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Supported Systems and Content

- Which Systems and instruments are included for DP 2019 R1?
 - o ACQUITY UPLC "Classic", ACQUITY UPLC I/H-Class Series, ACQUITY UPC2, APC, Arc, Arc Bio
 - QDa, SQD, TQD and SQD2
 - WFMA, ISM
 - HPLC and UPLC Detectors and Accessories
- Which Systems and instruments are NOT included for DP 2019 R1?
 - Waters' Model 2432 Conductivity Detector
 - o WFC3
 - o PATROL Process Sample Manager
 - o 25X5 Series Pumps
- What features are specifically supported for the ACQUITY UPLC PLUS Series Instruments or ACQUITY UPLC Systems that have been upgraded to PLUS and included in DP 2019R1?
 - Please review the <u>Instrument Control Software Driver Packs (ICOPs) and Third Party</u>
 Control Wiki
 - Solvent Manager enhancements:
 - New degasser hardware vacuum performance is supported by firmware enhancements in BSM, QSM, QSM-R and ISM in DP 2019 R1.
 - Implemented in Console Troubleshooting Menu, in BSM, QSM, QSM-R and now in DP 2019 R1 the ISM, the Degasser Health Check provides enhanced self-diagnostic behavior and error checking upon installation and start-up. If an error is found, more intuitive error messages and alarms help pinpoint the source of failure leading to simplified troubleshooting and faster instrument recovery.
 - Sample Manager enhancements:
 - Firmware Sample compartment cooling performance improvements independent of ambient environmental conditions – FTN and FL
- Are there any changes in the Driver Pack that would affect customers' existing methods?
 - No, all existing methods are supported.

- Can DP 2019 R1 be supported with IVD Systems?
 - No, although ACQUITY UPLC I-Class (PLUS) is supported by DP 2019 R1, the IVD version is not.
- What are the major new features included in DP 2019 R1?
 - There is a new Start-up Work Flow to simplify equilibration of the systems before use. It is implemented for all ACQUITY UPLC System Series and all ACQUITY Arc Systems
 - The DP 2019 R1 simplifies configuration of the new ACQUITY UPLC H-Class Binary System is supported. The BSM has a means to configure the pump for use in an ACQUITY UPLC I-Class System at 18,000 backpressure maximum pressure or in an ACQUITY UPLC H-Class System at 15,000 backpressure maximum
 - o Enhancements to the ACQUITY QDa
 - Defects for HPLC Detectors were addressed
 - o The DP media includes Waters Model 2707 Autoinjector

Ordering, Installation and Service

- How can customers obtain the new Driver Pack?
 - The new firmware included on the media will be implemented into manufacturing and shipped with instruments in May 2019. DP 2019 R1 includes new firmware for the BSM, QSM, QSM-R and ISM.
 - DP 2019 R1 will be included in all major System Kits: ACQUITY UPLC "Classic", ACQUITY UPLC
 I/H-Class Series, ACQUITY UPC², APC, Arc, Arc Bio
 - Customers can order using p/n 667005973 (at no charge) or it will be available to download from waters.com (Services and Support> Software Services and Support> Drivers/Updates) at this LINK (available mid May 2019)
- How should DP 2019 R1 be deployed/installed?
 - As usual, the recommended and evaluated deployment of a new DP is to use a "Typical" installation. You should first check if the firmware that is currently installed on instruments is at a version compatible with the new Driver Pack.
 - o If a subset of the Driver Pack is installed, ("Custom" install) there is a risk that full functionality may not be possible. For example: if you choose <u>not</u> to install a new version of an existing instrument driver, there is a possibility that the new infrastructure in DP 2019 R1 will overwrite that of the older driver and the existing ICS will stop functioning. This is because some files included in the driver packs are common and will be updated, regardless of whether a specific ICS is omitted. The greater the difference in version between the driver packs the higher the risk this issue could occur. Consult with WGS Global support to discuss the customer's specific example.
- How do I use the Compatibility Matrix?
 - The matrix is designed to show which ICS (version 1.XX.XXXX) and [Firmware] versions are compatible with a given driver pack. Additionally, for Empower Enterprise, it indicates the

interoperability of the LAC/Es, as each may have a different driver pack installed. On any LAC/E only one driver pack and its complementary firmware should be installed.

- Should the module firmware be updated before DP 2019 R1 is installed?
 - Yes, the firmware should match the driver pack that has been installed, either use the AutoLoader to update the firmware before or after loading the Instrument Control Software Drivers. The AutoLoader is part of the ACQUITY UPLC Systems Deployment manager. Without the firmware some of the new hardware and/or features will not be available or work as well. For regulated customers check when their next system re-qualification is due and advise them to update then
- Can I install the new DP 2019 R1 Firmware on older instruments?
 - The current version of firmware is designed to work with older ICSs. In some cases this may not be possible. Consult the CIG to learn about any issues.
- Can I install the new DP 2019 R1 ICS with instruments that use older versions of Firmware?
 - In general, the current version of firmware is designed to work with current ICSs. This is the
 recommended way to operate and allows the users to access all the features of a specific
 ICS. If the firmware is older than the ICS any new features will not be supported.
 - In many cases this may be possible. Consult with WGS Global support to discuss the customer's specific example.

MassLynx

- Which SCNs is DP 2019 R1 currently supported with?
 - The new DP has been tested with SCN 984 and 976 specifically.
- Are all the systems contained in DP 2019 R1 fully supported with Windows 10 OS?
 - o For Windows 10 compatibility many of the current MassLynx SCNs (version 4.2) already support Windows 10 because these SCNs incorporate DP 2017 R1. For most installations Waters recommends using DP 2017 R1 as this has been tested with the specific SCN required. However, it is acceptable to keep the firmware for new instruments at the current version. The evaluation of DP 2019 R1 included testing to confirm upgrading to DP 2019 R1 performed correctly. However, DP 2019 R1 has not been tested with each current SCN.

Empower

- What version of Empower is DP 2019 R1 compatible with?
 - DP 2019 R1 is fully compatible with Empower 3 from base to current version. The DP 2019 R1 has been tested with Empower 3 SR3 and FR4.
- Many customers are looking at updates to support Windows 10 with Empower, is DP 2019 R1 a good choice.
 - DP 2019 R1 driver pack enables Windows 10 compatibility and includes the latest features and firmware for the majority of Waters' systems and is an excellent choice for a user considering a major upgrade of Empower to support Windows 10 OS. Consult

with your customer and Informatics Specialists and consider what is best and easiest for each user in terms of immediate change.

How do we navigate the discussion with customers (especially Empower Enterprise customers) regarding the purchase of new system purchase, correction of a defect or a general upgrade to an existing install, where installation of DP 2019 R1 would be the most advantageous? Note:
 When ACQUITY UPLC PLUS System firmware is downgraded to firmware versions available prior to DP 2019 R1, then effectively the systems functionality will be equivalent to non-PLUS ACQUITY UPLC Systems and will support the same compatibility as current ACQUITY UPLC Systems

Example 1 - A new ACQUITY UPLC H-Class Binary System

- For new purchases of ACQUITY UPLC PLUS Series Systems including ACQUITY UPLC H-Class Binary Systems, upgrading to DP 2019 R1 is recommended, so the customer can leverage all the new "PLUS" features and configure the new ACQUITY UPLC H-Class Binary System backpressure maximum available in DP 2019 R1. Depending on the implementation, if the customer is utilizing an existing Empower Enterprise, there are a variety of options for this situation:
 - Option 1: Install UPLC PLUS Series hardware under customers' existing driver pack (depending on how far back the version of the current driver), Then update to the most up-to-date driver when the customer plans to update their infrastructure. All new UPLC PLUS Series systems will work under the older driver pack, however, the customer will not experience the full benefits of the system. It is strongly recommended that you do not downgrade the firmware, as in general new firmware is compatible with older driver packs.
 - Option 2: Update to Driver Pack 2019 R1 on the server and leave the LAC/E modules with at their current driver pack level for existing instruments and only host the Driver Pack 2019 R1 on LAC/E modules supporting the new systems. In this case, any currently systems or instruments on the LAC/E where DP 2019 R1 will be deployed must be upgraded to DP 2019 R1 versions.
 - Option 3 Update full infrastructure to Driver Pack 2019 R1. Again, any currently systems or instruments on the LAC/E where DP 2019 R1 will be deployed must be upgraded to DP 2019 R1 versions.

For these examples of an Empower Enterprise Installation, a conversation with your Informatics Data Specialist is required.

Third Party CDS (Analyst, Chromeleon, XCalibur etc.)

- Is DP 2019 R1 compatible with Analyst Software from AB Sciex?
 - Yes, DP 2019 R1 was tested with Analyst version 1.7X and both Windows 7 and 10 OS.
- Which third party CDS software with the new Driver Pack?

- Currently, Waters only tests AB Sciex Analyst Software. DP 2019 R1 has been evaluated with version 1.7.X of Analyst CDS. All security modes for Analyst software are supported.
- Agilent (OpenLab and ChemStation), Bruker (HyStar) and Thermo (Chromeleon and XCalibur), test their own drivers were notified of the release of Driver Pack 2019 Release 1 and will incorporate the new driver, based upon their own business decisions.
 - Thermo has announced to some of their users that ACQUITY UPLC QSM and FTN will be updated (XCalibur) and the addition of ACQUITY Arc support (Chromeleon, which already supports H-Class) is targeted for 2018.
- The existing Third Party Interface was implemented in Driver Pack 2018 Release 1 and so Waters does not expect any changes to the existing compatibility and compatibility restrictions. Waters does not anticipate that DP 2019 R1 would not work with the CDSs currently supported by earlier Driver Packs, only that the formal testing would not have been completed.

Compatibility Requirements and Regulatory/Validation

- What is not included in DP 2019 R1 media and is Windows 10 Compatible?
 - Waters 2432 Conductivity Detector ICS version 1.65 is not available with DP 2019 R1, but was evaluated with DP 2019 R1 to confirm both are compatible with Woindows 10 OS.
- What is not included in DP 2019 R1 media and is not Windows 10 Compatible?
 - WFC3 and PATROL and M-Class
 - Contact Liz Hodgdon for information on Windows 10 status for these instruments
- What type of Qualification is available?
 - All existing sQT protocols will be supported with Empower for the systems supported by DP 2019 R1. The same is true for the existing QWB's available with MassLynx and MS.
- What Empower version is required for full qualification?
 - DP 2019 R1 is compatible with Empower 3 from base to current. The current version of SQT has the same compatibility.
- Is re-qualification needed after installing DP 2019 R1?
 - Yes, in general at a minimum a software re-qualification is needed, depending on the user's procedures. Note: a firmware upgrade in most cases will trigger the need for requalification.