

Global Service Standards

How To Use Generic Codes for Hardware Issues

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DOCUMENT INFORMATION

General Information

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Document History

Version	Reason for change	Date (mm/dd/yyyy)
1.0	first release	12/19/2002
1.1	added code C19	07/05/2004
2.0	added Please Specify codes and Not Applicable codes	01/27/2005
4.0	changed to v4.0 to be compliant with DocIT versioning added section Problem Description Visits changed code description for code C10 changed short and expanded definitions of codes F00, F12, F99, C00, C10, C99, R00, R06, R10 & R99	03/30/2006

6.0	Document name changed changed to v6.0 to be compliant with Global Service Standard versions Introduction chapters shortened New rules for mandatory problem description reporting Added Function codes F97, F98 Added Cause codes C97, C98, removed codes C14 and C17 Added Remedial codes R97, R98 Introduced dependencies between Function & Cause codes	As of approval
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Distribution

Department / Area / Function
via DMT homepage

Purpose

The purpose of this document is to provide additional information for local service organizations on how to use Global Service Standard codes when reporting hardware problems fixed by service specialists.

Provision of this additional “How to use –“ information is needed to ensure that all country organizations use Global Service Standards in their local CRM tools in such a way as to provide comparable reporting output, to enable us to utilize this information to improve our products.

Mandatory Problem Description Reporting

If the First Classification Code (which documents the customer allegation) classifies the respective case as complaint it is mandatory to provide a coded problem description. This can be done either with

- Application codes,
- IT / Software codes or
- Hardware codes (which are described in this document)

Complaint-type First Classification codes are

- Assay Performance,
- Instrument Malfunction,
- Software Malfunction,
- Labeling / Documentation / Packaging or
- DC-Assessment

and a proper problem description reporting is a must for these cases.

In all other cases it is ok to leave the problem description codes as “Please Specify”. This especially applies to “Roche initiated activities” (like PM or installations), for “Information Requests” additional information might be helpful therefore it is recommended to also use these codes for this type of cases.

Function Codes

Code	Description	Definition
F00	Please Specify	Default selection in Clarify
F01	Reagent System	Failure of electronic, mechanical or hydraulic components related to reagent delivery
F02	Sample System	Failure of electronic, mechanical or hydraulic components related to sample delivery
F03	Measurement System	Failure of electronic, mechanical or optical components related to the optical measurement system and Measuring Cells (optical), LASER system
F04	Transport System	Failure of electronic, mechanical components related to any transport mechanism
F05	Waste System	Failure of electronic, mechanical or hydraulic components related to the waste removal system
F06	Temperature Control Systems	Failure of electronic, mechanical or cooling components related to the internal environmental conditions e.g. air conditioning, cooling fans etc
F07	Electronic systems	Failure of non-measuring system related electronic components, e.g. Photocouplers, power supplies, cabling.
F08	User Interface (Hardware)	Failure of operator communication systems e.g. printers, monitors, keyboards etc
F09	LIS & Host Communication	Failure LIS computer system or host interface connection
F10	Chassis, Housing, Packaging	Defective, damaged covers, housings, chassis etc
F11	OEM Systems	Failure of external ancillary systems e.g. water supply, UPS, mains power supplies; pneumatic systems etc
F12	No Problem Found	No problems found
F13	Electrodes / Measuring systems (ISE)	Failure of Electrodes including Ion Selective Electrodes and Measuring Cells (electronic)

Code	Description	Definition
F14	Fluidic Systems	General failure of the fluidic / Hydraulic system
F15	Code Identification	Failure of Sample or Reagent Identification Systems
F16	User Interface (Software)	Failure of the Input/Output system / Problems with software
F97	Empty Field	for internal data processing, not to be used in Clarify
F98	Not Global	for internal data processing, not to be used in Clarify
F99	Not Applicable	for internal data processing, not to be used in Clarify

Cause Codes

Code	Description	Definition
C00	Please Specify	Default selection in Clarify
C01	Electronic Failure	Failure of a electronic component e.g. PCB, fuse, wiring etc
C02	Mechanical Failure	Failure of a mechanical component e.g. bearings, hardware mounting etc
C03	Fluidics Failure	Failure of a fluidic component e.g. valves, syringes, tubing, pumps etc
C04	Optical Failure	Failure of a optical component e.g. position detectors, optical measurement device etc.
C05	Damaged	Failure due to misuse, excessive wear or external damage.
C06	Environment	Failure due to external environmental factors e.g. room temperature, power supplies, water quality, contamination etc
C07	Operator Error	Failure of a electronic, mechanical, fluidic, optical device or software due to operator error
C08	Consumables	Failure due to issues related to consumables, cuvettes, sample cups, probes, tips etc
C09	Reagent	Failure due to issues related to reagents, calibrators, controls etc.
C10	No Cause found	No cause found, e.g. failure could not be reproduced or verified
C11	Software Failure	Failure of the Operating or Application software
C12	Vacuum / Pressure / Hydraulic Failure	Failure in Components of the hydraulic or vacuum/pressure system
C13	Contamination	Failure due to Bacterial Contamination of Components

Code	Description	Definition
C15	System Configuration Error	Failure due to a wrong system set-up
C16	Misadjusted	Failure due to incorrect or misadjusted components
C18	Liquid Level Detection	Failure due to problems with the liquid level detection system
C19	Security Issue	Failure due to a virus/worm or a hacker attack
C97	Empty Field	for internal data processing, not to be used in Clarify
C98	Not Global	for internal data processing, not to be used in Clarify
C99	Not Applicable	for internal data processing, not to be used in Clarify

Remedial Codes

Code	Description	Definition
R00	Please Specify	Default selection in Clarify
R01	Replace	Replacement of an electronic, mechanical, fluidic or optical device, including complete instrument replacement
R02	Retrofit	Perform remedial retrofit (quote ECN)
R03	Clean / lubricate	Clean & lubricate affected part or parts
R04	Adjust /Re-align	Adjust / re-align tighten effected part or parts
R05	Communicate	Report problem / issue to Roche, third party or supplier
R06	No Remedial Actions	No remedial action done due to not reproducible problem
R07	Reload Software	Reload of the software
R08	Corrective Maintenance	Perform Maintenance
R09	Re-Connect	Parts or Components are disconnected and reconnected
R10	Training Update	Additional Training on Site / inhouse / via phone
R11	Check	Testing the functionality of the system
R12	Return to workshop	Return instrument to workshop to repair/modification
R13	System booted	Reboot System
R97	Empty Field	for internal data processing, not to be used in Clarify
R98	Not Global	for internal data processing, not to be used in Clarify
R99	Not Applicable	for internal data processing, not to be used in Clarify

Function & Cause Code Matrix	F00 - Please Specify	F01 - Reagent System	F02 - Sample System	F03 - Measurement System	F04 - Transport System	F05 - Waste System	F06 - Temperature Control Systems	F07 - Electronic systems	F08 - User Interface (Hardware)	F09 - LIS & Host Communication	F10 - Chassis, Housing, Packaging	F11 - OEM Systems	F12 - No Problem Found	F13 - Electrodes / Measuring systems (ISE)	F14 - Fluidic Systems	F15 - Code Identification	F16 - User Interface (Software)
C00 - Please Specify	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X
C01 - Electronic Failure		X	X	X	X	X	X	X	X	X		X		X	X	X	
C02 - Mechanical Failure		X	X	X	X	X	X		X		X	X		X	X	X	
C03 - Fluidics Failure		X	X	X		X	X					X		X	X		
C04 - Optical Failure		X	X	X	X							X		X		X	
C05 - Damaged		X	X	X	X	X	X	X	X	X	X	X		X	X	X	
C06 - Environment		X	X	X	X		X	X	X	X		X		X		X	
C07 - Operator Error		X	X	X	X	X		X	X	X		X		X	X	X	X
C08 - Consumables		X	X	X	X	X						X		X			
C09 - Reagent		X												X			
C10 - No Cause found		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
C11 - Software Failure		X	X	X	X	X		X		X		X				X	X
C12 - Vacuum / Pressure / Hydraulic Failure		X	X	X		X	X					X		X	X		
C13 - Contamination		X	X	X								X		X	X		
C15 - System Configuration Error					X			X	X	X		X				X	X
C16 - Misadjusted		X	X	X	X		X	X				X		X	X	X	
C18 - Liquid Level Detection		X	X			X						X			X		
C19 – Security issue										X							X

Function Code Expanded Definition

F00	Please Specify	Default selection in Clarify
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Code F00 Please Specify. This code must not be used in a problem description visits (see list of these activities above)! It is only available as a default code prior to the selection of the actual function code.

Note1: In exceptional circumstances, e.g. where the problem to be described in a problem description visit can not be assigned to an existing Function Code, the event should be recorded and forwarded to the local member of the DMT for the appropriate change request

F01	Reagent System	Failure of electronic, mechanical or hydraulic components related to reagent delivery
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Code F01 Reagent System, is to be used when defining instrument failures associated with the delivery of reagent or multiple reagents to the reaction/measuring vessel or cuvette, would typically include syringes, valves, tubing, pumps, motors, controlling electronics etc, dedicated to the reagent delivery function.

F02	Sample System	Failure of electronic, mechanical or hydraulic components related to sample delivery
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Code F02 Sample system, is to be used when defining instrument failures associated with the delivery and mixing of patient samples, controls, standards, calibrators etc to the reaction/measuring vessel or cuvette, would typically include syringes, valves, tubing, pumps, motors, controlling electronics etc, dedicated to the sample/controls/ standards/calibrators delivery and mixing function.

F03	Measurement System	Failure of electronic, mechanical or optical components related to the optical measurement system and Measuring Cells, LASER system
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Code F03 Measuring system, is to be used when defining failures associated with the instrument's optical measuring system, would typically include measurement light sources, filters, monochromators, gratings, optical measuring detectors, optical measuring cells, photomultiplier tubes etc, together with associated electronics and power supplies, dedicated to the systems optical measurement system.

F04	Transport System	Failure of electronic, mechanical components related to any transport mechanism
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Code F04 Transport system, is to be used when defining failures associated with the instruments internal transport systems, typically this would include mechanisms for the transport of reaction vessels into the measuring system, systems for the movement of reagent cassettes, patient samples/ controls, together with mechanisms for the movement or supply of clean reaction cuvettes etc.

Function Code Expanded Definition continued

F05	Waste System	Failure of electronic, mechanical or hydraulic components related to the waste removal system
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Code F05 Waste System, is to be used when defining failures associated removal of both solid e.g. used cuvettes, sample tubes etc, together with all forms of liquid waste, would typically include, valves, tubing, pumps, motors, controlling electronics etc, dedicated to the solid or liquid waste removal function.

F06	Temperature Control Systems	Failure of electronic, mechanical or cooling components related to the internal environmental conditions e.g. air conditioning, cooling fans etc
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Code F06 Temperature Control Systems, is to be used when defining failures associated the instruments internal temperature control systems, typically this would include both dedicated air conditioning systems for the control of analysis temperature, reagent and sample cooling, together with more general temperature control systems e.g. electronic card cage fans.

F07	Electronic systems	Failure of non-measuring system related electronic components, e.g. Photo-couplers, power supplies, cabling.
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Code F07 Electronic Systems, is to be used when defining instrument failures not associated with a specific function, (common to many functions), e.g. power supplies, CPU, RAM, ROM, card cage, cabling, Photo-couplers, connectors etc.

F08	User Interface (Hardware)	Failure of operator communication systems e.g. printers, monitors, keyboards etc
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Code F08 User interface hardware, is to be used when defining instrument failures associated with user / instrument communication, typically this would include, keyboards, monitors, printers, etc together with there supporting cabling, connectors and electronics.

F09	LIS & Host Communication	Failure LIS computer system or host interface connection
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Code F09 LIS & Host Communication, is to be used to define failures associated with the laboratory's LIS computer systems, together with Instrument / host interfacing failures. Typically this would include dedicated interface electronics, cabling, connectors and software.

F10	Chassis, Housing, Packaging	Defective, damaged covers, housings, chassis etc
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Code F10 Chassis, Housing, Packaging, is to be used to define instrument failures or activities associated with non-function hardware problems, typically this would include repair, replacement of damaged or defective instrument infrastructure components, e.g. doors, covers, chassis, housing etc.

Function Code Expanded Definition continued

F11	OEM Systems	Failure of external ancillary systems e.g. water supply, UPS, mains power supplies; pneumatic systems etc
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Code F11 OEM Systems, is to be used when defining activities associated with OEM (Other Equipment Manufactures) systems, typically this would include external water supply systems, UPS (Uninterruptible Power Supplies) power supply conditioners, external pneumatic systems, etc.

F12	No Problem Found	No problems found
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Code F12 No Problem Found, is to be used when a reported instrument problem could not be found or reproduced.

F13	Electrodes / Measuring systems (ISE)	Failure of Electrodes including Ion Selective Electrodes and Measuring Cells
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Code F13 Electrodes / Measuring Systems, is to be used when defining failures associated with the instrument's electronic measuring systems, would typically include, ISE (Ion Selective Electrodes), measuring cells, impedance measurement systems etc, together with all associated electronics, power supplies, connectors, cabling etc, dedicated to the instruments electronic measurement system.

F14	Fluidic Systems	General failure of the fluidic / Hydraulic system
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F14 Fluidic Systems, is to be used when defining fluid or hydraulic failures not associated with a specific or defined functions e.g. main compressor failure, internal reservoir fault, vacuum/ air pressure failure etc.

F15	Code Identification	Failure of Sample or Reagent Identification Systems
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F15 Code Identification, is to be used when defining failures associated with the instruments sample or reagent identification systems, typically this would include both handheld and internal barcode readers, optical, magnetic ID systems, together with all there associated electronic, cabling, connectors and hardware components.

F16	User Interface (Software)	Failure of the Input/Output system / Problems with software
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Code F16 User Interface (Software), is to be used when defining problems associated with both, user communication software and / or general instrument operating software problems, typically software bugs, crash's, lock-up's etc.

Function Code Expanded Definition continued

F97	Empty Field	for internal data processing, not to be used in Clarify
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Code F97 Empty Field. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Instrument Function Code will be set to F97 Empty Field if the respective code field does not contain any information.

F98	Not Global	for internal data processing, not to be used in Clarify
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Code F98 Not Global. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Instrument Function Code will be set to F98 Not Global if the coded information received is not available in the list of global codes

F99	Not Applicable	for internal data processing, not to be used in Clarify
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Code F99 Not Applicable. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Instrument Function Code will be set to F99 Not Applicable if

- the current code setting is F00 Please Specify and
- a valid and released Problem Category Code is used in this case (problem is described with generic application codes)

Cause Code Expanded Definition

C00	Please Specify	Default selection in Clarify
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Code C00 Please Specify. This code must not be used in a problem description visits (see list of these activities above)! It is only available as a default code prior to the selection of the actual cause code.

Note1: In exceptional circumstances, e.g. where the problem to be described in a problem description visit can not be assigned to an existing Cause Code, the event should be recorded and forwarded to the local member of the DMT for the appropriate change request

C01	Electronic Failure	Failure of a electronic component e.g. PCB, fuse, wiring etc
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Code C01 Electronic Failure, to be used in conjunction with the Function code to define the reason for failure, typically an electronic component, or associated connectors or wiring.

C02	Mechanical Failure	Failure of a mechanical component e.g. bearings, hardware mounting etc
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Code C02 Mechanical Failure, to be used in conjunction with the Function code to define the reason for failure, typically a failure of a hardware mechanism, bearing, mounting, push- rod etc, due to normal use.

C03	Fluidics Failure	Failure of a fluidic component e.g. valves, syringes, tubing, pumps etc
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Code C03 Fluidics Failure, to be used in conjunction with the Function code to define the reason for failure, typically a failure of a fluidic component, pump, valve, syringe etc, due to normal use.

C04	Optical Failure	Failure of a optical component e.g. position detectors, optical measurement device etc.
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Code C04 Optical Failure, to be used in conjunction with the Function code to define the reason for failure, typically failure of an optical component, optical measuring device, position detector etc, due to normal use.

C05	Damaged	Failure due to misuse, excessive wear or external damage.
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Code C05 Damage, to be used in conjunction with the Function code to define the reason for failure, typically the failure of any component, mechanical, electronic, hydraulic or fluidic, due to misuse, damage or extensive (unusual) wear.

Cause Code Expanded Definition continued

C06	Environment	Failure due to external environmental factors e.g. room temperature, power supplies, water quality, contamination etc
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Code C06 Environment, to be used in conjunction with the Function code to define the reason for failure, typically the failure of the instrument, and or any component, mechanical, electronic, hydraulic or fluidic, due to external environmental issues e.g. room temperature, power supplies, water quality, external contamination etc.

C07	Operator Error	Failure of a electronic, mechanical, fluidic, optical device or software due to operator error
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Code C07 Operator Error, to be used in conjunction with the Function code, to define reason for failure, typically the failure of the instrument / software, and or any component, mechanical, electronic, hydraulic or fluidic, due to operator error.

C08	Consumables	Failure due to issues related to consumables, cuvettes, sample cups, probes, tips etc
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Code C08 Consumables, to be used in conjunction with the Function code to define the reason for failure, typically the failure of the instrument or a measurement due to issues related to consumables, cuvettes, sample cups, probes tips etc

C09	Reagent	Failure due to issues related to reagents, calibrators, controls etc.
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Code C09 Reagent, to be used in conjunction with the Function code to define reason for failure, typically the failure of the instrument or a measurement due to issues related to reagents, controls, calibrators, standards etc

C10	No Cause found	No cause found, e.g. failure could not be reproduced or verified
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Code C10 No Cause, to be used with Function code F12 (No Problem), when a reported instrument problem could not be reproduced or verified.

C11	Software Failure	Failure of the Operating or Application software
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Code C11 Software Failure, to be used in conjunction with the Function code to define the reason for failure, typically the failure of the instrument or a measurement due to issues related the application or operating software.

Cause Code Expanded Definition continued

C12	Vacuum / Pressure / Hydraulic Failure	Failure in Components of the hydraulic or vacuum/pressure system
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Code C12 Vacuum/Pressure/Hydraulic Failure, to be used in conjunction with the Function code to define the reason for failure, typically the failure of compressors, vacuum chambers hydraulic units and associated components

C13	Contamination	Failure due to Bacterial Contamination of Components
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Code C13 Contamination, to be used in conjunction with the Function code to define the reason for failure, typically, the failure of the instrument, and or any component, mechanical, electronic, hydraulic or fluidic, due to bacterial contamination.

C15	System Configuration Error	Failure due to a wrong system set-up
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Code C15 system configuration error, to be used in conjunction with the Function code to define reason for failure, typically an instrument, measurement, or analysis error due to the incorrect system configuration.

C16	Misadjusted	Failure due to incorrect or misadjusted components
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Code C16 Misadjusted, to be used in conjunction with the Function code to define the reason for failure, typically a failure of the instrument, hardware, electronics, fluidics, etc due to incorrect or maladjustment

C18	Liquid Level Detection	Failure due to problems with the liquid level detection system
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Code C18 Liquid Level Detection, to be used in conjunction with the Function code to define the reason for failure, typically a failure of the instrument, or measurement due to problems associated with the Liquid Level Detection system and associated electronics, hardware, cabling, connectors etc.

C19	Security Issue	Failure due to a virus/worm or a hacker attack
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Code C19 Security Issue, to be used in conjunction with the Function code to define the reason for failure, typically a failure of the instrument or instrument software due to a virus /worm infection or illegal access to private data stored on an instrument or LIM/LIS system. Additionally activities done to prevent further damages because of the reasons mentioned above should be reported against this code.

Cause Code Expanded Definition continued

C97	Empty Field	for internal data processing, not to be used in Clarify
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Code C97 Empty Field. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Instrument Cause Code will be set to C97 Empty Field if the respective code field does not contain any information.

C98	Not Global	for internal data processing, not to be used in Clarify
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Code C98 Not Global. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Instrument Cause Code will be set to C98 Not Global if the coded information received is not available in the list of global codes

C99	Not Applicable	for internal data processing, not to be used in Clarify
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Code C99 Not Applicable. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Instrument Cause Code will be set to C99 Not Applicable if

- the current code setting is C00 Please Specify and
- a valid and released Application Cause Code is used in this case (problem is described with generic application codes)

Remedial Code Expanded Definition

R00	Please Specify	Default selection in Clarify
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Code R00 Please Specify. This code must not be used in a problem description visits (see list of these activities above)! It is only available as a default code prior to the selection of the actual remedial code.

Note1: In exceptional circumstances, e.g. where the problem to be described in a problem description visit can not be assigned to an existing Remedial Code, the event should be recorded and forwarded to the local member of the DMT for the appropriate change request

R01	Replace	Replacement of an electronic, mechanical, fluidic or optical device, including complete instrument replacement
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Code R01 Replace, Used in conjunction with the Cause codes to define the actual repair activity, typically to replace, due to failure, of any electronic, mechanical, optical or fluidic device on a “like for like” basis

R02	Retrofit	Perform remedial retrofit (quote ECN)
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Code R02 Retrofit, Used in conjunction with the Cause codes to define the actual repair activity, typically to perform a update or upgrade of the instrument, software or component parts

R03	Clean / lubricate	Clean & lubricate affected part or parts
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Code R03 Clean/Lubricate, Used in conjunction with the Cause codes to define the actual repair activity, typically to clean and lubricate mechanical parts, also used when cleaning electrical contacts, relay points etc.

R04	Adjust /Re-align	Adjust / re-align tighten effected part or parts
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Code R04 Adjust/Re-align, used in conjunction with the Cause codes to define the actual repair activity, typically used when re-setting mechanical devices, also used when making optical, electronic or fluid adjustments.

R05	Communicate	Report problem / issue to Roche, third party or supplier
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Code R05 Communicate, used when unable to perform actual repair and need to inform other's (third party, applications, product management, suppliers etc) of the need for their involvement.

Remedial Code Expanded Definition continued

R06	No Remedial Actions	No remedial action done due to not reproducible problem
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Code R06 No Remedial Actions, used in conjunction with Cause code C10 (No Cause) when no remedial action was done as the reported failure has not been found / could not be reproduced.

R07	Reload Software	Reload of the software
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Code R07 Reload Software, used in conjunction with the Cause codes, to indicate repair was accomplished by a system or application software reload.

R08	Corrective Maintenance	Perform Maintenance
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Code R08 Corrective Maintenance, used in conjunction with the Cause codes to indicate that the repair was achieved by performing a full or part, un-scheduled maintenance.

R09	Re-Connect	Parts or Components are disconnected and reconnected
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Code R09 Re-Connect, used in conjunction with the Cause codes to indicate that the repair was achieved by performing a re-connection, typically electronic connectors but also use when re-connecting tubing, mechanical devices etc,

R10	Training Update	Additional Training on Site / inhouse / via phone
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Code R10 Training Update, used in conjunction with the Cause codes to indicate that additional, unplanned training took place on site, at a Roche site or via phone.

R11	Check	Testing the functionality of the system
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Code R11 Check, used in conjunction with the Cause codes to indicate that an instrument performance check was carried out, without other remedial e.g. repair, retrofit actions taking place.

R12	Return to workshop	Return instrument to workshop to repair/modification
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Code R12 Return to Workshop, used in conjunction with the Cause codes to indicate that the complete instrument was returned to the workshop for repair, retrofit etc.

Remedial Code Expanded Definition continued

R13	System booted	Reboot System
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Code R13 System Booted, used in conjunction with the Cause codes to indicate that the instrument repair was accomplished by restarting the instrument and or the operating software.

R97	Empty Field	for internal data processing, not to be used in Clarify
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Code R97 Empty Field. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Instrument Remedial Code will be set to R97 Empty Field if the respective code field does not contain any information.

R98	Not Global	for internal data processing, not to be used in Clarify
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Code R98 Not Global. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Instrument Remedial Code will be set to R98 Not Global if the coded information received is not available in the list of global codes

R99	Not Applicable	for internal data processing, not to be used in Clarify
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Code R99 Not Applicable. This code should neither be used nor seen in Clarify. It is only needed for internal data processing.

An Instrument Remedial Code will be set to R99 Not Applicable if

- the current code setting is R00 Please Specify and
- a valid and released Application Fix Code is used in this case (problem is described with generic application codes)