Baxter

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 (Trade name: "Home PD system Kaguya" Hereinafter referred to as "Kaguya"), which allows authorized users (Healthcare professionals) to remotely view, manage and monitor treatment information sent from Kaguya (Remote monitoring). Settings and Device Program information of Kaguya can also be managed remotely(Remote device setting). This product also aids in the review, analysis, and evaluation of patients' historical treatment results.

This product is utilized via internet connection using a general purpose browser.

Primary Functions

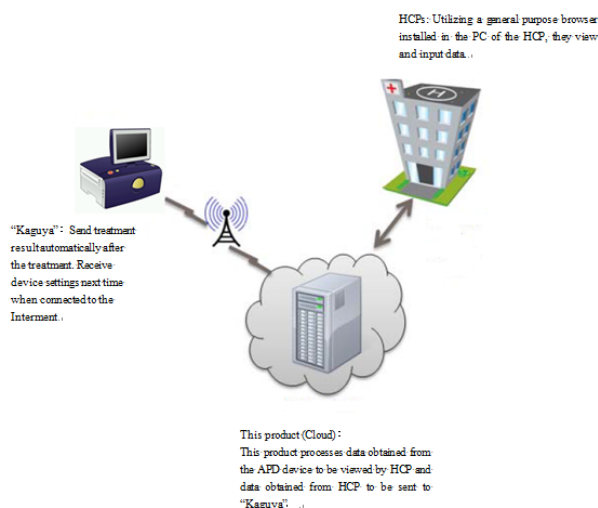| Item	Descriptions
Remote Monitoring	To display information obtained from Kaguya for remote monitoring. 1.　Treatment Dashboard: Displays the list of patients that have been Treated in the last 28 days with [Patient Event] icons for previous 7 days (The user can review icons for 28 days by clicking the arrows).　[Patient Event] icons show information related to: ・ 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 cycler and the dialysis center ・ Three or more treatments occurred on the same day ・ Treatment was reviewed by an authorized user ※Flag = a visual indicator to clinicians that a clinician-defined event occurred during treatment. 2.　Patient Clinical Information: Displays the following information: ・ Device information ・ Treatment information(Last treatment, Treatments in the last 90 days) ・ A calendar for the current month with the corresponding [Patient Event] icons. (The user can go back 3 months using the arrows on the calendar.) ・ Links to view the patient's [Device Settings] screen and [Patient Snapshot] 3.　Patient Snapshot: Provides the following information for the past 7 or 30 days both numerically and graphically(The user can go back 3 months using the arrows on the calendar.): ・ Night Ultrafiltration (UF) ・ Pre and Post Treatment Weight※ ・ Pre and Post Treatment Blood Pressure※ ・ Pre and Post Treatment Pulse※ ※ Patient make measurements by themselves and enter in the device manually. 4.　Treatment Summary: Displays the full treatment summary information about all applicable flag symbols, their descriptions, and the treatment data for the day selected. Information displayed includes: ・ Flag symbols and their descriptions (if any) ・ Prescribed Device Program ・ Actual Treatment Completion Information (including deviations)
Remote Device Settings	To remotely configure Kaguya. The setting parameters are same as Kaguya.
Treatment Results Analysis and Evaluation Aids	To aid in the review, analysis, and evaluation of patients' historical treatment results and generating reports, using the data obtained from Kaguya. Available reports are: ・ Patient Clinical Data (Total UF Volume, Pre and post treatment weight, blood pressure, blood glucose and temperature, and flags) ・ 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

Secondary Functions (Non medical device functions)

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

Working Principle

Kaguya 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 Baxter data server to be organized and presented to the clinicians.

A Healthcare Professional (HCP) remotely views and manages the data obtained from Kaguya to review, analyze and evaluate patient's data. 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.

HCPs: Utilizing a general purpose browser installed in the PC of the HCP, they view and input data.

"Kaguya": Send treatment result automatically after the treatment. Receive device settings next time when connected to the Internment.

This product (Cloud): This product processes data obtained from the APD device to be viewed by HCP and data obtained from HCP to be sent to "Kaguya".

【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, remotely manage Device setting of Kaguya, and to review, analysis, and evaluation of patients' historical treatment results.

This is a program medical device 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

The information about browsers that can be used with this product will be provided to users (HCPs) when they are contacted about registration with this product also that will be provided in the answer to Q: Why am I having trouble viewing certain web pages? on the Help & FAQs screen of this product

How to Use

This product is available after Baxter 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). Once an account is created, an email will be sent to the user with instructions on how to initially log into the system.

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:
・Settings for Kaguya（Editable only for Device Manager）:

〔Report〕 Tab
・Generate reports:

〔Clinic Settings〕 Tab
（Displayed only for Kaguya Clinic Setting Manager）
・Create templates or set flag rules.

〔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）
・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.

〔Precautions Related to Usage Method〕

1. 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. 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 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.

〔Medical Devices Used in Conjunction〕

"Home PD System Kaguya"

（Approval# 22800BZX00454000）

【Precautions】

1. Important Precautions

(1) This product 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 this product after you are finished using it.

(3) Special caution should be used in order to match a patient to the correct Device Program.

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):
Baxter Limited
TEL: 03 (6204) 3700

Manufacturer: Baxter Healthcare Corporation (United States of America)

Baxter and Kaguya and Sharesource are registered trademarks of Baxter International Inc.

Marketing Authorization Holder (Imported by)
Baxter Limited