



Approval No. 30100BZX00092000

Program (02) Program for Treatment

Highly Controlled Medical Device Program for developing treatment plan for Peritoneal Dialysis 41049003

Sharesource Adequest

【Shape, Structure and Principle】

Outline

This product is a tool to assist clinicians in defining patient peritoneal membrane transport characteristics and peritoneal dialysis adequacy as well as in modeling of solute clearances, fluid removal and carbohydrate absorption based on therapy parameters provided by the clinician.

This product is stand-alone software (not an accessory), used in calculations for both Continuous Ambulatory PD (CAPD) and Automated PD (APD). Its use is not dependent upon any information from PD instrumentation and this product will not autofill or directly input any therapy models (regimens) into the PD instrumentation.

This product is a cloud-based software which utilizes the same platform as “Sharesource” (Approval No.: 22800BZX00345000, Baxter KK) and is accessed via internet connection using a general-purpose browser accessing to the same URL as “Sharesource” with the same account information.

Primary functions

Item	Descriptions
(1) Calculation and display using 24h collection data	This product calculates and displays indexes related to residual renal functions and dialysis adequacy, using the basic patient data and 24 h collection data registered by user. [Output (Calculated values)] Total Body Water / Body Surface Area / UF / Fluid Removal / Urea Kt/V / CCL / nPCR / Est GFR / Urea Generation Rate / Creatinine Generation Rate
(2) Calculation and display using PET collection data	This product calculates and displays indexes related to peritoneal membrane transport characteristics, using the basic patient data and PET collection data registered by user. [Output (Calculated values)] <Standard PET, Modified PET, Fast PET> Total Body Water / Body Surface Area / D/P Urea nitrogen / D/P Cre / D/D0 Glu (only for Standard PET) / D/P Na (Only for Modified PET) / QL / Residual Dialysate Volume / LPA In addition, PET curve and transport classification (Low, Low Average, High Average, High) are displayed.

Item	Descriptions
(2) Calculation and display using PET collection data (Continued)	<Mini PET> Total Body Water / Body Surface Area / UFSP / FWT / DipNa / Dip D/P Na / NaR
(3) Prediction and display of dialysis indexes based on regimen	This product predicts dialysis efficacy indexes for the patient treated by the specific regimen given by the user. [Output (Calculated values)] UF / Effluent / Carbohydrates Absorbed // Urea Kt/V / CCL
(4) Report generation	This product generates the following reports: <ul style="list-style-type: none"> • Clinic Quality Assurance Targets (all patients that are below the targets set in the Adequest Clinic Setting screen) • Clinic Report-Patients with 24 Hour Collections • Clinic Report-Patients with PET Collections • Clinic Report-Patients with Regimens • Patient History-24 Hour Collections (Patient-specific report that displays all 24 hour collections for the date range Entered) • Patient History-PET Collections (Patient specific report displaying all PET collections for the date range entered) • Patient History-Regimens (Patient specific report displaying all saved regimens for the date range entered)
(5) Adequest Clinic wide setting	This product allows users to set units, target values, calculation method and creatinine correction factor used in the clinic.
(6) Adequest Patient management	This product allows users to add patients from “Sharesource” to this product, available for edit, view and search in this product.

Ensure to refer to user guide

Secondary functions (Non medical device functions)

	Item	Descriptions
(1)	Patient Administration	This product allows users to register, edit, view and search patient's information.
(2)	User Management	This product allows users to register, edit, view, search and assign roles and responsibilities to users.

In case the user is using "Sharesource", those functions will be shared with "Sharesource" (It is not mandatory to use Primary Functions of "Sharesource" (Clinical tab) to use this product. When the user doesn't have the role to use it, it will be not shown).

Principle

Outline

When the user input data on a web browser in general purpose computer, the data will be sent to this program in the servers via internet. After processing the data as necessary, this program sends the result back to the web browser of the user via internet and displays it on the browser.

Principle of primary functions

When the user input the patient basic data and 24 h and PET collection data, this program calculates indexes related to (1) peritoneal dialysis adequacy including residual renal function and (2) patient peritoneal membrane transport characteristics. In addition, when a regimen is given, the program applies those regimen parameters and pre-calculated patient specific values as necessary to the mass transportation model and (3) predict dialysis effect indexes in case the patient is treated with the given regimen.

Calculation principle

(1) Calculation and display using 24h collection data

Calculations are made using the known calculation methods reported in JSDT PD guideline and NKF KDOQI guideline (PERITONEAL DIALYSIS ADEQUACY) and the four basic arithmetic operators.

(2) Calculation and display using PET collection data

QL and LPA calculations are based on the known equations describing the dialysate volume as a function of time (equation 21 of Vonesh EF, Lysaght MJ, Moran J, Farrell P: Kinetic modeling as a prescription aid in peritoneal dialysis. Blood Purif 9: 246-270, 1991) and use measurements from PET. Other calculations are made by the four basic arithmetic operators.

(3) Prediction of dialysis indexes based on regimen

Predictions of dialysis indexes are determined by simulations using the mathematical model based on two compartment model by Pyle-Popovich with adoption of three-pore theory by Ripple et al. Calculations are based on the mass balance equations published in the literature (equations A1 and A2 of Vonesh EF, Vonesh EF, Story KO, O'Neill WT for the PD Adequest International Study Group: A multinational clinical validation study of PD Adequest 2.0. Perit Dial Int 1999; 19:556-571.) and the model utilizes the lumped sum reflection coefficients that have been shown to be mathematically equivalent to the three-pore kinetic model (Vonesh EF, Rippe B: Net fluid absorption under membrane transport models of peritoneal dialysis. Blood Purif 10: 209-226, 1992). The differential equations of the mathematical model are solved using Runge-Kutta fourth-order numerical method to predict fluid and solute removal (i.e. dialysis indexes).

Refer to Sharesource Adequest User Guide Appendix A for calculation details

【Intended Use or Indications】

This product is intended to assist clinicians in defining patient peritoneal membrane transport characteristics and peritoneal dialysis adequacy as well as in modeling of solute clearances, fluid removal and carbohydrate absorption based on therapy parameters provided by the clinician.

It is not intended to be a substitute for good clinical management practices, nor does its operation create decisions or treatment pathways.

【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. Information will also 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. ^{Note 1)}

1. Preparation and initial login

Contact the registered clinic user manager to apply for a user account. ^{Note 2)} Clinic user manager will create an account, assign proper roles (Patient Manager, Basic Adequest Access, Sharesource Adequest Data Manager, Sharesource Adequest Setting 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.

[Adequest] Tab

• Adequest Dashboard-

Displays patient lists, allow you to search patients and add patient from "Sharesource".

• Patient Summary

Allows you to use functions related to 24 h collections, PET collections and regimens of a patient. Click an appropriate link or button to edit or add new data and obtain calculations and predictions.

• Adequest setting (editable only for Sharesource Adequest Setting Manager)

Allows you to set units, target values, calculation method and creatinine correction factor used in the clinic

[Report] Tab ^{Note 3)}

Generate reports:

[Patient Administration] Tab ^{Note 3)} (Displayed only for Patient Manager)

• Click this tab to add new patients or search, view and edit patient information.

[Users] Tab ^{Note 3)} (Displayed only for Clinic User Managers)

• Click this tab to 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.

Note 1) Clinics already using “Sharesource” still need to apply for use of this product.

Note 2) For users already using “Sharesource”, request Clinic user manager for additional roles related to this product.

Note 3) For users using “Sharesource”, these tabs are shared with “Sharesource

(5) Edward F Vonesh, et al. Kinetic modeling as a prescription aid in peritoneal dialysis. Blood Purif. 1991; 9: 246-270.

Refer to Sharesource Adequest User Guide Appendix C for more references.

[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. To obtain more accurate results, ensure that data input is correct.
6. The activation link for account set-up expires in 10 days, so you must complete your account set-up within that time.
7. The activation link for account set-up expires in 10 days, so you must create a password within that time.
8. Users must change their passwords every 365 days.

【Contact Information for marketing authorization holder and manufacturer】

Marketing Authorization Holder (Imported by):
Baxter Limited
TEL: 03 (6204) 3700 (The same as the contact for references)

Manufacturer:
Baxter Healthcare Corporation (United States of America)

【Precautions】

1. Important Precautions

- (1) Regimens need to be decided by doctors, referring to PD guideline from JSDT, etc. and considering all indexes for dialysis adequacy. [Results of calculation by this product is reference purpose only.]
- (2) 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.
- (3) For security reasons, ensure to always completely log out of this product after you are finished using it.

【References and contact information for requests for disclosure】

1. References

- (1) PD guideline revision WG, ed. PD guideline 2019. Igakutosho shuppan. 2019.
- (2) Vonesh EF, Story KO, O'Neill WT. A multinational clinical validation study of PD ADEQUEST 2.0 Perit Dial Int. 1999; 19: 556-571.
- (3) Edward F Vonesh, et al. Peritoneal dialysis kinetic modeling: validation in a multicenter clinical study. Perit Dial Int. 1996; 16: 471-481.
- (4) Vonesh EF, Rippe B: Net fluid absorption under membrane transport models of peritoneal dialysis. Blood Purif. 1992; 10: 209-226.

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Baxter Limited