Cortenic™ Connectivity

The Technology behind Cortenic™

At Bayer, we envision a future where every power injected procedure is delivered from well connected hardware, software, and services. When technology is securely and seamlessly connected through our Cortenic™ Connectivity Platform, processes can be streamlined, data can drive better management decisions, and your team is able to focus on what matters most—the patient.

Data Derivation Guide

for the Bayer Radiology Data Bridge for IT Professionals*

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* This document was confirmed by the Bayer Radiology Cybersecurity and Connectivity Subject Matter Expert and deemed accurate at the time of publishing.

1 Introduction

1.1 Purpose

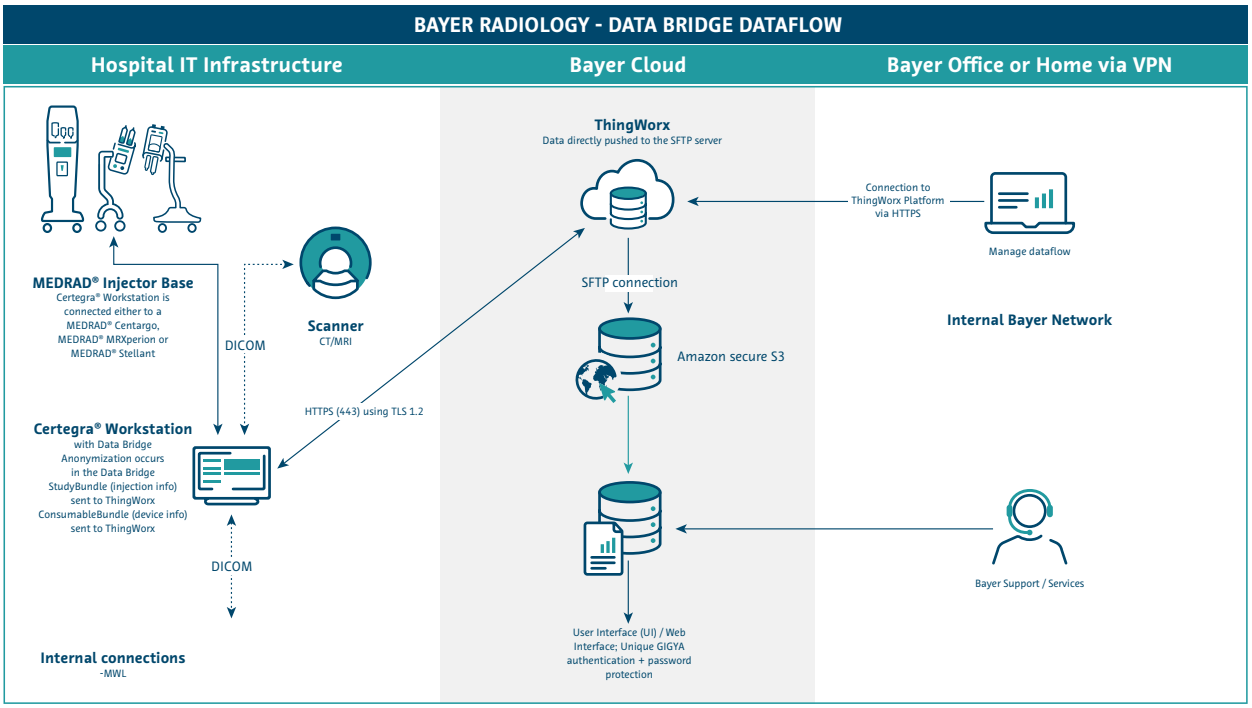
The purpose of this document is to provide a summary of data that will be extracted using a Data Bridge from a Certegra® Workstation to compute benchmarking statistics and analytics that illustrate how customers use Bayer MEDRAD® Contrast Injection products. The guide will detail what data is collected and efforts taken to protect it through the use of encryption and anonymisation.

Note: Compatibility with Data Bridge will require a Bayer MEDRAD® Injector to be equipped with a Certegra® Workstation and Workflow Solutions Software. These components will be used to receive inbound patient and exam data from the customer's Modality Worklist Service, and from a DICOM query of the scanner located in the imaging suite. Not all Bayer MEDRAD® Injectors are compatible with these components and thus may not be compatible with Data Bridge.

This document defines the structure of JSON data sent from the Certegra® Workstation to ThingWorx, using Data Bridge, and ultimately to the Bayer internal analytics platform. An overview of the workflow can be found in section 1.2.

Data Bridge can send two types of data files to ThingWorx: a Study Bundle and a Consumable Bundle. A study bundle contains anonymized patient, study, injection, and injector information. Consumable bundle contains syringe information and injector information, such as insert/remove times and syringe type.

1.2 Data Flow



1.3 Definitions, Acronyms, and Abbreviations

- **ArrayOfString** – A collection of string values, where the property name is “string” and the value is an array contain string data type.
- **PHI** – Protected Health Information, as defined by HIPAA Privacy Rule, is individually identifiable health information that relates to: (i) the individual’s past, present, or future physical or mental health or condition or (ii) the provision of health care to the individual, or (iii) the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is reasonable basis to believe can be used to identify the individual. PHI includes demographic information, and includes many common identifiers (e.g.: name, address, birth date, Social Security Number) when they can be associated with the health information enumerated previously.

2 Design Element Overview

Prior to understanding the structure used to represent the data stored in Certegra® it is important to understand a few key concepts.

2.1 Contrast Delivery

A contrast delivery is used as a somewhat generic term to represent the planning, programming, and delivery of contrast (and other associated fluids) to a patient as part of an examination.

2.2 Plan

Generally, when delivering contrast and other fluids to a patient a plan or strategy is typically defined to specify how the fluid should be delivered to a patient. For example, a very simple plan would have one step which would be to deliver 50 mL of Ultravist® 370 at 3 mL /s. A more complicated plan may have multiple steps. For example, first the step may be to perform a test injection (patency check) and then deliver 50 mL of Ultravist® 370 at 3 mL /s followed by 20 mL of saline at 2 mL /s.

For power injectors these plans are typically managed on the injector or centrally and distributed to each injector system. Management of plans is typically performed by some combination of MEDRAD® clinical specialists, site administrators, and radiologists.

Once stored, a plan can be recalled or programmed on an injector system (programmed means it is selected and appears on the injector screen) and then delivered to a patient.

A plan can represent three different pieces of data:

- Plan Templates - What was prescribed or recommended for a specific study.
- Programmed Plans - What was actually programmed on the injector.
- Delivered Plans - What was actually delivered to the patient.

The first piece of data listed above describes what was prescribed or recommended and is often referred to as an injector protocol. The Certegra Platform refers to them as templates (plan templates).

In addition, templates can be pre-defined so that they do not change from one patient to the next or they can be "personalized" so that certain factors are considered for each study such as the patient's weight, renal function, contrast concentration, or tube voltage. P3T® Cardiac, Abdomen, and PA are examples of personalization algorithms.

Templates can then be programmed on an injector system and then as mentioned before delivered. During delivery the programmed plan may not be delivered as expected. For example, the injector may pressure limit during the second of three phases programmed on the injector causing the injector to disarm. As a result, Certegra stores along with what was recommend and programmed, a version of the plan as it was actually delivered.

2.3 Step

Every plan must have at least one step except the default SyncRight plan template that does not contain any step. Steps represent a collection of tasks\actions that should be performed. These tasks\actions are typically called phases.
For example, consider the following plan:

- **Step 1:**
  - Perform a test injection (patency check).
- **Step 2:**
  - Deliver 50 mL of Ultravist® 370 at 3 mL /s
  - Followed by 20 mL of saline at 2 mL /s

The first step has one phase (to perform a test injection) and the second step has two phases (one for the contrast and another for the saline).
An injection may contain one or more steps and a step may contain one or more phases.

2.4 Injection

Injection is a term that has a lot of different meanings depending on the context and who is asked. One could describe a vaccine shot as an injection or a power injector protocol containing 4 different phases of contrast and saline as well as a patency check as a single injection.

Because the term injection has such a variable meaning and because many people have their own view regarding this term Certegra Platform tries to, at least in its data model, use plans and or a set of one or more steps to represent an injection.

For the purposes of this interface no element directly corresponds to an "injection." For reporting and display purposes if desired a contrast delivery or delivered plan can be considered an injection. In addition, each individual step in a plan could be considered an injection. The distinction is not made in this interface and is a decision to be made when consuming and sending contrast data to users and other external systems.

3 Detailed Design and Interface

3.1 Data Protection

Bayer will collect, transmit, process, and store data extracted from a Bayer Certegra® Workstation using Encryption and Anonymisation protocols to promote the security, privacy of customer data, and de-identification of customer data.

Encryption: will be used to secure data in motion between the external environment and the Bayer environment.
Anonymisation: will be used to protect the privacy of sensitive customer information so that the associated data may not be rendered to a readable format with the original values found in the Certegra environment. Anonymisation is used where appropriate. Anonymisation may occur a couple of different ways depending on the data element:

- Original value will be replaced with a new value via SHA-256 hashing function, containing a 64-character hexadecimal string.
- Original value will be replaced with a new value via SHA-512 hashing function, containing a 128-character hexadecimal string.
- Original value will be replaced with "********"

<Null> Values: will be used when no value was extracted from the Certegra database.

3.2 Study Bundle Overview and Types

A study bundle is a container for the data sent from the Certegra® Workstation. The Study Bundle sent contains up to one contrast delivery and associates it with a particular study identified by its Certegra Study ID.

3.2.1 Type Definition

3.2.1.2 Element Description

Member	Anonymised	Type	Description
Version	false	integer	This is the version number of the data sent from Data Bridge. Each change to this document and\or the structure of the JSON study bundle sent to ThingWorx from Data Bridge will be considered a change to the interface's version. Each study bundle is associated with a version in order to gracefully handle interface changes and to easily identify what version a study bundle originated from. The initial version for this will be 1.
CertegraBridgepoint	true	string	The location of the Certegra Exposure Bridge service that sent the study bundle. For example, http://192.168.1.100:8734/Certegra/ExposureBridge. This information can be used if needed to invoke operations on the Exposure Bridge if callbacks or other two-way communication is required. This field will be anonymised for the purposes of Data Bridge.
StudyContrastReport	false	Object:StudyContrast-DeliveryReport	Please see the section "StudyContrastDeliveryReport" for more details.
GeneratedAt	false	string	Contains the date and time (in UTC) that the study bundle was generated by the Certegra.ExposureBridge.Service. This is stamped when the Certegra. ExposureBridge.Service generates the study bundle. The format of the datetime is "YYYY-MM-DDTHH:mm:ss.fffZ"
ProcessingTokens	false	string	When a study bundle is created, if the match was of type Revoked, this property will contain "E33BD4BC-FBC5-4707-802A-3F3A38E87135". Else it will be null or undefined. This field is used internally.
CertegraVersion	false	string	The Certegra Software Version that Exposure Bridge is currently running on.
IsUpdate	true	bool	This will be true if Data Bridge has attempted to transfer a Study Bundle for the same match before. This will be false if Data Bridge has not previously attempted a transferred a Study Bundle for the same match. Note, it is possible for Study Bundles to be sent out of order, so the system should perform a check if the Study Bundle already exists before blindly checking this flag.
MatchCertegraId	false	string	A unique GUID that represents a linkage between study and injection. Matches can be revoked, which is the removal of association between study and injection. This field will be anonymised via SHA-256 hashing function, containing a 64 character hexadecimal string.
AssetOrganization	false	string	This is the written name of the organization the injector belongs to as tracked in the ThingWorx system.
orgAccountSMGNumber	false	string	This is the Service Max Reference Number or SAP reference Number
OrganizationLocation2	false	string	This contains the physical location's name and address of the organization associated to the injector
locSAPAccountNumber	false	string	SAP Reference Number for the hospital location. All equipment at that site is assigned to that account.
masterAssetNumber	false	string	The top level system number. All the parts and other work orders and contracts are associated to this number.
masterPartNumber	false	string	This is the part number of the system that the display is connected to in SAP.
masterSerialNumber	false	string	This is the part number of the system that the display is connected to in SAP.
cruSerialNumber	false	string	The Control Room Unit's Serial Number

3.2.2 StudyContrastDeliveryReport

The heart of a study bundle is the StudyContrastDeliveryReport. This represents an association between a study, a patient, and a single contrast delivery. Injector systems have the capability to perform multiple injections for a study. For the purposes of Data Bridge, even though a study may have more than one contrast delivery associated with it, each Study Bundle file will only contain one contrast delivery. If a study has more than one contrast delivery associated with it, more than one study bundle file would be sent to the ThingWorx where each file contains a different contrast delivery and the same study.

3.2.2.1 Type Definition

3.2.2.2 Element Description

Member	Anonymised	Type	Description
ContrastDelivery Summary	false	Object:Contrast DeliverySummary	Please see the section “ContrastDeliverySummary” for more details.
StudyInfo	false	Object:StudyInfo	Container element used to group study related information. Please see the section “StudyInfo” for more details.
ModalityType	false	string	Modality Type (If it is performed by MR injectors the value will be MR otherwise CT) Possible values: CT, MR
PatientInfo	false	Object:PatientInfo	Container element (label) used to group patient related information. For further detail see section 3.2.4
ContrastDeliveryReports	false	Array:Contrast DeliveryReport	A study can be associated with more than one contrast delivery, but for the purposes of Data Bridge, will only contain one contrast report per study bundle. Please see the section “ContrastDeliveryReport” for more details.

3.2.3 StudyInfo

High level data related to the study associated with the contrast delivery. This data is DICOM sourced typically from the scanner or work list.

Data Bridge will send all studies associated with an injection in separate study bundles (if an injection was performed for 3 studies,three separate bundles containing one study and the same injection will be sent).

3.2.3.2 Element Description

3.2.3.2 Element Description

Member	Anonymised	Type	Description
StudyCertegra Id	true	string	GUID which identifies a unique study in the Certegra database. This field will be anonymised via SHA-256 hashing function, containing a 64 character hexadecimal string.
StudyInstanceUid	true	string	The DICOM sourced study instance uid that should be considered the key used to uniquely identify the study across various systems. This value can be null. If this value is null, please refer to StudyCertegraID as a unique identifier for the study. This field will be anonymised via SHA-512 hashing function, containing a 128 character hexadecimal string.
Description	false	string	The description of the study. This is typically sourced from the worklist or the scanner.
AccessionNumbers	true	ArrayOfString	List of accession numbers associated with the study. This field will be anonymised for the purposes of Data Bridge.
Number	true	string	Study ID (Study Number in Certegra) This field will be anonymised for the purposes of Data Bridge.
StudyDateTime	false	string	Study Date Time in UTC. It is the time when the technologist starts the procedure by selecting a patient from a worklist. Format is “YYYY-MM-DDTHH:mm:ss.fffZ”.

3.2.4 PatientInfo

The patient info object contains a high level set of data that identifies the patient associated with the study and the contrast delivery.

3.2.4.1 Type Definition

3.2.4.2 Element Description

Member	Anonymised	Type	Description
PatientMrn	true	string	Patient's Medical Reference Number. Used to uniquely identify the patient. This field will be anonymised for the purposes of Data Bridge.
FirstName	true	string	Patient's first (given) name. This field will be anonymised for the purposes of Data Bridge.
MiddleName	true	string	Patient's middle name. This field will be anonymised for the purposes of Data Bridge.
LastName	true	string	Patient's last name. This field will be anonymised for the purposes of Data Bridge.
Prefix	true	string	Patient's name prefix such as Mr. or Mrs. This field will be anonymised for the purposes of Data Bridge.
Suffix	true	string	Patient's name suffix such as M.D. This field will be anonymised for the purposes of Data Bridge.
DateOfBirth	true	string	Patient's date of birth. The system captures date only, but format is "YYYY-MM-DDTHH:mm:ssZ" This field will be anonymised for the purposes of Data Bridge.
Gender	true	string	The patient's gender as a string. Possible values include: • Unknown • Male • Female • Other • Hidden This field will be anonymised for the purposes of Data Bridge.
HeightMeter	true	float	The patient's height in meters. This field will be anonymised for the purposes of Data Bridge.
WeightKg	true	float	The patient's weight in kilograms. This field will be anonymised for the purposes of Data Bridge.
SerumCreatinine	true	float	The patient's serum creatinine level at the time of the study. The units used for this measurement are found in the SerumCreatinineUnits field. This field will be anonymised for the purposes of Data Bridge.
SerumCreatinineUnit	true	string	The units used to measure the patient's serum creatinine. Possible values: • Unknown • mmol/L • mg/dL This field will be anonymised for the purposes of Data Bridge. This field will always be masked with "********"."
EGFR	true	float	The patient's estimated Glomerular Filtration Rate (estimate renal function). The units of this value are specified in the field eGFR This field will be anonymised for the purposes of Data Bridge.
EGFRUnit	true	string	The units used for EGFR. Possible values: • Unknown • mL/min • mL/min/BSA This field will be anonymised for the purposes of Data Bridge. This field will always be masked with "********".
ObservationDate	true	string	The date of observation for the data contained in the patient info object. For example the patient's weight may change over time and EGFR may be calculated for a certain visit. The system captures date only, but the format is "YYYY-MM-DDTHH:mm:ssZ". This field will be anonymised for the purposes of Data Bridge.

3.2.5 ContrastDeliverySummary

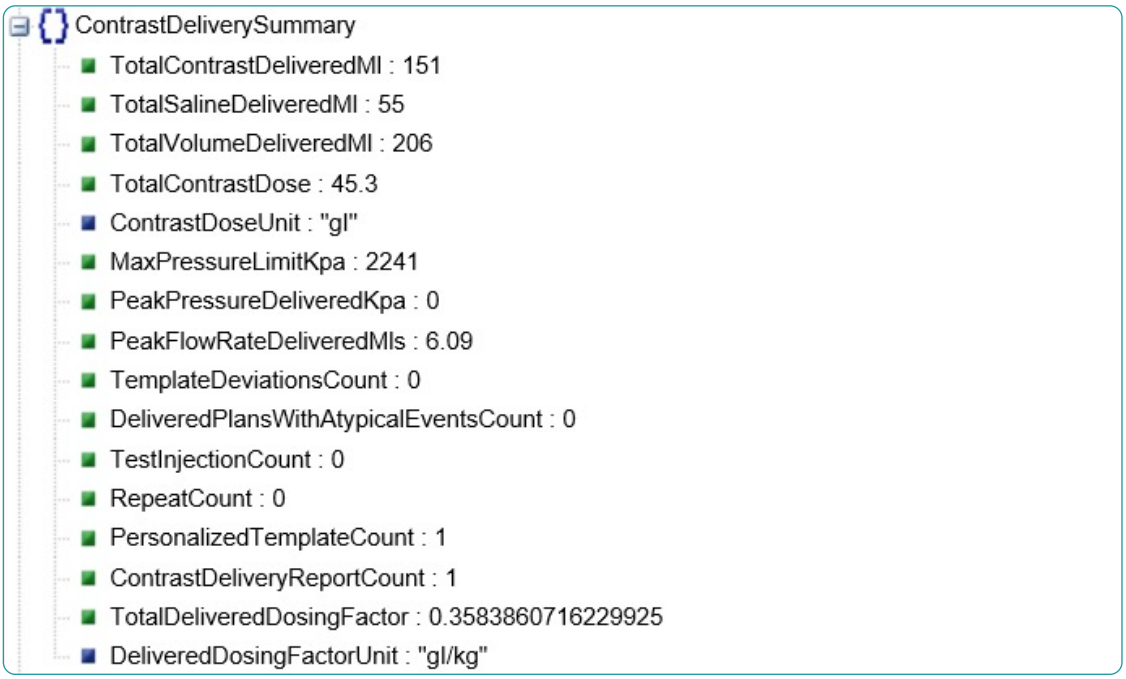
The contrast delivery summary object provides a normalized view of the data found throughout ContrastDeliveryReport. It contains aggregated volumes, counts, and events associated with a set of templates, programmed, and delivered.

This type can be found at multiple "levels" of the study bundle and depending on the level it is found will change to what degree the data is aggregated. This is so that a common structure can be used to represent this data, but it can be broken into multiple levels or slices for easy analytics purposes.

The current levels/slices that this object will be found in are:

- **StudyContrastDeliveryReport:** Summary of all contrast deliveries matched with the study contained in this study bundle. All values will be cumulative across contrast deliveries performed for the study. Each study bundle only contains one injection, but a study can be associated with multiple injections. Thus, this level will contain the cross-study totals if multiple injections are performed for the same study. This will result in a difference between StudyContrastDeliveryReport and ContrastDeliveryReport in the repeat study scenario.
- **ContrastDeliveryReport:** Summary of data for a single contrast delivery (a single set of template, programmed, and delivered).

3.2.5.1 Type Definition



3.2.5.2 Element Description

Member	Anonymised	Type	Description
TotalContrast DeliveredMl	false	float	The cumulative total milliliters of contrast delivered at this level.
TotalSalineDeliveredMl	false	float	The cumulative total milliliters of saline including keep vein open volume delivered at this level.
TotalVolumeDeliveredMl	false	float	The cumulative total milliliters of all fluids delivered at this level.
TotalContrastDose	false	float	The cumulative total contrast dose at this level. This differs from the total volume delivered because all contrast agents have a concentration associated with them. Depending on the concentration and the volume of fluid delivered the total dose of contrast will be different. For example if 100 mL of contrast is delivered to a patient using a contrast agent with a concentration of 300 mg of iodine / mL the total contrast dose for the patient is 30 grams of iodine. The units of this measurement vary and are captured in the ContrastDoseUnits element.
ContrastDoseUnit	false	string	The unit used to measure the contrast dose. Possible values: • Unknown • gI • mmol “gI” stands for grams of iodine and is usually used in CT. “mmol” stands for Millimols and is used for Gadolinium based agents in MR.
MaxPressureLimitKpa	false	float	The maximum pressure limit at this level. The injector allows for the user to define a maximum pressure limit that can be used to prevent the system from exceeding a certain pressure when injecting the patient. Units are in kilopascals (kpa).
PeakPressureDelivered-Kpa	false	float	The peak (highest) pressure achieved at this level. The injector constantly monitors the pressure during an injection. This value represents the highest value observed during the study. Units are in kilopascals (kpa).
PeakFlowRate DeliveredMls	false	float	The peak (highest) flow rate achieved at this level. Flow rate is measured in milliliters per second (mL/s).
Template DeviationsCount	false	int	The number of template deviations. This value represents a delta between the template (the injector plan\ protocol prescribed for the study) and what was actually used to deliver contrast to the patient with the injector. If multiple changes are found for a template, only this will only count as one deviation. Note: The template deviation is determined by the delta of the following values • Number of the steps • Phase Type • Flow Rate • Contrast Percentage • Contrast Volume • Saline Volume For InjectorType MRXperion the system will ignore Test Inject step when comparing a template and programmed plan because programmed test inject (patency check) is not part of the plan template/protocol so it should not cause any deviation.
DeliveredPlansWithA-typicalEvents Count	false	int	The number of plans that have atypical or abnormal events. For example, if a contrast delivery is aborted due an over pressure disarm, this would be considered an atypical event and would cause this count to increase.
TestInjectionCount	false	int	The number of test injections used at this level.
RepeatCount	false	int	The number of times any contrast delivery had to be repeated. For example, if the technologist had to disarm the injector in the middle of an injection due to the patient complaining of pain and then re-do the injection, this may be considered a repeat and cause this count to increase.

3.2.5.2 Element Description - continued

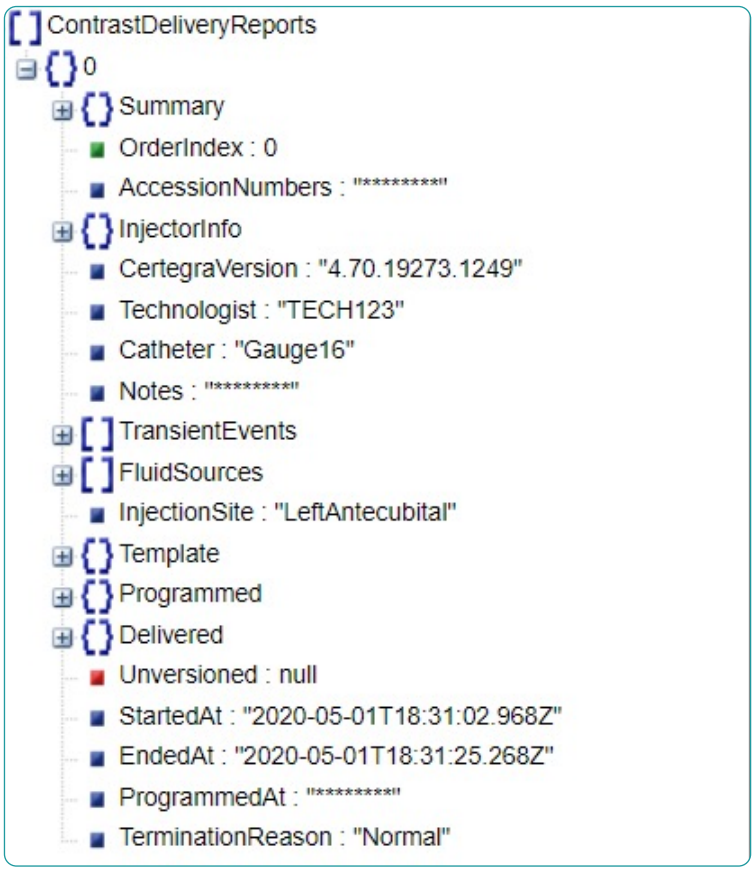
Member	Anonymised	Type	Description
PersonalizedTemplate-Count	false	int	The number of personalized templates used. In this case personalized refers to any method of protocoling that involves a personalized injector protocol for the patient based on various factors such as weight, tube voltage, or renal function. P3T is an example of a personalization.
ContrastDeliveryReport-Count	false	int	The number of contrast delivery reports.
TotalDeliveredDosing-Factor	false	float	Contrast dose / patient weight (kg) If patient weight is not provided the value will be null.
DeliveredDosing FactorUnit	false	string	The unit used to measure the dosing factor Possible Values • Invalid • Unknown • gI/kg • mmol/kg

3.2.6 ContrastDeliveryReport

A contrast delivery report is at its core a collection of a template, programmed, and delivered plan.

These three elements represent what was prescribed\recommend (template), what was actually programmed on the injector (programmed), and what was actually delivered (delivered).

3.2.6.1 Type Definition



3.2.6.2 Element Description

Member	Anonymised	Type	Description
Summary	false	Object: Contrast DeliverySummary	High level summary of information contained in this contrast delivery. Please see the section “ContrastDeliverySummary” for more details.
OrderIndex	false	int	The zero-based order index of the ContrastDeliveryReport in case there are multiple injections in a study.
AccessionNumbers	true	ArrayOfString	List of accession numbers associated with this contrast delivery. For studies with multiple accession numbers associated with them, only certain accession numbers may be associated with a contrast delivery. Further, multiple accession numbers may be associated with one contrast delivery. This field will be anonymised for the purposes of Data Bridge.
InjectorInfo	false	Object: InjectorInfo	Describes the injector used for this contrast delivery. Please see the section “Injector Info” for more details.
Technologist	false	string	The last technologist that performed this contrast delivery. Originally this is a list and not just one because a tech may start, but not complete a procedure or there may be multiple techs operating the injector however for this version the last Technologist name will be exported. This field would qualify as PHI but is not anonymized as the value is required for data bridge KPI displays. Technologist identifier entered by end user.
Catheter	false	string	The last technologist that performed this contrast delivery. Originally this is a list and not just one because a tech may start, but not complete a procedure or there may be multiple techs operating the injector however for this version the last Technologist name will be exported. This field would qualify as PHI but is not anonymized as the value is required for data bridge KPI displays. Technologist identifier entered by end user. A few examples would be: • Unknown • Gauge16 • Gauge18 • Gauge20 • Gauge22 • Gauge24 • PICC • CentralLine
Notes	true	ArrayOfString	A list of free-form notes typically made by the technologist regarding the contrast delivery. This field will be anonymised for the purposes of Data Bridge.
TransientEvents	false	Array:TransientEvent	List of transient events associated with the contrast delivery. Please see the section “TransientEvent” for more details.
FluidSources	false	Array:FluidSourceInfo	List of fluid sources associated with the contrast delivery. Please see the section “FluidSources” for more details.
InjectionSite	false	string	The last injection site used for the contrast delivery. Typically, only one injection site will be used, but it could be changed. There are typical values used, but these could be variable and configurable for a particular site. A few examples would be: • Unknown • Other • Multiple • LeftAntecubital • RightAntecubital • RightHand • RightFoot • PICC • CentralLineCentralize
Template	false	Object: Plan	The prescribed or recommend plan for this contrast delivery. Often referred to as a protocol. Typically, templates are managed by Bayer clinical support and/or radiologists or administrators in the hospital and are recommended for particular types of studies. Templates do not have any delivery values such as PeakFlowRateMls populated. See the section “Plan” type for more details.

3.2.6.2 Element Description - continued

Member	Anonymised	Type	Description
Programmed	false	Object: Plan	The plan programmed on the injector at the time it was armed. This could be the same as the template, but it could also be modified for a variety of reasons. For example, the template might say to deliver 50 mL of contrast at 6 mL/s, but the patient for a particular study is elderly and requires a lower flow rate so the tech programs 50 mL of contrast at 4 mL /s. Programmed plans do not have any delivery values such as PeakFlow-RateMls and Sample data populated. See the section “Plan” type for more details.
Delivered	false	Object: Plan	The plan that was actually delivered to the patient and may vary from both the template and the plan programmed when the injector was armed. This will contain all the delivery values such as PeakFlowRateMls and sample data. See the section “Plan” type for more details.
Unversioned	true	string	Soft-typed data which is used for data that doesn’t fit into the defined Study Bundle schema. This field is not supported by this API version. This field will be anonymised for the purposes of Data Bridge. This field will always be reported as null.
StartedAt	false	string	The date and time that the contrast delivery started. This should correspond to the StartedAt value of the delivered plan. The format is “YYYY-MM-DDTHH:mm:ss.fffZ”
EndedAt	false	string	The date and time that the contrast delivery ended. This should correspond to the EndedAt value of the delivered plan. The format is “YYYY-MM-DDTHH:mm:ss.fffZ”
ProgrammedAt	true	string	The date and time that the contrast delivery was programmed. This should correspond to the ProgrammedAt value of the programmed\delivered plan. The format is “YYYY-MM-DDTHH:mm:ss.fffZ”. This field will be anonymised for the purposes of Data Bridge.
TerminationReason	false	string	The reason that the contrast delivery terminated. Anything other than Normal is considered an abnormal termination. Possible values: • Normal • AbortedByRequest • AbortedByOverPressure • AbortedByOtherInternal • InjectorCommLoss • InjectorCriticalError • AbortedByStalling • AbortedByHoldTimeout • AbortedByAirDectection • AbortedByDisposableRemoval • AbortedByCriticalBatterLevel” • AbortedByHoldTimeout • AbortedBysScanner For example, aborted by request likely means that the injector was disarmed by the technologist intentionally.

3.2.7 InjectorInfo

This element describes the power injector system used to perform the contrast delivery.

The reason that InjectorInfo is provided as part of ContrastDeliveryReport and not StudyContrastDeliveryReport is that it is possible to have a situation where an injector is stored in the closet as a backup. If one of the main injectors go down the site will roll out the backup from the closet and use it. So, one could imagine a scenario where an exam is started and in the middle of the exam the injector has an issue is swapped out with the backup. In this case there would be the same study instance uid, accession number, etc. but with two contrast deliveries each done with a different injector.

3.2.7.1 Type Definition

3.2.7.2 Element Description

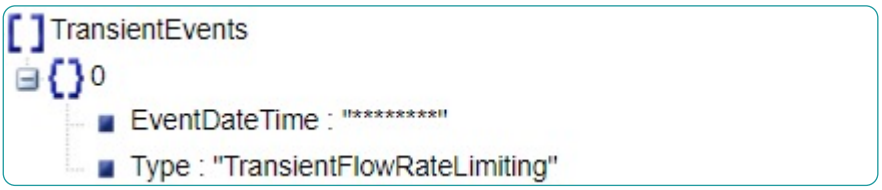
Member	Anonymised	Type	Description
InjectorCertegraId	true	string	The internal GUID used by Certegra to uniquely identify the injector. This field will be anonymised via SHA-256 hashing function, containing a 64 character hexadecimal string.
Facility	false	string	The facility that the injector is located in. For example, “Memorial Hospital East Side”.
Suite	false	string	The suite within the facility where the injector is located. For example, “MH CT1”.
InjectorName	false	string	The user defined name of the injector.
InjectorSerialNumber	false	string	The serial number used to identify the injector. This is assigned as part of the manufacturing process and cannot be changed.
SoftwareVersion	false	string	The injector software version e.g. “S2-CRU-100.89-C1.06_WIN_HU”
InjectorType	false	string	The type, typically the model, of the injector.
VirtualNodePath	true	string	Injectors are considered nodes in configurations where there is a central sever managing multiple injector systems. As part of managing these nodes the site can device virtual node paths which are essentially organizational hierarchies for management purposes. For example, there may be 1 central server that has 5 nodes directly reporting to it. However, the user may choose to define a structure such as “MMES\Radiology\Suite1\”. This field will be anonymised for the purposes of Data Bridge. This field will always be reported as null.

3.2.8 TransientEvent

Transient events are non-terminal injector events (they do not cause the injector to disarm) that can occur for a period of time during an injection.

For example, MEDRAD® Stellant has a feature that if the pressure reaches the pressure limit programmed by the injector the injector can automatically attempt to “pressure limit” which means it attempts to reduce the flow rate to continue the injection. This may also occur more than one time during the injection if the pressure begins to exceed the defined limit.

3.2.8.1 Type Definition



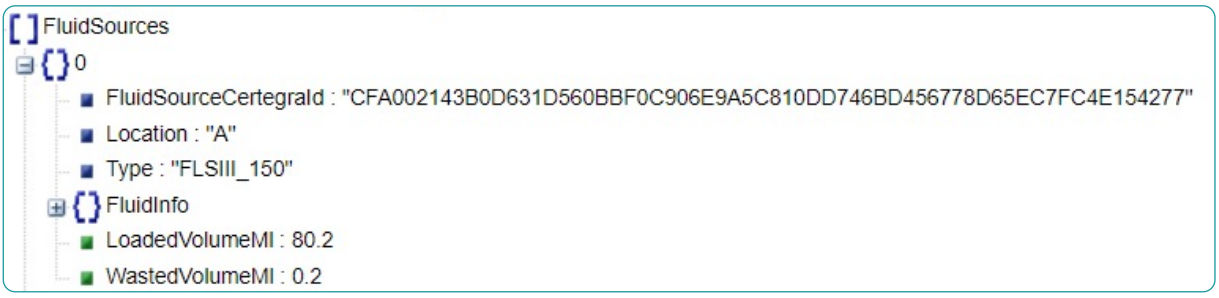
3.2.8.2 Element Description

Member	Anonymised	Type	Description
EventDateTime	true	string	The date and time in UTC format when the event occurred. The format is “YYYY-MM-DDTHH:mm:ss.fffZ” This field will be anonymised for the purposes of Data Bridge.
Type	false	string	The type of transient event. Possible values: • TransientFlowRateLimiting • TransientStalling • TransientKvoStart • TransientKvoEnd

3.2.9 FluidSourceInfo

Describes a source of fluid used for an injector. This is generically named because although many injectors use some sort of a syringe to hold fluid prior to delivery, other injectors such as bulk fluid injectors may feed from bags, directly from the contrast package, or other cartridges.

3.2.9.1 Type Definition



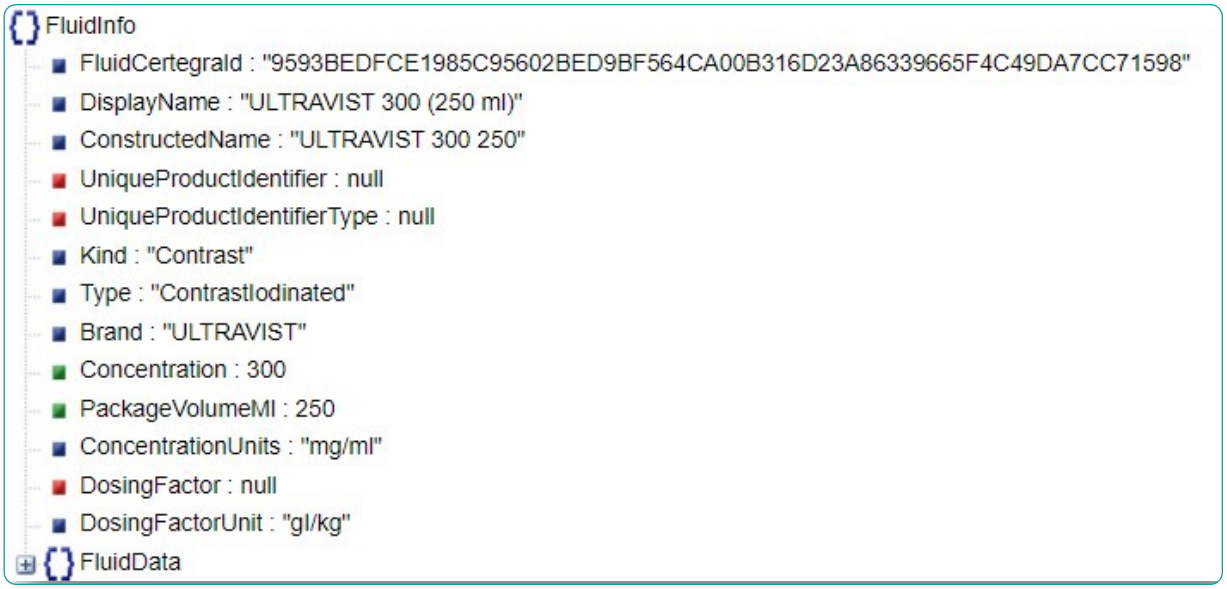
3.2.9.2 Element Description

Member	Anonymised	Type	Description
FluidSourceCertegraId	true	string	The internal Certegra GUID used to uniquely identify this fluid source. This field will be anonymised via SHA-256 hashing function, containing a 64 character hexadecimal string.
Location	false	string	The location of the fluid source when it is installed\attached\connected to the injector. Each injector has one or more fluid source locations that can be used when attaching a fluid source. For example, MEDRAD® Stellant has two fluid source locations, A and B. A is intended for contrast and is labelled green on the injector. B is intended for saline and is labelled blue.
Type	false	string	This is typically either the fluid source model or generic syringe classification. For example, the fluid source may be a typical syringe used by Stellant such as the FLSII or a pre-filled syringe such as those commonly used in Japan. Possible values include: • FLSII • PFA100 • PFA150 • PFABracco • FLSIII_200 • FLSIII_150 • MRXP_QWIKFIT_115 • MRXP_QWIKFIT_65 • MRXP_PFA_1 • MRXP_PFA_2 • MRXP_PFA_3 • MRXP_PFA_4
FluidInfo	false	Object: FluidInfo	Describes the fluid associated with a fluid source. Some fluid sources are filled with contrast and others with saline. Please see the section “FluidInfo” for more details.
LoadedVolumeMl	false	float	The remaining volume in mL left in the syringe before the injection starts.
WastedVolumeMl	false	float	The remaining volume in mL left in the syringe after the injection completes Please note that the system cannot guarantee that this value is the “wasted” volume since the technologist can perform another injection on the same patient with the remaining fluid from the previous injection.

3.2.10 FluidInfo

This type describes fluids of various sorts, for example the contrast agent Ultravist® 370. Also includes data required to look up and identify the fluid such as its unique product identifier, lot, batch, and expiration date.

3.2.10.1 Type Definition



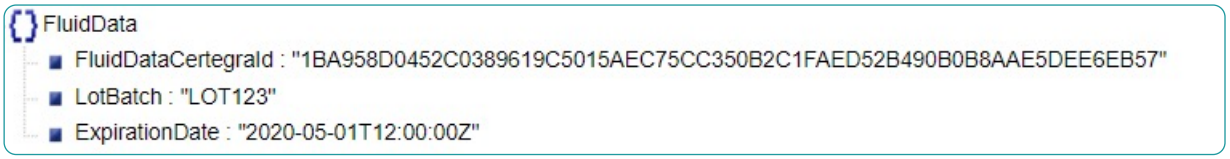
3.2.10.2 Element Description

Member	Anonymised	Type	Description
FluidCertegraId	true	string	The internal GUID used by Certegra to uniquely identify the fluid. This field will be anonymised via SHA-256 hashing function, containing a 64 character hexadecimal string.
DisplayName	false	string	Fluid display name
ConstructedName	false	string	Brand Name + Concentration + PackageVolumeMl + DosingFactor
UniqueProductIdentifier	false	string	Not supported. Certegra does not collect this data.
UniqueProductIdentifierType	false	string	Not supported. Certegra does not collect this data.
Kind	false	string	The more generic kind of fluid such as contrast (referring to any form of contrast such as iodinated or gadolinium). Possible values include: • Contrast • Flush
Type	false	string	The specific type of fluid such as iodinated contrast or saline. Possible values include: • ContrastIodinated • ContrastGadolinium • ContrastOther • FlushSaline • FlushOther”
Brand	false	string	The brand or manufacturer of the contrast such as “Bayer”.
Concentration	false	float	The concentration of the primary active ingredient (typically contrast) found in the fluid. The units of this concentration are found in the “ConcentrationUnits” element.
PackageVolumeMl	false	float	Fluid is packaged in containers of some sort. This volume represents the size in Ml of the package the fluid was shipped in. This is different than that the fluid sources volume.
ConcentrationUnits	false	string	The units used to measure the concentration of a fluid: Possible values: • mg/ml (milligrams per milliliter) • mmol/mL (Millimoles per milliliter) • % (Saline may be shown as % wtvol)
DosingFactor	false	float	Package dosage. It is used in MR. This value is null in CT. The unit of this dosing factor is specified in DosingFactorUnit element.
DosingFactorUnit	false	string	Package dosage unit. (mmol/kg)
FluidData	false	Object: FluidData	Please see the section ‘FluidData’ below.

3.2.11 FluidData

This type describes data required to look up and identify the fluid such as unique fluid data identifier, lot batch, and expiration date.

3.2.11.1 Type Definition



3.2.11.2 Element Description

Member	Anonymised	Type	Description
FluidDataCertegraId	true	string	The internal GUID used by Certegra to uniquely identify the fluid Data. This field will be anonymised via SHA-256 hashing function, containing a 64 character hexadecimal string.
LotBatch	false	string	The lot and batch identifier this fluid originated from.
ExpirationDate	false	string	The date (in UTC format) when the fluid expires and is no longer usable. format is “YYYY-MM-DDTHH:mm:ssZ”.

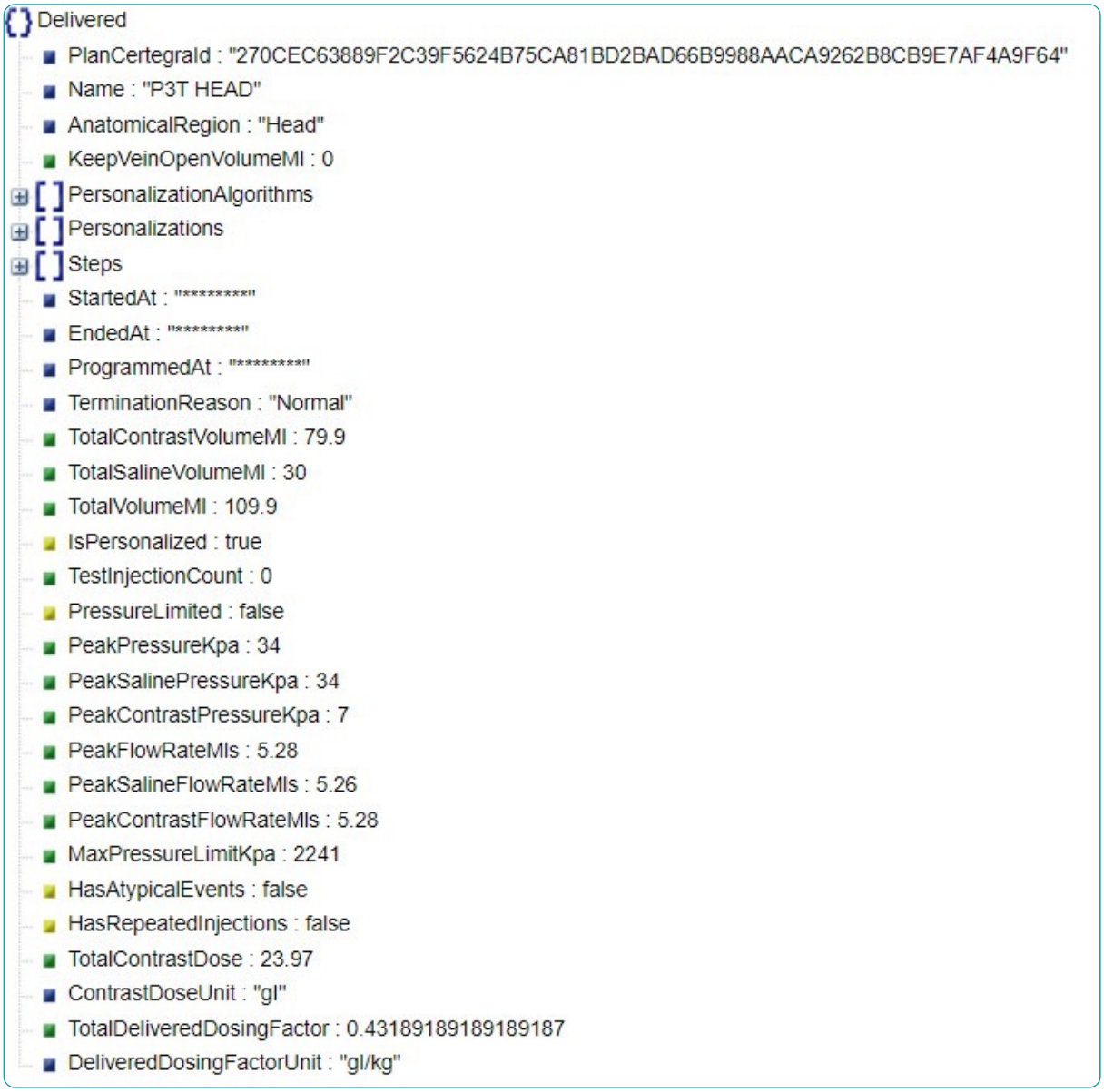
3.2.12 Plan

A plan can be used to define any of the following pieces of data

- What was prescribed or recommended for a particular study.
- What was actually programmed on the injector.
- What was actually delivered to the patient.

Please see section 3.2 for more details.

3.2.12.1 Type Definition



3.2.12.2 Element Description

Member	Anonymised	Type	Description
PlanCertegraId	true	string	The internal GUID used by Certegra to uniquely identify the plan. This field will be anonymised via SHA-256 hashing function, containing a 64 character hexadecimal string.
Name	false	string	User defined name for the plan. Used for display and identification purposes.
AnatomicalRegion	false	string	The anatomical region associated with the plan. Possible values: • Chest • Extremities • Head • Abdomen
KeepVeinOpenVolumeMl	false	float	The volume to be used to keep a vein opens during a plan. This is typically used in MRI.
Personalization Algorithms	false	ArrayOfString	A list of the personalization algorithm names used as part of this plan.
Personalizations	false	Array:Personalization	List of Personalization (Algorithms) that is applied in the injection. This value is only available in Template when P3T protocol is selected to perform an injection as Exposure Bridge will recalculate the Steps and Phases based on the P3T parameters specified in the last programmed step which provides the complete set of P3T parameters. Personalizations will be empty for Programmed and Delivered Plan. See the section “Personalization” for more detail.
Steps	false	Array:Step	List of one or more steps that make up this plan. See the section “Step” for more details.
StartedAt	true	string	The date and time (UTC format) of when the delivered plan started. Used when representing delivered plans. This will not be set if this plan is being used to represent a template or programmed plan. The format is “YYYY-MM-DDTHH:mm:ss.fffZ” This field will be anonymised for the purposes of Data Bridge. This field will always be reported as null for Programmed Plan and Template Plan.
EndedAt	true	string	The date and time (UTC format) of when the delivered plan ended. Used when representing delivered plans. This will not be set if this plan is being used to represent a template or programmed plan. The format is “YYYY-MM-DDTHH:mm:ss.fffZ” This field will be anonymised for the purposes of Data Bridge. This field will always be reported as null for Programmed Plan and Template Plan.
ProgrammedAt	true	string	The date and time (UTC format) of when the delivered plan was programmed. Used when representing delivered and programmed plans. This will not be set if this plan is being used to represent a template. The format is “YYYY-MM-DDTHH:mm:ss.fffZ” This field will be anonymised for the purposes of Data Bridge. This field will always be reported as null for Template Plan.
TerminationReason	false	string	The reason why this plan terminated. Any plan that terminates as expected will have a termination status of Normal. Any other reason is considered abnormal. Possible Values: • Unknown • Normal • InjectorCriticalError • InjectorCommLoss • AbortedByStalling • AbortedByRequest • AbortedByOverPressure • AbortedByOtherInternal • AbortedByHoldTimeout

3.2.12.2 Element Description - continued

Member	Anonymised	Type	Description
TotalContrastVolumeMl	false	float	The cumulative total milliliters of contrast delivered across all steps that are part of this plan.
TotalSalineVolumeMl	false	float	The cumulative total milliliters of saline delivered across all steps including keep vein open volume that are part of this plan.
TotalVolumeMl	false	float	The cumulative total milliliters of all fluids delivered across all steps that are part of this plan.
IsPersonalized	false	bool	Flag that indicates whether personalized templates used in this plan. In this case personalized refers to any method of protocoling that involves a personalized injector protocol for the patient based on various factors such as weight, tube voltage, or renal function. P3T is an example of a personalization.
TestInjectionCount	false	int	The number of test injection steps that are part of this plan.
PressureLimited	false	bool	Only populated for delivered plans. True if pressure limiting (reducing the flow rate of one or more phases in order to stay below the defined pressure limit) occurred at any part during this plan.
PeakPressureKpa	false	float	The peak (highest) pressure achieved during the delivery of this plan. The injector constantly monitors the pressure during an injection. This value represents the highest value observed across all samples associated with the plan. Units are in kilopascals (kpa).
PeakContrastPressure Kpa	false	float	The peak (highest) pressure achieved during the saline delivery of this plan. The injector constantly monitors the pressure during an injection. This value represents the highest value observed across all samples associated with the plan. Units are in kilopascals (kpa).
PeakSalinePressureKpa	false	float	The peak (highest) pressure achieved during the saline delivery of this plan. The injector constantly monitors the pressure during an injection. This value represents the highest value observed across all samples associated with the plan. Units are in kilopascals (kpa).
PeakFlowRateMls	false	float	The peak (highest) flow rate achieved as part of the delivery of this plan. Flow rate is measure in milliliters per second (mL/s).
PeakContrastFlow-RateMls	false	float	The peak (highest) flow rate achieved for contrast delivery in this plan. Flow rate is measure in milliliters per second (mL/s).
PeakSalineFlowRateMls	false	float	The peak (highest) flow rate achieved for saline delivery in this plan. Flow rate is measure in milliliters per second (mL/s).
MaxPressureLimitKpa	false	float	The maximum pressure limit used across all steps for this plan. Typically pressure limits do not change across steps.
HasAtypicalEvents	false	bool	Only populated for delivered plans. True if any atypical\abnormal events occur such as an abnormal termination reason (any reason other than normal).
HasRepeatedInjections	false	bool	Only populated for delivered plans. True if Certegra detects that an injection has been repeated for various reasons such as error, patient discomfort, non-diagnostic images, etc.
TotalContrastDose	false	float	The cumulative total contrast dose across all steps in this plan. This differs from the total volume delivered because all contrast agents have a concentration associated with them. Depending on the concentration and the volume of fluid delivered the total dose of contrast will be different. For example, if 100 mL of contrast is delivered to a patient using a contrast agent with a concentration of 300 mg of iodine / mL the total contrast dose for the patient is 30 grams of iodine. The units of this measurement vary and are captured in the ContrastDoseUnits element.

3.2.12.2 Element Description - continued

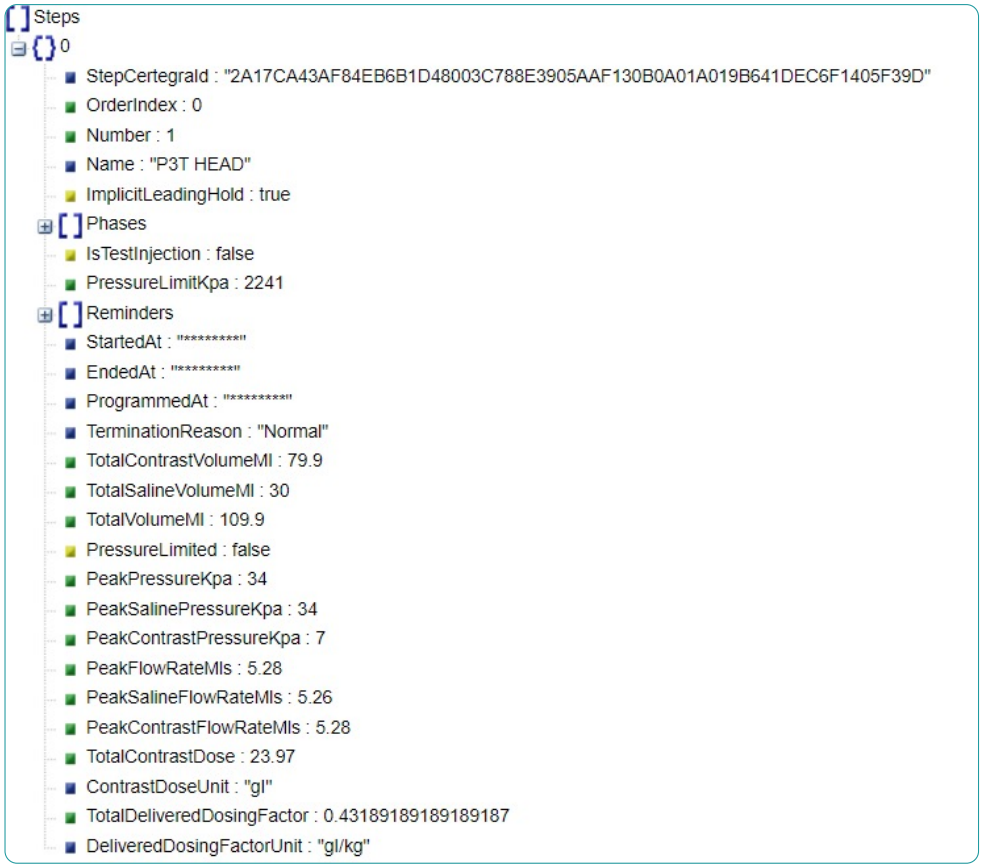
Member	Anonymised	Type	Description
ContrastDoseUnit	false	string	The unit used to measure the contrast dose. Possible values: • Unknown • gI • mmol "gI" stands for grams of iodine and is usually used in CT. "mmol" stands for Millimols and is used for Gadolinium based agents in MR.
TotalDeliveredDosing-Factor	false	float	Contrast dose / patient weight (kg) If patient weight is not provided the value will be null.
DeliveredDosing FactorUnit	false	string	The unit used to measure the dosing factor Possible Values • Invalid • Unknown • gI/kg • mmol/kg

3.2.13 Step

Every plan must have at least one step. Steps represent a collection of tasks\actions that should be performed. These tasks\actions are typically called phases.

Please find a more detailed explanation of steps in section 3.3.

3.2.13.1 Type Definition



3.2.13.2 Element Description

Member	Anonymised	Type	Description
StepCertegraId	true	string	The internal GUID used by Certegra to uniquely identify the step. This field will be anonymised via SHA-256 hashing function, containing a 64 character hexadecimal string.
OrderIndex	false	int	The order that the step should be performed and displayed. The first step of the plan should have its order index set to 0. Each step after that should have its order index incremented accordingly.
Number	false	int	Step Number should be used as a sequence number on the UI since OrderIndex starts from zero. (OrderIndex + 1)
Name	false	string	User defined name for the step. Used for display and identification purposes.
ImplicitLeadingHold	false	bool	Indicates if there is a hold prior to this step starting. If this value is set to true there may be a hold programmed on the injector UI which would require the operator to manually start the injection again when they are ready or that in order to perform this step the system must be locked, armed, and started again. For example, if you have a plan with a test injection typically the first step will be a test injection followed by another step with this value set to true to indicate that the system should not continue until the user specifies they are ready.
Phases	false	Array:Phase	Please see the section “Phase” for more details.
IsTestInjection	false	bool	Boolean indicated that this step is a test injection. Test injection steps behave just like any other and this flag is typically used for display or other purposes by the injector system.
PressureLimitKpa	false	float	The maximum pressure in kpa that is allowed before the system begins to pressure limit (automatically reduce the flow rate) or disarm.
Reminders	false	Array:Reminder	Please see the section “Reminder” for more details.
StartedAt	true	string	The date and time (UTC format) of when the delivered step started. Used when representing delivered step. This will not be set if this step is being used to represent a template or programmed plan. Note that this time may be before fluid is delivered. For example, after a test injection the next step will be marked as having an implicit leading hold. Even though fluid will not start being delivered until the user takes action the next step is started and waits until user interaction indicates it is acceptable to deliver fluid. The format is “YYYY-MM-DDTHH:mm:ss.fffZ” This field will be anonymised for the purposes of Data Bridge. This field will always be reported as null for Programmed Plan and Template Plan.
EndedAt	true	string	The date and time (UTC format) of when the delivered step ended. Used when representing delivered plans. This will not be set if this plan is being used to represent a template or programmed plan. The format is “YYYY-MM-DDTHH:mm:ss.fffZ” This field will be anonymised for the purposes of Data Bridge. This field will always be reported as null for Programmed Plan and Template Plan.
ProgrammedAt	true	string	The date and time (UTC format) of when the delivered\programmed step was programmed (typically when it appears on the injector screen). Used when representing delivered and programmed plans. This will not be set if this plan is being used to represent a template. The format is “YYYY-MM-DDTHH:mm:ss.fffZ” This field will be anonymised for the purposes of Data Bridge. This field will always be reported as null for Template Plan. Flow rate is measure in milliliters per second (mL/s).

3.2.13.2 Element Description - continued

Member	Anonymised	Type	Description
TerminationReason	false	string	The reason why this step terminated. Any step that terminates as expected will have a termination status of Normal. Any other reason is considered abnormal. The last step's termination status is typically considered the plans final termination status. Possible values: - Normal - InjectorCommLoss - InjectorCriticalError - AbortedByOverPressure - AbortedByStalling - AbortedByAirDetection - AbortedByDisposableRemoval - AbortedByCriticalBatteryLevel - AbortedByHoldTimeout - AbortedByRequest - AbortedByScanner - AbortedByOtherInternal
TotalContrastVolumeMl	false	float	The cumulative total milliliters of contrast delivered across all phases that are part of this step.
TotalSalineVolumeMl	false	float	The cumulative total milliliters of saline delivered across all phases that are part of this step.
TotalVolumeMl	false	float	The cumulative total milliliters of all fluids delivered across all phases that are part of this step.
PressureLimited	false	bool	Only populated for delivered steps. True if pressure limiting (reducing the flow rate of one or more phases in order to stay below the defined pressure limit) occurred at any part during this step.
PeakPressureKpa	false	float	The peak (highest) pressure achieved during the delivery of this step. The injector constantly monitors the pressure during an injection. This value represents the highest value observed across all samples associated with the step. Units are in kilopascals (kpa).
PeakContrastPressureKpa	false	float	The peak (highest) pressure achieved during the contrast delivery of this step. The injector constantly monitors the pressure during an injection. This value represents the highest value observed across all samples associated with the step. Units are in kilopascals (kpa).
PeakSalinePressureKpa	false	float	The peak (highest) pressure achieved during the saline delivery of this step. The injector constantly monitors the pressure during an injection. This value represents the highest value observed across all samples associated with the step. Units are in kilopascals (kpa).
PeakFlowRateMls	false	float	The peak (highest) flow rate achieved as part of the delivery of this step.
PeakContrastFlow-RateMls	false	float	The peak (highest) flow rate achieved for contrast delivery in this step. Flow rate is measure in milliliters per second (mL/s).
PeakSalineFlowRateMls	false	float	The peak (highest) flow rate achieved for saline delivery in this step. Flow rate is measure in milliliters per second (mL/s).
TotalContrastDose	false	float	The cumulative total contrast dose across all phases in this step. This differs from the total volume delivered because all contrast agents have a concentration associated with them. Depending on the concentration and the volume of fluid delivered the total dose of contrast will be different. For example, if 100 mL of contrast is delivered to a patient using a contrast agent with a concentration of 300 mg of iodine / mL the total contrast dose for the patient is 30 grams of iodine. The units of this measurement vary and are captured in the ContrastDoseUnits element.

3.2.13.2 Element Description - continued

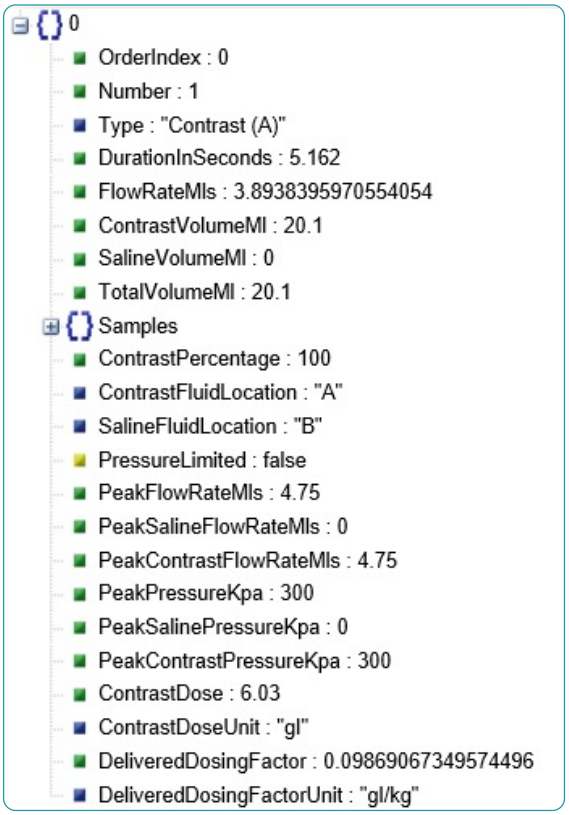
Member	Anonymised	Type	Description
ContrastDoseUnit	false	string	The unit used to measure the contrast dose. Possible values: • Unknown • gI • mmol "gI" stands for grams of iodine and is usually used in CT. "mmol" stands for Millimols and is used for Gadolinium based agents in MR.
TotalDeliveredDosing-Factor	false	float	Contrast dose / patient weight (kg) If patient weight is not provided the value will be null.
DeliveredDosingFacto-rUnit	false	string	The unit used to measure the dosing factor Possible Values • Invalid • Unknown • gI/kg • mmol/kg

3.2.14 Phase

Steps represent a collection of tasks\actions that should be performed. These tasks\actions are typically called phases.

There are several types of phases which can be used for delivery of contrast or saline as well as for specifying delays for timing purposes.

3.2.14.1 Type Definition



3.2.14.2 Element Description

Member	Anonymised	Type	Description
OrderIndex	false	int	Sequence of Phases. The first phase in the step is set to zero.
Number	false	int	Phase Number should be used as a sequence number on the UI since OrderIndex starts from zero. (OrderIndex + 1)
Type	false	string	Phases can represent several different types of actions on the injector. The following are the currently support phase types: • Invalid • Unknown • Delay • Contrast (A) • Other (B): It is not Saline (B) because Technologist might not always use Saline • % (A/B): Dual Flow/Mixed
			The number of seconds this phase will take to complete.
DurationInSeconds	false	float	The rate in milliliters per second that fluid should be injected.
FlowRateMls	false	float	The total contrast volume in milliliters that should be delivered for this phase.
ContrastVolumeMl	false	float	The total saline volume in milliliters that should be delivered for this phase.
SalineVolumeMl	false	float	The total volume of all fluids in milliliters that should be delivered for this phase.
TotalVolumeMl	false	float	Please see the section “Samples” for more details.
Samples	false	Object: Samples	For contrast phases this will be 100, for flush phases this will be 0. For ratio phases this will be a typically be a value between 5 and 95.
ContrastPercentage	false	float	The location of the fluid source that this phase will use for dispensing contrast. Each injector has one or more fluid source locations that can be used when attaching a fluid source. For example, MEDRAD® Stellant has two fluid source locations, A and B. A is intended for contrast and is labeled green on the injector. B is intended for saline and is labeled blue.
ContrastFluidLocation	false	string	The location of the fluid source that this phase will use for dispensing Saline. Each injector has one or more fluid source locations that can be used when attaching a fluid source. For example, MEDRAD® Stellant has two fluid source locations, A and B. A is intended for contrast and is labeled green on the injector. B is intended for saline and is labeled blue.
SalineFluidLocation	false	string	Only populated for delivered phases. True if pressure limiting (reducing the flow rate of one or more samples in order to stay below the defined pressure limit) occurred at any part during this phase.
PressureLimited	false	bool	"The peak (highest) pressure achieved during the delivery of this phase. The injector constantly monitors the pressure during an injection. This value represents the highest value observed across all samples associated with the phase. Units are in kilopascals (kpa).
PeakPressureKpa	false	float	The peak (highest) pressure achieved during the contrast delivery of this phase. The injector constantly monitors the pressure during an injection. This value represents the highest value observed across all samples associated with the phase. Units are in kilopascals (kpa).

3.2.14.2 Element Description - continued

Member	Anonymised	Type	Description
PeakSalinePressureKpa	false	float	The peak (highest) pressure achieved during the saline delivery of this phase. The injector constantly monitors the pressure during an injection. This value represents the highest value observed across all samples associated with the phase. Units are in kilopascals (kpa).
PeakFlowRateMls	false	float	The peak (highest) flow rate achieved as part of the delivery of this phase. Flow rate is measure in milliliters per second (mL/s).
PeakContrastFlow-RateMls	false	float	The peak (highest) flow rate achieved for contrast delivery in this phase. Flow rate is measure in milliliters per second (mL/s).
PeakSalineFlowRateMls	false	float	The peak (highest) flow rate achieved for saline delivery in this phase. Flow rate is measure in milliliters per second (mL/s).
ContrastDose	false	float	The cumulative total contrast dose across all steps in this phase. This differs from the total volume delivered because all contrast agents have a concentration associated with them. Depending on the concentration and the volume of fluid delivered the total dose of contrast will be different. For example, if 100 mL of contrast is delivered to a patient using a contrast agent with a concentration of 300 mg of iodine / mL the total contrast dose for the patient is 30 grams of iodine. The units of this measurement vary and are captured in the ContrastDoseUnits element.
ContrastDoseUnit	false	string	The unit used to measure the contrast dose. Possible values: • Unknown • gI • mmol “gI” stands for grams of iodine and is usually used in CT. “mmol” stands for Millimols and is used for Gadolinium based agents in MR.
DeliveredDosingFactor	false	float	Contrast dose / patient weight (kg) If patient weight is not provided the value will be null.
DeliveredDosingFacto-rUnit	false	string	The unit used to measure the dosing factor Possible Values • Invalid • Unknown • gI/kg • mmol/kg

3.2.15 Samples

The sample type essentially represents a flattened array of data. Each of the elements contained in this type should have the same number of comma separated entries which can be used to create an array of other sequence like data structure.

For example, you may see the following data:
<ElapsedFromPhaseStartInSeconds>0,0.437,0.677,0.998,...</
ElapsedFromPhaseStartInSeconds><ContrastFlowRateMls>0,0.93,1.98,2.02,2.02,1.99,...</ContrastFlowRateMls>

Which can be used to determine that at .998 seconds after the phase started the contrast flow rate was 2.02 mL/s.

3.2.15.1 Type Definition

Samples
ElapsedFromPhaseStartInSeconds : "0,0.419,0.656,0.907,1.143,1.394,1.634,1.875,2.117,2.362,2.607,2.855,3.096,3.345,3.581,3.83,4.075,4.314,4.565,4.802,5.048,5.292,5.532,5.793,6.045,6.262
ContrastFlowRateMls : "0,4.76,6.07,6.04,6.04,6.01,6.06,6.01,6.04,6,6.06,6.04,6.01,6.04,6.01,6.04,6.04,6.03,6.03,6.02,6.03,6.04,6.01,6.04,6.03,6.01,6.06,6.04,6.03,6.03,6.04,6.01,6.06,6.01,6.07,6
ContrastPressureKpa : "0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0"
SalineFlowRateMls : "0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0"
SalinePressureKpa : "0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0"

3.2.15.2 Element Description

Member	Anonymised	Type	Description
ElapsedFromPhase StartInSeconds	false	string	A comma separated list containing a data point for each interval in seconds from the phase start that a sample was taken.
ContrastFlowRateMls	false	string	A comma separated list containing a data point for each contrast flow rate sample (in milliliters per second) taken by the injector during the delivery of this phase. Each data point in this element will align with a data point in each of the other sample lists.
ContrastPressureKpa	false	string	A comma separated list containing a data point for each contrast pressure sample (in KPA) taken by the injector during the delivery of this phase. Each data point in this element will align with a data point in each of the other sample lists.
SalineFlowRateMls	false	string	A comma separated list containing a data point for each saline flow rate sample (in milliliters per second) taken by the injector during the delivery of this phase. Each data point in this element will align with a data point in each of the other sample lists.
SalinePressureKpa	false	string	A comma separated list containing a data point for each saline pressure sample (in KPA) taken by the injector during the delivery of this phase. Each data point in this element will align with a data point in each of the other sample lists.

3.2.16 Reminder

Used to remind or notify the user or an external system at a configurable time after the first phase of the step starts.

Often used for exams that have complicated timing where the user may have to wait several minutes prior to performing the next step of the exam.

3.2.16.1 Type Definition

3.2.16.2 Element Description

Member	Anonymised	Type	Description
Name	true	string	The user defined name of the reminder used for display purposes. This field will be anonymised for the purposes of Data Bridge.
Description	true	string	User defined description explaining the purpose\use of the reminder. This field will be anonymised for the purposes of Data Bridge. This field will always be reported as null.
PostStepTriggerDelay InSeconds	false	float	The number of seconds to wait after the first phase has started before displaying the reminder.
NotifyExternalSystem	false	bool	Some injector scanner integrations such as ISI 900 use reminders to notify the scanner of certain events. If this reminder should notify the scanner or another external system, the flag is set to true. Otherwise it is set to false.
StartAfterStepCompletes	false	bool	This field indicates whether the reminder should start after the step completes or not.
DisplayHints	false	ArrayOfString	This field indicates how the system should display the reminder on the UI. Possible Values: Invalid, Unknown, CountUp, CountDown, Visual, Audible, ForegroundCount, BackGroundCount

3.2.17 Personalization

This represents parameters that the technologist has provided before performing a P3T® injection. In general, the calculation type of each step can be Test Injection, Transit Bolus, Diagnostic or Adjusted Diagnostic. Please note that if Transit Bolus is selected the following step will be Adjusted Diagnostic or it will be Diagnostic otherwise. The outputs of the calculation are variant by the calculation type and the input parameters.

Personalization in Study Bundle is only available in Template and contains the outputs of the calculation from the last step. In the current version the calculation of the last step can either be Diagnostic or Adjusted Diagnostic. The outputs of Test Injection and Transit Bolus calculation are transformed into phases in each step so there is no need to add extra fields in this section. See example below.

Template

- **Personalizations**

o **Personalization[0]**

- **Configuration Parameters**
  - **Calculation = Diagnostic**
  - **…**
- **Input Parameters**
  - **…**
- **Outputs**
  - **The outputs of Diagnostic. (No outputs of TI and TB in this section)**

- **Steps**

o **Steps[0]**

- **IsTestInject = True**
- **Phases**
- **… → the output of Test Inject step**

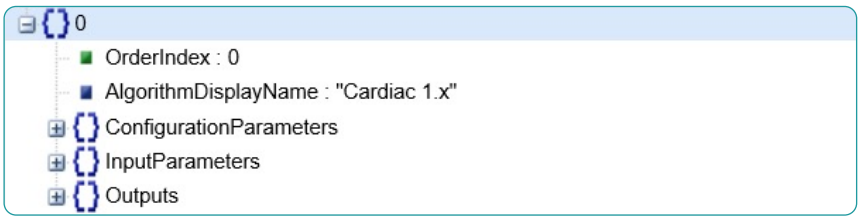
o **Steps[1]**

- **Phases**
- **… → the output of Transit Bolus step (if any)**

o **Steps[2]**

- **Phases**
  - **…**

3.2.17.1 Type Definition



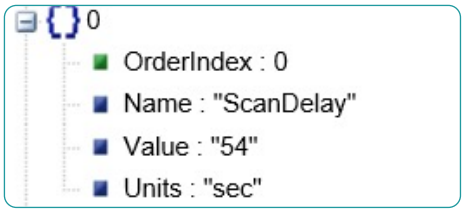
3.2.17.2 Element Description

Member	Anonymised	Type	Description
OrderIndex	false	int	The zero-based index of the Personalization
AlgorithmDisplayName	false	string	The Algorithm Display Name
Configuration Parameters	false	Array:Parameter	The configuration parameters defined in - DF*-110828 (P3T Cardiac 1.x Algorithm) - DF*-113081 (P3T Pulmonary Angiography 1.x Algorithm) - DF*-110827 (P3T Abdomen 1.x Algorithm) Please see the section “Parameter” for more details. *These DFs are for internal reference only
InputParameters	false	Array:Parameter	The input parameters defined in - DF-110828 (P3T Cardiac 1.x Algorithm) - DF-113081 (P3T Pulmonary Angiography 1.x Algorithm) - DF-110827 (P3T Abdomen 1.x Algorithm) Please see the section “Parameter” for more details.
Outputs	false	Array:Parameter	The calculated outputs based on the Calculation Type of the last Step in the P3T template. It is either the output of Diagnostic or Adjusted Diagnostic. Please see refer to the documents below. - DF-110828 (P3T Cardiac 1.x Algorithm) - DF-113081 (P3T Pulmonary Angiography 1.x Algorithm) - DF-110827 (P3T Abdomen 1.x Algorithm) Please see the section “Parameter” for more details.

3.2.18 Parameter

This represents each P3T® parameter. Exposure Bridge will not export other properties of the Parameter that is used for calculation because the outputs are already calculated in StudyBundle.

3.2.18.1 Type Definition



3.2.18.2 Element Description

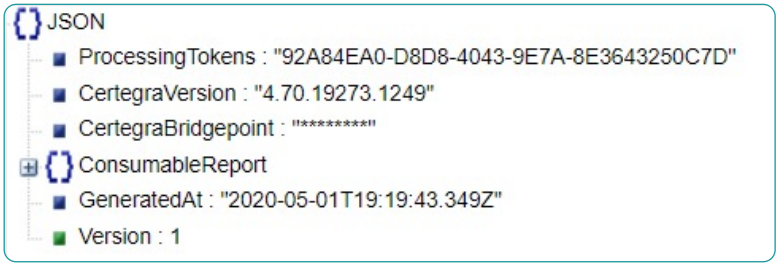
Member	Anonymised	Type	Description
OrderIndex	false	int	The zero-based index of the parameter
Name	false	string	Parameter name e.g. ExactPatientWeight
Value	conditional	string	If the Parameter name for is “ExactPatientWeight” or “PatientWeightBinIndex”, this value will be anonymised with a masked value of “********”. Else, the value is not anonymised. Parameter value e.g. 144
Units	false	string	Parameter units e.g. lb

3.3 Consumable Bundle Overview and Types

3.3.1 ConsumableBundle

A consumable bundle is a container for the syringe data sent from Data Bridge to ThingWorx. It contains information about the time the consumable was connected, removed, and what injector the consumable was associated with. This is also referred to as the “Syringe Utilization Bundle”.

3.3.1.1 Type Definition



3.3.1.2 Element Description

Member	Anonymised	Type	Description
ProcessingTokens	false	string	Internal value used for processing the ConsumableBundle. This will be set to 92A84EA0-D8D8-4043-9E7A-8E3643250C7D.
Version	false	int	Each change to this document and\or the structure of the study bundle sent to ThingWorx for Data Bridge will be considered a change to the interface’s version. Each study bundle is associated with a version in order to gracefully handle interface changes and to easily identify what version a consumable bundle originated from. The current version is 1.
CertegraVersion	false	string	The Certegra Version that ExposureBridge is currently running on.
CertegraBridgepoint	true	string	The location of the Certegra.ExposureBridge.Service instance that sent the study bundle. For example, http://192.168.1.100:8734/Certegra/ExposureBridge. This information can be used if needed to invoke operations on the Exposure Bridge if callbacks or other two-way communication is required. This field will be anonymised for the purposes of Data Bridge.
ConsumableReport	false	Object:ConsumableReport	Please see the “ConsumableReport” section for more details.
GeneratedAt	false	string	The date and time (in UTC) that the study bundle was generated. This is stamped when the Exposure Bridge generates the consumable bundle The format is “YYYY-MM-DDTHH:mm:ss.fffZ”.

3.3.2 ConsumableReport

The ConsumableReport is the heart of the ConsumableBundle. It contains the attach time, detach time, consumable location, Syringe Barcode data and information about the injector.

3.3.2.1 Type Definition

3.3.2.2 Element Description

Member	Anonymised	Type	Description
InjectorInfo	false	Object:ConsumableInjectorInfo	The InjectorInfo contains information about the injector for which the consumable is associated. Please see details in section "ConsumableInjectorInfo" for more details.
ConsumableCertegraId	true	string	The internal GUID in the Certegra database. In the event more than one internal record is sent the first internal Id will be used. This field will be anonymised via SHA-256 hashing function, containing a 64 character hexadecimal string.
ConsumableLocation	false	string	The location of the consumable. For syringes this will be "A" or "B".
ConsumableAttachDateTime	false	string	The date and time (in UTC) when the consumable was connected to the injector system. The format is "YYYY-MM-DDTHH:mm:ss.fffZ".
ConsumableDetachDateTime	false	string	The date and time (in UTC) when the consumable was disconnected to the injector system. The format is "YYYY-MM-DDTHH:mm:ss.fffZ".
ConsumableInjection-Count	false	string	The number of injections that has occurred while the consumable was connected to the injector system.
ConsumableType	false	string	The type of Syringe. Possible Values are • FLSII • PFA100 • PFA150" • PFABracco • FLSIII_200 • FLSIII_150 • LEXAN • MRXP_Lexan_Saline • MRXP_Lexan_Contrast • MRXP_QWIKFIT_115 • MRXP_QWIKFIT_65 • MRXP_PFA_1 • MRXP_PFA_2 • MRXP_PFA_3 • MRXP_PFA_4
ConsumableEtchedDateTime	false	string	The date and time (in UTC) when the barcode symbol was applied to the syringe barrel. The format is "YYYY-MM-DDTHH:mm:ss.fffZ" Example: 2018-12-06T21:14:12.800Z
ConsumableLaserEtch-Data	false	int	The laser etching line on which the syringe was etched. Values between 0 and 255. Example: 1
LotIdentifier	false	string	Syringe manufacturing batch data. Example: Lot Identifier = 8739
ConsumableShelfLife	false	int	Shelf Life of a syringe. This is recorded with number of Months. Example: 48
IsConsumableExpired	false	bool	This Boolean flag indicates whether the syringe is expired at the time of usage or not. T – Expired F – Unexpired
IsCounterFeit	false	bool	This Boolean flag indicates whether it's a Bayer syringe or a counterfeit. T – Counterfeit F – Bayer

3.3.3 ConsumableInjectorInfo

This contains information about the injector that a consumable is associated.

3.3.3.1 Type Definition

3.3.3.2 Element Description

Member	Anonymised	Type	Description
InjectorCertegraId	true	string	The internal GUID used by Certegra to uniquely identify the injector. This field will be anonymised via SHA-256 hashing function, containing a 64 character hexadecimal string.
Facility	false	string	The facility that the injector is located in. For example, “Memorial Hospital East Side”.
Suite	false	string	The suite within the facility where the injector is located. For example, “MH CT1”.
InjectorName	false	string	The user defined name of the injector.
InjectorSerialNumber	false	string	The serial number used to identify the injector. This is assigned as part of the manufacturing process and cannot be changed.
SoftwareVersion	false	string	The injector software version e.g. “S2-CRU-100.89-C1.06_WIN_HU”
InjectorType	false	string	The type, typically the model, of the injector. Possible values: • Unknown • StellantDx • StellantSx • SpectrisSolaris • MRXperion • Centargo • StellantFlex
VirtualNodePath	true	string	Injectors are considered nodes in configurations where there is a central server managing multiple injector systems. As part of managing these nodes the site can devise virtual node paths which are essentially organizational hierarchies for management purposes. For example there may be 1 central server that has 5 nodes directly reporting to it. However, the user may choose to define a structure such as “MMES\Radiology\Suite1\”. This field will be anonymised for the purposes of Data Bridge. This field will always be reported as null.
ModalityType	false	string	Modality Type (If it is performed by MR injectors the value will be MR otherwise CT) Possible values: CT, MR

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