optional)</p> | <p>1. Notification Notification is available for the patient if value exceeds specified threshold configured in the clinic setting tab on adherence, drain time, fill time and alarm increase. It displays evaluation period, threshold and present value. The notification can be temporarily paused for the patient for a specified period of 7, 14, 30 or 60 days.</p> <p>2. Analytics Using the treatment data obtained from Kaguya, perform and displays the patient's analytics on the following items. The trends are reported at 30, 60, 90 and 180-day periods. (7-day report is available for fill time and drain time)</p> <ul style="list-style-type: none"> • Adherence (Adherence of the patient and clinic(%), Lost treatment days (%), Completed treatment days (%), Lost treatment time from completed treatments (%), Lost dwell time from completed treatments (%), Treatment time, Dwell time) • Catheter Health (Drain time, fill time) • Alarms (average number of alarms per treatment for that patient and the clinic, the patient's total alarm count, detailed alarm trends) <p>3. Guidance display(Optional) As an auxiliary function of therapy result analytics, displays the general guidance text based on recognized guidelines and literatures. It is not intended to suggest therapy to each individual patient.</p> |
|---|---|

| | |
|-------------------------------------|---|
| | <p>information about all applicable flag symbols, their descriptions, and the treatment data for the day selected. Information displayed includes:</p> <ul style="list-style-type: none"> • Flag symbols and their descriptions (if any) • Vitals (First and last Weight / Pressure / Pulse / Glucose / Temperature, and Urine output) • Prescribed CAPD Program setting (refer to "Remote CAPD therapy Settings") • Actual Treatment Completion Information (Number of bag exchange, Exchange time, Solution type / concentration, Fill volume, Fill time, Dwell time, Drain time, Drain volume, UF, Drug survey) |
| <p>Remote CAPD Therapy Settings</p> | <p>Create CAPD therapy program/patient setting and send to MyPD</p> <p>1. CAPD therapy program</p> <ul style="list-style-type: none"> • Number of day and night exchanges • Solution type • Dextrose concentration (only available when solution is selected) • The volume of solution bags (only available when solution and concentration are selected) • [Optional] Estimated UF expected per each exchange • [Optional] Time duration of each exchange (includes the fill, dwell and drain time) <p>Items calculated by platform: Total dry time/ Total therapy time/ Total therapy volume/estimated dwell time</p> <p>2. Patient settings Set up patient input items and range if applicable (as well as target weight when Weight is set).</p> <p>First and last Weight/ Pressure/ Pulse/ Glucose / Temperature, Urine output Drug survey</p> |

CAPD remote management (Optional) (5C9500)

| Item | Descriptions |
|--------------------------|---|
| <p>Remote Monitoring</p> | <p>To display information obtained from MyPD for remote monitoring.</p> <p>1. Treatment Dashboard Displays the list of patients that have been Treated in the last 28 days with [Patient Event] icons for previous 7 days (The user can review icons for 28 days by clicking the arrows). [Patient Event] icons show information related to:</p> <ul style="list-style-type: none"> • Treatment was completed without any problems • Treatment had at least one high priority flag occur • Treatment had at least one priority flag occur • No treatment data was received • No communication occurred between MyPD and the dialysis center • Three or more treatments occurred on the same day • Treatment was reviewed by an authorized user <p>2. Patient Snapshot Provides treatment overview for the past 7 or 30 days both numerically and graphically (The user can go back 3 months using the arrows on the calendar.)</p> <p>3. Treatment Summary Displays the full treatment summary</p> |

Secondary Functions (Non medical device functions)

| Item | Descriptions |
|-------------------------------|--|
| <p>Patient Administration</p> | <p>Allows to register, edit, view and search patient's information.</p> |
| <p>User Management</p> | <p>Allows to register, edit, view, search and assigning roles and responsibilities to users.</p> |
| <p>Clinic Settings</p> | <p>Allow to create and edit clinic-specific Templates for device settings and to set flag rules and analytics notification for a clinic.</p> |

Accessory: MyPD (Optional) (5C9600)

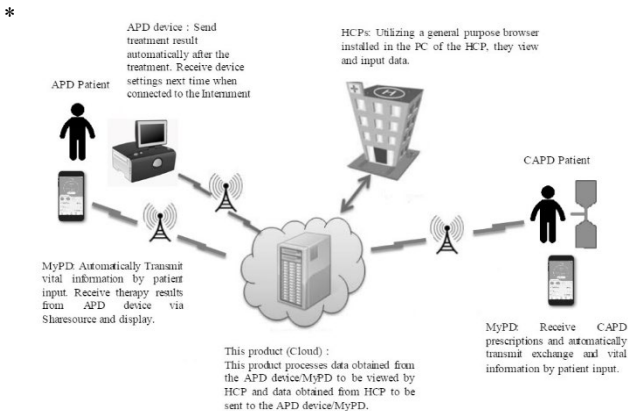
| Item | Descriptions |
|--|--|
| <p>Display prescriptions (CAPD)</p> | <p>Display CAPD therapy prescriptions received from Sharesource. Issue notice if prescriptions are modified. Number of exchange, Solution type / Concentration / Volume, Threshold UF, Target exchange time</p> |
| <p>Input exchange information (CAPD)</p> | <p>Input actual bag exchange and submit to Sharesource. Solution type / Concentration / Volume (when changed), Start and finish time of fill and drain, drain volume Items calculated by MyPD: Fill time, Dwell time, Drain time</p> |

| | |
|--|---|
| Input vitals (APD and CAPD) | Input vitals designated by HCP and send to Sharesource. * It is possible to select automatic input by pairing with a compatible Bluetooth enabled device for recording vitals data. |
| Display therapy results (APD and CAPD) | Obtain treatment results from Sharesource and display them by data and graphics. <ul style="list-style-type: none"> APD exchange information (Display APD device data for last 1 week) <ul style="list-style-type: none"> Treatment status, the date, UF History (Display therapy results of specific date up to past 90 days) <ul style="list-style-type: none"> APD: UF, Vitals CAPD: UF, Solution type /concentration / volume, Fill time, Fill volume, Dwell time, Drain time, Drain volume, Vitals Chart (Display trend graph of UF and vitals) |

Working Principle

Kaguya and MyPD has the ability to remotely communicate with the internet such that when they are placed in a treatment location (e.g. the patient’s home), the treatment results are transferred to the Sharesource cloud located on a data server to be organized and presented to the clinicians.

A Healthcare Professional (HCP) remotely views and manages the data obtained from Kaguya and MyPD to review, analyze and evaluate patient’s data. For APD, when a HCP creates and submits the setting data of Kaguya, Kaguya will receive the changes the next time it is connected to the Internet, and will set itself accordingly if the user approves the new changes. For CAPD, a HCP programs therapy settings on Sharesource and submits, MyPD will receive them, and the patient does exchanges using prescribed solutions according to the prescription and inputs results to MyPD to submit.



*** [Intended Use or Indications]**

The Sharesource Kaguya portal is intended for use by healthcare professionals to remotely view, manage and monitor treatment information sent from Kaguya and the dedicated patient mobile application, remotely manage Device setting of Kaguya or communicate CAPD treatment parameters with the patient mobile application, and to review, analysis, and evaluation of patients’ historical treatment results.

This is a medical device program intended to aid HCPs to make treatment or diagnosis, providing required information for HCPs who make treatment or diagnosis.

*** [Usage Method, etc.]**

Working conditions and Preparation

Sharesource:

The support web browsers for Sharesource are Edge (including Internet Explorer mode), Chrome, Firefox, and Safari. For the information about browsers whose compatibility with this product were verified, refer to the answer to Q: Why am I having trouble viewing certain web pages? on the Help & FAQs screen of this product

MyPD:

MyPD can be used with a mobile device on which iOS 13.2.3 or later or Android 9.0 or later is operating. For the information about the operation systems and the devices whose compatibility with MyPD were verified, refer to the operation manual of MyPD.

How to Use

Sharesource:

This product is available after Vantive has registered the hospital/clinic information and a “clinic user manager” on the system.

1. Preparation and initial login

Contact the registered clinic user manager to apply for a user account. Clinic user manager will create an account, assign proper roles (Either of Basic Clinical Access, Kaguya Device Manager, Patient Manager and Clinic setting manager, Mobile User Manager, CAPD Mobile Device Manager and CAPD Mobile Clinic Settings Manager). Once an account is created, an email will be sent to the user with an activation link. Click this link to activate your account and follow the instructions on Sharesource Portal to complete the account setup.

2. Returning User Login

Access the URL of this product and log in with the registered e-mail address and password.

3. Use of functions

Click on appropriate tabs or links according to the purpose of use. Note that the displayed content or the editable fields are different depending on the roles assigned to each user.

[Clinical] Tab

- View treatment results:
- Program settings
 - Settings for Kaguya (Editable only for Kaguya Device Manager)
 - Settings for CAPD therapy (Editable only for CAPD Mobile Device Manager)
- View analytics

[Report] Tab

- Generate reports:

[Clinic Settings] Tab

(Displayed only for Kaguya Clinic Setting Manager and CAPD Mobile Clinic Settings Manager)

- Create templates or set flag rules or analytics notification.

[Patient Administration] Tab (Displayed only for Patient Manager)

- Add new patients or search, view and edit patient information.

[Users] Tab (Displayed only for Clinic User Managers and Mobile User Manager)

- Assign roles to users, add new users, search, view and edit user information.

4. Logging out

Click (Logout) at the upper right corner of the screen.

MyPD:

MyPD becomes available for patient after downloading the app from app store and patient registration by HCP on Sharesource.

1. Log in

Input mail address and password to log in (Biometrics is also available).

2. Use of functions

Tap on an appropriate tab according to the purpose and use the functions following the GUI.

[Home] Tab

- View of therapy progress, next available action and notifications.

[Vitals] Tab

- Record vital metrics like weight and blood pressure.

[Exchange] Tab

- Record your exchange data for CAPD or review exchange data for APD.

[Therapy] Tab

- Review prescription details, therapy data and charts.

[Medical Devices Used in Conjunction]

“Home PD System Kaguya”

(Approval# 22800BZX00454000)

[Precautions Related to Usage Method]

- * 1. For Sharesource, use of one of the browsers listed in the [Usage method, etc.] is recommended.
- 2. Never share registered e-mail address or password and securely manage the information.
- * 3. Sharesource users will be automatically logged out after 30 minutes of inactivity. Ensure to save the data without delay after making necessary activities.
- * 4. Do not operate Sharesource with multiple browsers and do not log in from multiple computers at the same time.
- 5. Changes to the Kaguya Device Settings are only possible after the patient’s treatment is complete and when the Kaguya is powered on, where the data is transmitted between Kaguya and this program. Note that the change in setting will be reflected from the next treatment.
- * 6. Changes to the program will be retrieved from Sharesource immediately. If your patient is not logged into MyPD, the program will be transmitted next time your patient logs into MyPD. The changed program will be applied to the next treatment.
- * 7. The activation link for Sharesource account set-up expires in 10 days, so you must complete your account set-up within that time.
- * 8. The activation link for Sharesource account set-up expires in 10 days, so you must create a password within that time.
- * 9. Users must change their Sharesource passwords every 365 days.
* Provide the following instructions to the patients for use of MyPD:
- * 10. Never share registered e-mail address or password and securely manage the information.
- * 11. Do not log in from multiple personal digital assistant devices at the same time.

*【Precautions】

1. Important Precautions

- * (1) Sharesource is used by making connection to the data center via the Internet. Pay special attention to computer viruses and information security, and access this product under monitoring of resident security software.
- * (2) For security reasons, ensure to always completely log out of Sharesource after you are finished using it.
- (3) Special caution should be used in order to match a patient to the correct Device Program.
- * Provide the following instructions to the patients for use of MyPD:
- * (4) MyPD is used by making connection to the data center via the Internet. Pay special attention to information security, and access this product following the directions in the user manual. The resident security functions of the mobile device will not interfere with MyPD.
- * (5) Once logged in, you stay logged into the app for 3 days. When staying logged in, use security controls provided on your mobile device to control access as necessary.

2. Malfunctions and Adverse Events

If a Device Program that doesn’t match the patient’s prescription is created for some reason such as a mistake in selecting a patient, and the data is sent to Kaguya, the therapy can be implemented with the wrong prescription for the patient. Serious adverse events can result from any mismatch or a misuse of this product such as incorrect therapy, an IIPV situation, or dehydration.

**【Contact Information for marketing authorization holder and manufacturer】

Marketing Authorization Holder (Importer):

Vantive Japan

TEL: 03 (4595) 4750

Manufacturer: Baxter Healthcare Corporation (United States of America)

Marketing Authorization Holder (Imported by)

Vantive Japan