

pts connect™ Universal Solution

Portable connectivity and data management system

User Guide

Intended Use

The PTS Connect™ universal solution is intended for use by the professional customer. The professional customer will be able to connect wired and wireless PTS Diagnostics analyzers to the PTS Connect universal solution. The PTS Connect universal solution will collect test results from the connected devices, generate patient reports, and allow the user to export data.

Materials Needed

- PTS Connect universal solution device
- CardioChek Link® cables (used for connecting CardioChek® PA or CardioChek Plus analyzers to the PTS Connect universal solution device)
- PTS Connect adapter featuring Bluetooth® technology (used for connecting CardioChek PA or CardioChek Plus analyzers to the PTS Connect universal solution device)
- PTS Connect dock (used for transferring the results from the A1CNow® system and the PTS Detect® cotinine system)
- Computer, tablet, or smartphone (to access web interface)

Creating an Event

1. Plug the AC adapter into the PTS Connect universal solution device and plug into a wall outlet.
2. Allow at least 1 minute for the PTS Connect universal solution device to boot up.
3. Connect to the PTS Connect universal solution wireless network by searching for "PTSConnect" in your available wireless networks application on your device using the password: "theptsconnect."
4. Once connected to the PTS Connect universal solution wireless network, open a web browser and type <http://192.168.42.1/client> in the address bar.
5. The PTS Connect universal solution login screen will appear.
6. Login to the PTS Connect universal solution using:
Username: admin
Password: admin
7. Click the "Add New Event" button.
8. Enter the "Event Name," "Company Name," and "Event Description."
9. Select the test that will be used for the event by clicking the "Use" button next to each test. You do not have to click the "Don't Use" button for the other tests; this is the default selection.
10. Select the parameters that will be available during the event by ensuring there is a checkmark in the "Include" box located to the right of the parameter.
11. Click the "Add" button to finish adding the event.

Uploading an Eligibility File to the Event

1. If you are not already in an "Event," click the "Show All Events" button and click the event from the event list.
2. Click the "Upload Eligibility File" button.
3. An "Open" box will appear. Browse to the location of the CSV eligibility file. Then select the file and click the "Open" button.
4. After a few seconds, a list of the uploaded participants will appear. Click "OK" to accept the upload.
5. You will now see the total number of participants listed next to "Participants Tested."

Participant Testing with the PTS Connect Universal Solution

1. Power up the PTS Connect universal solution device with any desired cables attached.
2. Login to the PTS Connect universal solution using:
Username: admin
Password: admin
3. Click the "Show All Events" button and click the "Event" that you would like to use.
4. Click the "Use this Instrument" button next to the analyzer that you would like to use.
5. Click the "Select this Test" button next to the test type that you would like to use.
6. Click the "Show All Patients" button and select the appropriate participant.
7. Enter the "Participant Observation" information in the appropriate fields. (All fields do not have to be completed—only complete the fields for the information you will be collecting.)
Note: Height, weight, and blood pressure, tobacco and diabetes questions must be filled in and answered for a Cardiac Age to be calculated.
8. Check the "Signed Consent Form" box and click the "Save" button.
9. If you are using the PTS Connect dock to capture the results from the A1CNow system and/or PTS Detect cotinine system, click the "Get Dock Result" button and follow the onscreen prompts. You will need to click this button between each capture of these two devices.
10. Click the "Queue Participant" button to prepare the PTS Connect universal solution to receive the CardioChek results. If you are using the CardioChek Plus wirelessly, the name of the participant will be displayed on the screen of the CardioChek Plus analyzer.
11. The PTS Connect universal solution will display a "Waiting for Results from Instrument" message. Perform the test on the analyzer.
12. Once the testing on the analyzer has completed, the results will be transferred to the PTS Connect universal solution. The results will be displayed on the "Clinician View Report." To access the "Participant Report," click the "Participant Report" button located at the bottom of the screen.
13. The "Participant Report" can be printed using the print function of your chosen web browser or you can download a PDF file of the report by clicking the "Download Report (PDF)" button. Once you have finished using the "Participant Report," close the tab in your web browser.
14. To continue to the next participant, click the "Next Participant" button located at the bottom of the screen.

Uploading the Event to the Cloud, Downloading the CSV report, and Closing Events

1. Power up the PTS Connect universal solution device.
2. Login to the PTS Connect universal solution using:
Username: admin
Password: admin
3. Connect the PTS Connect universal solution to the network using an Ethernet cable plugged into the Ethernet port on the device.
4. Click the "Upload" button. A message will appear stating that the PTS Connect universal solution is attempting to upload the event database to the cloud. This may take a minute. Once done, click the "OK" button. This process must be completed for each event as the PTS Connect universal solution has the ability to hold 10 events. If this upload process has not been completed prior to closing an event, one event will be deducted from the 10 allotted events.
5. Once the upload has completed, a "Successfully uploaded event data to cloud host" message will appear. Click the "OK" button to complete.
6. Click the "Download Event Data" button.
7. A CSV file with the name of the event and the date will begin to download to your default download folder. Once this file download is complete, the event can be closed.
8. Click the "Close Event" button. A warning message will appear stating that clicking the "Closing the Event" will delete the event AND all associated patient health information.
IMPORTANT: This process must be completed for each event as the PTS Connect universal solution has the ability to hold 10 events. If this upload process has not been completed prior to closing an event, one event will be deducted from the 10 allotted events. This is a permanent delete and the data cannot be retrieved if the event has not been uploaded to the cloud host prior to clicking the "Close Event" button.
9. Click the "Close Event" button next to the warning message. A message will pop up confirming the closing of the event. Click the "OK" button.
10. An "Event Closed" message will appear. Click the "OK" button.
11. The event has now been removed from the PTS Connect universal solution, and all associated data deleted.

Administration

1. Power up the PTS Connect universal solution device.
2. Login to the PTS Connect universal solution using:
Username: su
Password: su
3. Click the "Admin" button located at the top center of the screen.

Adding New Users in the New User Section

1. Enter desired username in the "Email Address/Username" field.
2. Enter desired password in the "Password" field.
3. Click the "Add" button. You will need to do this for each user to be added to the system.

Changing the SSID and Password of the Wireless Access Point in the Administration Section

1. Enter the desired SSID in the top box. "PTSConnect" is the default SSID name.
2. Enter the desired wireless password in the second box (password must be at least 8 characters). "theptsconnect" is the default wireless password.
3. Click the "Update WiFi Configuration" button. You will need to power off the PTS Connect universal solution for the changed to take effect.

Configuration of the PTS Connect Universal Solution

NOTE: The PTS Connect universal solution is designed to be used with CardioChek PA and CardioChek Plus analyzers operating in the English language.

1. If you would like to add a custom logo, click the "Upload New Logo" button and browse to the location of your logo.
2. Select the units that you would like the results to be captured in by clicking the "US or Metric" button.
3. There are two report types available. Standard contains large graphs with ranges and can typically take 2 to 4 pages for a complete report. The Condensed report contains smaller graphs and typically takes only 2 pages for the complete report.
4. The date and time of the PTS Connect universal solution can be set using the date and time boxes.
5. Once all configuration settings have been selected, click the "Save Configuration" button to save all changes.

Customizing Participant Observation Parameters

This section contains the parameters that are available for capture in the PTS Connect universal solution. These parameters can be removed or new custom parameters can be created. Please contact PTS Diagnostics Customer Service for assistance with customizing these parameters.

Updating Reference Ranges

The section allows customers to customize the target ranges of the graphs on the participant report. Please contact PTS Diagnostics Customer Service for assistance with customizing these ranges.

Customer Service

For assistance with the PTS Connect universal solution, call PTS Diagnostics Customer Service (M-F, 6 a.m. - 9 p.m. US EST):

Toll-free in the US: 1-877-870-5610

Direct: +1-317-870-5610

Fax: +1-317-870-5608

Email: customerservice@ptsdiagnostics.com

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Explanation of Symbols

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| LOT | Batch code | | This product fulfills the requirements of European Directive 98/79 EC on <i>in vitro</i> diagnostic medical devices. |
| REF | Catalog number | | Separate collection: batteries must be disposed of in accordance with laws in your country. Contact your competent local administration for information on the relevant laws regarding disposal and recycling in your area. |
| | Consult instructions for use | | Authorized representative in the European Community. |
| | Manufacturer | | Serial number |

