

PPR: Frequently Asked Questions

Paperless Process Recorder with Legendary™ Cloud Software: Frequently Asked Questions

1. PPR Setup and Configuration

1.1 How many inputs and outputs does the STLR version of PPR have available? Inputs:

- 1 STLR input (dual 3-wire PT1000 RTD)
- 1 SFLR input (mA)
- 1 Universal input (mA, V or 3-wire PT100 RTD)

Outputs:

- 4mA outputs: 0...20mA, 4...20mA out
- 4 relay outputs

Pasteurization Control Outputs:

- STLR Control Relay
- SFLR Control Relay (Hi flow and Loss of signal alarms set point control combined into one relay)

1.2 How many inputs and outputs does the non-STLR PPR have?

Inputs:

Up to 4 Universal inputs (mA, V or 3-wire Pt100 RTD)

Outputs

- 4mA outputs: 0...20mA, 4...20mA out
- 4 relay outputs

1.3 Will PPR have more inputs/outputs in the future?

PPR will have 8 universal inputs in the future. The number of analog outputs will remain at 4 but may be supplemented by Ethernet/IP in the future

1.4 Will PPR with STLR have STLR Relay Termination Board?

Yes, PPR is configurable with a similar STLR Relay termination board that is used in the AV9900 today.

1.5 Will PPR with STLR replace legal PLC?

No. A Legal PLC will still be required in most PMO pasteurization.

1.6 Does PPR have PID control?

No, if you're replacing a paper recorder that had PID control function they will either need to control the loop with the PLC or another standalone controller like the Anderson 801. mA retransmission is available on PPR.

1.7 Do I need to buy new sensors?

Probably not, analog sensors (RTD, mA, Voltage) that are common in recording applications will all work with the PPR

However, similar to current AV9900 if a new STLR system is being built, an SB Temperature sensor probe needs to be ordered separately.

- 1.8 Are the system power requirements the same as AV9000 & AV9900?

 No, to improve safety and reliability we have changed the power requirements from AC to 24VDC.
- **1.9** Does STLR PPR work with single element RTD for STLR measurement/control? No, PPR will continue to use dual Pt1000 RTD i.e. SB temperature sensor.

1.10 Will PPR STLR sensor imbalance cause a system divert event in UHT applications like AV9900 does today?

No, sensor imbalance conditions are adjusted in PPR to accommodate applications like UHT where rapid temperature fluctuations are common so that such an event will not divert the system. The dual RTD will continue to monitor permanent RTD drift and RTD failures and display the imbalance when measured.

- 1.11 Are there any other input or output changes I need to prepare for before installing a PPR Yes, PPR needs a 24VDC power supply and Ethernet connection that will allow the PPR to communicate through the company's network to the Legendary™ Cloud Software.
- 1.12 Who can configure and calibrate the PPR.

Uses managed by the Client's Legendary™ Administrator with Access Level =1 have the capability of configuring and calibrating the PPR. Note: the Run/Program jumper may also inhibit the ability to configure and calibrate the system

- 1.13 Can I save the current PPR configuration and copy it to a new unit in case of replacement?

 Not with the current version of software, look forward to this feature being added through a software update in the future.
- 1.14 How will a user change the current STLR diversion set point?

PPR allows for up to 15 STLR diversion set points to be configured when the PPR is in Program Mode. During runtime any user can select or change the current diversion setpoint through the PPR HMI. Configuration of these setpoints is inhibited while the PPR is in Run Mode. Remote STLR set points are not available on PPR at this time.

1.15 Can a user change the SFLR set points (flow alarms)?

PPR allows for configuration of the Loss of Signal and High Flow alarm set points when the PPR is in Program Mode. These two set points work together with the SFLR input measurement to drive the SFLR control relay output.

2. PPR - General

2.1 Will PPR work if there is no internet?

Yes, PPR will continue to work and record all process data regardless of internet connectivity. PPR users can continue to annotate and complete approval workflow even when there is no internet, but will need to do so at the PPR rather than in Legendary™.

2.2 What will happen to data collected and charts created while the PPR is not connected to the Legendary™ Cloud Software?

All records (digital charts, annotations and approvals) are always backed up locally within PPR regardless of internet connectivity and those created while internet was down will be synced with Legendary™ once the internet connectivity is restored.

2.3 How much data can PPR store internally?

PPR will store have a minimum of >7 years of process data, including sensor inputs, and user annotations as well as 2 Years of latest revision chart record images in internal (non-removable) memory

2.4 How much data can PPR store on the removable MicroSD card?

PPR also has a removable microSD memory card located on the System on Module Board that is used as a secondary backup. It will hold the last 100 days of the latest revision of each PPR record images as well as the last 100 days of 24 hour backup records.

2.5 Does PPR have a battery backup?

PPR has a CR2032 coin battery backup but solely for the purpose of maintaining the recorders real-time clock. The battery is field replaceable and will ensure system date/time is accurate for a minimum period of 1 month in an unpowered recorder.

If the battery is completely drained or is removed while PPR is powered off, PPR system date/time will have to be reconfigured through syncing with the Legendary™ Cloud Server.

Note: For PMO compliance, PPR needs to be powered through UPS capable of maintaining power to PPR for twenty (20) minutes.

2.6 Will PPR lose configuration/calibration if battery is removed?

No. PPR will save configuration/calibration information in its internal memory and will be preserved even if battery is removed or power is lost.

2.7 How many simultaneous records can PPR create?

The PPR can be configured to create just one record at a time, or up to one record per sensor input. This allows for multiple paper recorders to be consolidated to a single PPR in many applications.

2.8 Can I print a chart from the PPR?

Local printing from PPR is not available. However, record images can be downloaded and printed from Legendary™

2.9 Is PPR touchscreen capacitive or resistive?

Capacitive.

2.10 Is the PPR device and its touchscreen waterproof?

Yes, the Stainless enclosure is built for washdown environments. Product carries a NEMA 4X rating.

2.11 Can someone change PPR input and output configuration remotely?

No, to comply with some requirements within the PMO no PPR configuration changes can be executed remotely.

2.12 How do I know that internet connection through PPR is secure?

Transport Layer Security (TLS) is used for data communications and web service transmissions between the PPR and Legendary™ via secure Representational State Transfer (REST) API service calls over HTTPS. TLS encryption ensures that no third party may eavesdrop or tamper with any data in transit.

2.13 Can PPR work with an active directory of Microsoft Accounts?

PPR/Legendary™ currently does not support single sign-on (SSO) but it is on the future product roadmap.

However, PPR/Legendary[™] information can be imported into Legendary[™] using the data import tool, or using web services from source employee HR systems, of flat files. User access is granted or revoked by the organization's own Legendary[™] System Administrator.

2.14 How will the product be improved over time?

The PPR is designed to utilize over the air software and firmware updates so continuous improvements to the technology will be easy for a plant to install.

2.15 How often does the PPR software need to be updated?

Anderson-Negele plans to release a new software package periodically. These updates will include product improvements as well as bug fixes (if applicable). The expected cadence for the release of software updates in 2022 is quarterly.

2.16 Are software updates optional?

Yes, all software updates need to be installed by an authorized PPR user at the device (remote installation is not possible). Furthermore, the plant has the choice of if and when they will install updates and can align these updates with regulatory inspection or process down time.

3. Legendary™

3.1 How do I access Legendary™?

The URL to access Legendary[™] software for your organization will be emailed to you when your account is created. Contact your organization's Legendary[™] Administrator or Anderson-Negele customer success, if needed.

3.2 What do I need to install to access Legendary™?

Nothing, because Legendary[™] is cloud based, any web enabled device with an internet browser will allow you to access the Legendary[™] software.

3.3 How do I know if PPR is connected to Legendary™?

There is a visual cloud connectivity status icon in the top right corner of the PPR home screen. Checkmark is connected, X symbol means the system is disconnected.

3.4 Is there an on-premises version of Legendary™?

No, there is no on-premises version or Legendary TM . It is a cloud only solution and accessible from any device with internet access.

3.5 How will state inspector or other auditors sign-off records?

Inspectors and auditors can be granted access to the PPR and Legendary[™] by the organization's Legendary[™] Administrator using the "Inspector" Legendary[™] Role. Once set up they can execute the Inspector review workflow in Legendary[™] allowing them to add approvals or other notes to a record.

3.6 Will state inspector or other auditors be able to view our records or sign-off records remotely?

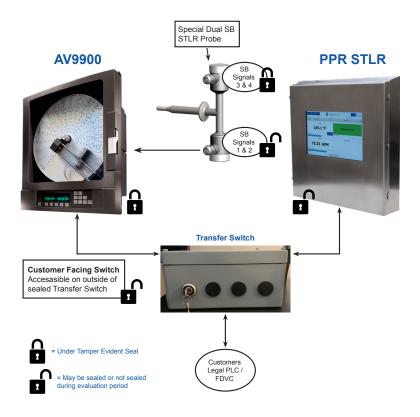
Yes, but only when the organization's Legendary[™] Administrator grants them access to do so through Legendary[™]. The organization's Legendary[™] Admin. can enable/disable access for any user at any time.

4. Regulatory

4.1 Can the PPR unit be installed in parallel with an existing paper recorder in STLR applications for an evaluation period?

Yes, Anderson-Negele can manufacture a Dual SB STLR Probe and Control Transfer Switch to connect PPR in parallel with the existing recorder/controller.

- -Dual SB STLR Probe: Will have four RTDs in total. One to two of them will go to existing recorder and the other two will go to the PPR. Both sets of 2 RTDs are completely independent of each other.
- -Control Transfer Switch: A control transfer switch box will have an external key switch which can be used to control/monitor FDVC either using existing recorder only or using existing recorder outputs/inputs in series with PPR.



4.2 Is PPR PMO approved?

PMO "Approval" doesn't really exist however;

The PPR currently meets the requirements of the PMO for non-STLR applications such as cold storage or CIP. No federal equipment review (FDA) is required for these applications. Anderson-Negele has published an application guide that shows how PPR meets each of the requirements in PMO Appendix H Section V.

The PPR also meets the requirements of the PMO for STLR&SFLR applications, in such applications many regulatory bodies do seek the FDA equipment review in the form of an equipment Memorandum (M-b). The Anderson-Negele team submitted the PPR to the Atlantic Midwest Dairy Equipment Review Committee (AMDERC) in May of 2021 as a first step to get their approval and ultimately an FDA (M-b) that shows compliance to PMO Appendix H Section VI requirement for use in all US states.

Anderson-Negele has published an application guide that shows how PPR meets each of the requirements in PMO Appendix H Section VI.

4.3 Can a dairy plant use PPR for PMO application without FDA memo?

For non-STLR applications, Yes. There is no need for, or way to obtain an FDA memo, the product is ready today.

For STLR application, Yes, In general, regardless of whether a system has an FDA memo or not, every state inspector must certify each system independently to validate that it meets all PMO requirements, which can happen today.

The benefit of having an FDA memo is that it gives assurance to the plant and state inspector that all PMO requirements are met, which reduces their risk in testing and accepting the system, that is why we are working diligently to obtain the memo for STLR applications

4.4 Is PPR 21 CFR Part 11 compliant?

The PPR is designed to meet the requirements of 21 CFR Part 11, however it is the client's responsibility to validate their application when using the PPR and Legendary™ for process recording.

4.5 Do I need to comply with 21 CFR Part 11 when I start recording electronically?

Possibly, when PPR is used in non-dairy applications for a process which creates a food or drug product, compliance to 21 CFR Part 11 typically required. Grade "A" Milk products are not subject to 21 CFR Part 11 as the PMO is not a federal regulation. Non grade "A" food applications that are regulated by FSMA (21 CFR Part 117) are exempt from 21 CFR Part 11 in 21 CFR 117.305(g). Check with applicable regulatory agencies for additional information.

4.6 Does PPR have physical tamper evident seals?

Yes, tamper evident sealing covers can be selected as part of the PPR order matrix, or as a spare part.

4.7 What if internet is down or Legendary[™] is not accessible during state inspection? If Legendary[™] is not accessible for any reason during an audit or state inspection, the microSD card can removed from PPR and used in any computer to access last 100 days of record imaged. Alternatively, those charts can be reviewed locally using PPR touch screen display.

4.8 Does PPR need to be used with Uninterrupted Power Supply (UPS)?

Yes, to comply with PMO Appendix H Section V the PPR will have to be powered through UPS capable of maintaining power to PPR for twenty (20) minutes. PPR consumes a maximum of 48 watts and would require ≥ 0.66 amp hour UPS.

5. Subscription

5.1 Can I just purchase PPR and not Legendary™ subscription?

No, a subscription to Legendary[™] software must be purchased with each PPR. In addition to the improved approval workflow that Legendary[™] offers it is also utilized for user management and PPR software updates.

5.2 How much is a subscription fee and how is it structured?

Refer to price page for latest software subscription fee. Subscription fee is per PPR and available in 3 or 5-year term. Discounts are available when multi-year terms are selected.

5.3 Does subscription depend on number of users? Is there a limitation on number of users? No, subscription is not dependent on number of users and there is no limitation to number of Legendary™ or PPR users.

6. Support

6.1 How do I get support if an issue is encountered in Legendary™?

Please contact Anderson-Negele customer success team, 800-833-0081 or PPR-LD-AE@ Anderson-Negele.com .

6.2 What if I have a PPR or Legendary™ related questions?

The PPR and Legendary™ Operating Manuals will have information required for typical product configuration, operation and troubleshooting. These documents and additional supporting material can be found on the Product Start Up Page

Anderson-Negele's <u>YouTube Channel</u> is a great resource for training and how to videos on the product.

If none of these sources answer your question, please contact Anderson-Negele customer success team, 800-833-0081 or PPR-LD-AE@Anderson-Negele.com

6.3 What is the warranty period?

2 years from date of shipment

Phone: 800-833-0081 Fax: 518-922-8997 info@anderson-negele.com Technical Support
PPR-LD-AE@anderson-negele.com
Phone: 800-833-0081