

HealthShare HS2020-04 Alert

2-APR-2020

Dear HealthShare Customer:

I am writing because you are listed as the security contact for your organization. When risks have been uncovered that concern your use of HealthShare®, InterSystems is committed to providing you the necessary information so that you can assess your situation as quickly as possible.

We have identified a number of risks that may affect you when using InterSystems HealthShare®, including an issue related to the processing CDA documents that requires your immediate attention.

Please read the information that follows. If you have any questions, please contact InterSystems Support at support@intersystems.com or +1.617.621.0700.

We understand and take very seriously our commitment to you to provide an effective and efficient solution while protecting patient safety and safeguarding patient information. Our HealthShare Alert process complements our existing support processes. If you have questions about our processes for data protection, privacy, and security, including our Global Trust program, you can reach our Data Protection Officer Ken Mortensen at dpo@intersystems.com.

If you ever have any privacy, security, patient safety or operations related questions about HealthShare, do not hesitate to contact the Worldwide Response Center (WRC) through support@intersystems.com or +1.617.621.0700, so that we can assist you.

Respectfully,

Jonathan Teich, MD
Director, Product Management – HealthShare

InterSystems
One Memorial Drive
Cambridge, MA 02142
TEL: +1.617.621.0600

Summary of Alerts & Advisories

This HealthShare Alert & Advisory ensures that InterSystems gets you the information you need to understand important clinical safety, privacy, security and operational risks that have been identified. The Alert & Advisory process complements our existing support processes.

This document contains the following Alerts & Advisories:

Alert or Advisory	Product & Versions Affected	Risk Category & Score
HS2020-04-01: Negation in CDA Documents is Ignored by HealthShare	All versions of HealthShare Information Exchange and Unified Care Record	Varies based on data
HS2020-04-02: Possible Race Condition during Health Insight Data Feed	The affected versions are: <ul style="list-style-type: none"> Health Insight 2018.1, 2019.1.0 and 2019.1.1 	2-Low Risk (Operational)
HS2020-04-03: Possible Data Integrity Issues after Adding Mirrored Database	The affected versions are: <ul style="list-style-type: none"> HealthShare 2019.2 built on IRIS HealthShare 2019.1 or earlier, built on Caché 	2-Low Risk (Operational)

We encourage you to read the information below and then reach out to InterSystems Support at support@intersystems.com or +1.617.621.0700 with any questions that might arise.

Detail of Alerts

HS2020-04-01: Negation in CDA Documents is Ignored by HealthShare

Issue date: 2-APR-2020

Risk Category and Score

Clinical Safety	Privacy	Security	Operational
Varies based on data	No Risk	No Risk	Varies based on data

Version and System Area Affected

HealthShare® Products and Versions: All versions of HealthShare Information Exchange and Unified Care Record

System areas affected: Data Integrity

Reference: HSIEC-2030/HSIEC-2219

Summary of Issue

Clinical Document Architecture (CDA) documents can contain clinical data that is "negated" to represent a clinical concept that is known to be absent or untrue. Negation may apply to general concepts, such as documenting that a patient does not have any known drug allergies or did not receive any medications during an encounter. Negation may also apply to specific concepts, such as documenting that a patient did not receive a specific vaccination.

When HealthShare processes CDA documents, it ignores this negation. For example, when the CDA document indicates that a patient *did not* receive an influenza vaccination, HealthShare records that the patient *did* receive that vaccination. For general concepts, the unified care record may include an entry such as "drug or medication" with no additional information.

A preliminary analysis from two data sets has identified the areas where negation is most prevalent. These are listed in the Technical Addendum.

This issue presents a clinical safety concern, as clinical data is modified to indicate the opposite of what was documented. It may also present an operational concern if the negated clinical data is used for operational or quality metrics.

The risk at each customer will vary based on the type of data for which negation is used and the specific entries that are negated. Therefore, it is recommended that customers use the provided utility to individually assess their risk.

InterSystems plans to correct the HealthShare transformations to account for negation, but this fix will take some time to implement. An interim fix is also planned that will simply discard entries that use negation, so that erroneous information does not appear in clinical data. Additionally, a utility that analyzes CDA documents stored in your repository is being made available with this alert.

Full details of the identified issue appear in the [Technical Addendum for HS2020-04-01](#).

Risk Assessment

The risk score and category for Risk & Safety Alerts are determined using the InterSystems Risk Rating process outlined in the addendum. Because the Clinical and Operational risk for this defect varies depending on whether negation is used and where negation is used in your CDA document feeds, a risk score has not been provided. InterSystems strongly recommends that you use this alert as a utility to analyze your data and gather the information necessary for you to assess the risk in your situation.

Recommended Actions

InterSystems recommends that customers take the following actions:

Short term:

Alert clinical users that a drug, medication, or vaccination with no further information, such as a date or dosage, may be erroneous. Examples appear in the [Technical Addendum for HS2020-04-01](#).

Use the provided utility to determine whether your site receives CDA documents that use negation. Follow the instructions included in the utility to perform an analysis on your results to see what types of information are affected and how prevalent the use of negation is in your data feeds. Based on the results, alert your clinical users as to the types of information that should be double-checked with patients before making clinical decisions. The InterSystems [Worldwide Response Center](#) (WRC) can assist you in interpreting the utility's output.

Medium term:

Apply the fix that discards entries where negation is used, once it is available.

Long term:

Implement the update that supports negation throughout the HealthShare suite of products when it becomes available.

If you have any questions regarding this alert, please contact the [Worldwide Response Center](#). Reference "Alert HS2020-04".

Technical Addendum for HS2020-04-01

Description of Issue

CDA documents allow an entry to specify `negationInd="true"` for certain sub-elements. Entries may negate a *general concept* (such as "problem" or "drug or medication") or a *specific concept* (such as "Influenza, seasonal, injectable"); examples of each are described below. When HealthShare processes CDA documents, it ignores `negationInd="true"`, reversing the meaning of the entry.

Negated general concepts

Some entries in CDA documents may negate a general concept, such as "drug or medication" or "problem", with the intended meaning that the patient was or is not affected by the negated concept or did not receive or did not have an occurrence of that concept during a specific encounter. When displayed in HealthShare, these entries are often missing common information typically associated with such entries, such as dates, dosages or even drug names. As such, these present a lower risk to patient safety. For example, the following CDA entry indicates that the patient did *not* have a drug or medication associated with an encounter. The unified care record records the value "drug or medication" in the Medication streamlet. (Depending on your Clinical Viewer configuration and customizations, these entries may or may not appear in the Clinical Viewer.)

```
<substanceAdministration xmlns="urn:hl7-org:v3" classCode="SBADM" moodCode="INT" negationInd="true">
<templateId extension="2014-06-09" root="2.16.840.1.113883.10.20.22.4.16"/>
<templateId root="2.16.840.1.113883.10.20.22.4.16"/>
<id root="A8AB2190-E0A6-11E9-9993-005056A428EE"/>
<statusCode code="completed"/>
<effectiveTime xsi:type="IVL_TS">
<low value="20170731095114.000-0400"/>
<high nullFlavor="NI"/>
</effectiveTime>
<doseQuantity nullFlavor="NI"/>
<consumable>
<manufacturedProduct classCode="MANU">
<templateId extension="2014-06-09" root="2.16.840.1.113883.10.20.22.4.23"/>
<templateId root="2.16.840.1.113883.10.20.22.4.23"/>
<manufacturedMaterial>
<code nullFlavor="OTH">
<originalText>
<reference value="#MEDPRODNKP"/>
</originalText>
<translation code="410942007" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="drug
or medication"/>
</code>
...
</substanceAdministration>
```

drug or medication

[< Back to Viewer](#)

Administration Details

Dose / Form	<input type="text"/>	Units	<input type="text"/>	Order Status	<input type="text" value="Inactive"/>
Drug Form	<input type="text"/>	Order Start Date	<input type="text"/>	Order Start Time	<input type="text"/>
Route	<input type="text"/>	Order End Date	<input type="text"/>	Order End Time	<input type="text"/>
Frequency	<input type="text"/>				
Duration	<input type="text"/>				
Number of Refills	<input type="text"/>				

Order Notes

Comments	<input type="text" value="Medication Administration not documented"/>
Text Instructions	<input type="text" value="Medication Administration not documented"/>

Order Details

Priority	<input type="text" value="Normal"/>	Entered At	<input type="text"/>
Ordering Clinician	<input type="text"/>	Entered By	<input type="text"/>
Authorising Clinician	<input type="text"/>	Entered On	<input type="text"/>
		Last Update Time	<input type="text"/>

A negated CDA entry shown in the Clinical Viewer

Negated specific concepts

Negated entries may also refer to a specific concept such as a specific immunization. Specific negated entries may present a higher risk to patient safety and may contain other information such as dates. For example, the following CDA entry indicates that the patient did *not* receive an influenza vaccination. The unified care record records the value "Influenza, seasonal, injectable" in the Vaccination streamlet and the Clinical Viewer displays the value "Influenza, seasonable, injectable" in the Immunizations chart, but with no dosage specified.

```
<substanceAdministration xmlns="urn:hl7-org:v3" classCode="SBADM" moodCode="EVN" negationInd="true">
<templateId extension="2015-08-01" root="2.16.840.1.113883.10.20.22.4.52"/>
<templateId root="2.16.840.1.113883.10.20.22.4.52"/>
<id root="ZMVHGEM815-4194-9HS7-47LP-53P994CMD2K0-0714381010-0018642403501415"/>
<statusCode code="completed"/>
<effectiveTime value="2011119080000.000-0500"/>
<consumable typeCode="CSM">
<manufacturedProduct classCode="MANU">
<templateId extension="2014-06-09" root="2.16.840.1.113883.10.20.22.4.54"/>
<templateId root="2.16.840.1.113883.10.20.22.4.54"/>
<manufacturedMaterial>
<code code="141" codeSystem="2.16.840.1.113883.12.292" codeSystemName="CVX" displayName="Influenza, seasonal, injectable">
...
</substanceAdministration>
```

Immunizations Date, Immunization				
Immunization	Dose	Source	Date	Details
Influenza, seasonal, injectable			01/30/2016	⋮

A negated CDA entry shown in the Clinical Viewer

Impacted data types

Based on a preliminary analysis from two data sets, the use of `negationInd="true"` is most prevalent in the following CDA sections:

- Allergies, Adverse Reactions, Alerts
- Immunizations
- Medications
- Social and Family History
- Cognitive/Functional Performance
- Encounter Diagnosis

Recommended Action

This defect may impact any customers who process CDA documents.

A utility that analyzes the CDA documents stored in your repository is being made available with this alert. The utility scans the document repository to identify cases of CDA entries where `negationInd="true"`. It generates the following output:

1. A summary report that categorizes the cases in each CDA section. Each category includes a count of cases of negation and a percentage indicating how prevalent this category is in the total number of cases of negation.
2. A detailed case report that categorizes the cases by value (e.g., "Problem", "influenza, seasonal, injectable", "drug or medication")
3. Sample CDA entries for each category, including an MRN and Assigning Authority which may be used to search for a patient in the Clinical Viewer to assess how the data is displayed or if it is displayed at all on your system.

Use the utility to determine whether your site receives CDA documents that use negation. Follow the instructions included in the utility to perform an analysis on your results to see what types of information are affected and how prevalent the use of negation is in your data feeds. Based on the results, alert your clinical users as to the types of information that should be double-checked with patients before making clinical decisions. The InterSystems [Worldwide Response Center](#) (WRC) can assist you in interpreting the utility output. If you find an issue that is particularly problematic, the WRC can assist you in deprecating the affected documents, so they no longer constitute part of the patients' records.

InterSystems plans to correct HealthShare CDA transformations to account for negation, but this fix will take some time to implement. An interim fix is also planned that will discard entries that use negation, so that erroneous information does not appear in clinical data.

InterSystems recommends that customers take the following actions:

Short term:

Alert clinical users that a drug, medication, or vaccination with no further information, such as a date or dosage, may be erroneous. Examples appear in the [Description of Issue](#) section, above.

Use the provided utility to determine whether your site receives CDA documents that use negation. Follow the instructions included in the utility to perform an analysis on your results to see what types of information are affected and how prevalent the use of negation is in your data feeds. Based on the results, alert your clinical users as to the types of information that should be double-checked with patients before making clinical decisions. The InterSystems [Worldwide Response Center](#) (WRC) can assist you in interpreting the utility's output.

Medium term:

Apply the fix that discards entries where negation is used, once it is available.

Long term:

Implement the update that supports negation throughout the HealthShare suite of products when it becomes available.

Information about the Correction

The negation indicator utility is available from the WRC. Please refer to issue HSIEC-2219. If you have any questions regarding this alert, please contact the [Worldwide Response Center](#) (WRC).

End of Alert HS2020-04-01

HS2020-04-02: Possible Race Condition during Health Insight Data Feed

Issue date: 2-APR-2020

Risk Category and Score

Clinical Safety	Privacy	Security	Operational
1-Very Low Risk	No Risk	No Risk	2-Low Risk

Version and System Area Affected

HealthShare® Products and Versions: Health Insight 2018.1, 2019.1.0 and 2019.1.1

System areas affected: Data Feed Process

Reference: HSHI-3365/SBS698

Summary of Issue

A very rare race condition may occur when feeding data from Unified Care Record or Information Exchange into Health Insight. If the race condition occurs, the data transfer process freezes without notifications, and subsequent processing of the message queue stops. When the data transfer process comes to a halt, the only means to resume processing is to manually kill a particular global. InterSystems strongly recommends that customers contact the WRC for help to resolve this issue.

In the released version of HealthShare 2019.1.2, this issue is resolved.

Full details of the identified issue appear in the [Technical Addendum for HS2020-04-02](#).

Risk Assessment

The risk score and category were determined using InterSystems' Risk Rating process (outlined in the addendum), and based on the following assessments:

Clinical Safety:	1 – Very Low Risk	Severity of typical adverse outcome = 1 out of 5 Likelihood of typical adverse outcome = 1 out of 5
Operational:	2 – Low Risk	Severity of typical adverse outcome = 4 out of 5 Likelihood of typical adverse outcome = 1 out of 5

Recommended Actions

InterSystems recommends that customer organizations take the following actions:

1. Contact the WRC for Ad hoc change file or full kit distribution
2. Follow the instructions to apply this change to your Health Insight environment

If you have any questions regarding this alert, please contact the [Worldwide Response Center](#). Reference “Alert HS2020-04”.

Technical Addendum for HS2020-04-02

Description of Issue

InterSystems has corrected a defect that can incur a race condition during the data transfer into Health Insight in HealthShare 2019.1 and older versions. Normally, the transfer business process (`HSAA.TransferSDA3.Process.Transfer`) sets a global that indicates a patient message is being-processed (for example, `^ISC.HSAA.TransferAnalyticsID`) and then the transfer business operation (`HSAA.TransferSDA3.Operation.Transfer`) kills the global after it has finished processing any messages for this patient. In the rare case that the race condition occurs, the transfer business process sets the global for a patient after the transfer business operation kills the global. When that happens, any subsequent messages will not be processed until the global is killed manually.

With the correction applied, the transfer business process first sets the global for the patient being processed before it sends an asynchronous request to the transfer business operation, thus ensuring that the global kill occurs after the global set.

Additionally, the correction adds logic to kill the global if any error is caught when sending the request to the transfer business operation. The transfer business operation still kills the global at the end of message processing, providing an additional step to ensure the global is killed.

Finally, the correction addresses a potential failover issue if a crash happens in the system during data transfer into Health Insight. In the event a crash occurs during the transfer, and the global for a patient does not get killed, any production messages that have not completed processing are re-queued. The system checks if the patient to be processed in the message queue is the patient that was being processed before the crash occurred and continues to process the re-queued message for that patient.

Recommended Action

InterSystems recommends that customer organizations take the following actions:

1. Contact the WRC for Ad hoc change file or full kit distribution
2. Follow the instructions to apply this change to your Health Insight environment

The correction HSHI-3365/SBS698 will be included in all future releases and is available as an Ad hoc distribution from the [Worldwide Response Center](#) (WRC).

If you have any questions regarding this alert, please contact the WRC. Reference "Alert HS2020-04".

End of Alert HS2020-04-02

HS2020-04-03: Possible Data Integrity Issues after Adding Mirrored Database

Issue date: 2-APR-2020

Risk Category and Score

Clinical Safety	Privacy	Security	Operational
No Risk	No Risk	No Risk	2-Low Risk

Version and System Area Affected

HealthShare® Products and Versions: All InterSystems HealthShare® products.

System areas affected: Mirroring

Reference: HYY2390

Summary of Issue

InterSystems has corrected a defect that can result in data integrity issues on systems using mirroring.

This defect is more likely to be encountered on HealthShare 2019.2 which is built on IRIS. It is highly unlikely to have occurred on systems running HealthShare 2019.1 or earlier built on Caché.

The issue can only occur in a situation that meets all of the following conditions:

1. A database is removed from a mirror.
2. A database is added to the same mirror – this can be the same database or another one.
3. There is no journal switch between removing the first database and adding the second one.

If a system encounters the defect, then the current journal file will be intact on the primary system where the database was added, *but* a small subset of updates in that journal file will be missing from the newly added mirrored database on all other mirror members – both failover and async members. All updates from subsequent journal files are correctly journaled.

Risk Assessment

The risk score and category were determined using InterSystems' Risk Rating process (outlined in the addendum), and based on the following assessments:

Operational: 2 – Low Risk Severity of typical adverse outcome = 2 out of 5
 Likelihood of typical adverse outcome = 2 out of 5

Recommended Actions

InterSystems recommends that customers take the following actions:

1. While there is no way to definitively determine if the defect has been encountered, if you think the conditions listed above apply to your use of mirroring, run the DataCheck utility to confirm mirror set consistency. For more information about DataCheck, see the "[Data Consistency On Multiple Systems](#)" section of the *Data Integrity Guide*.
2. Request an Ad hoc distribution from the InterSystems Worldwide Response Center (WRC).

The correction for this defect is identified as HYY2390 and will be included in all future product releases and is available by requesting an Ad hoc distribution from the InterSystems [Worldwide Response Center](#) (WRC).

If you have any questions regarding this alert, please contact the [Worldwide Response Center](#). Reference "Alert HS2020-04 Dev Key HYY2390".

The information provided in this message is proprietary information being shared with you on the basis of your identification as a contact for product updates from InterSystems. This message may contain confidential information, and you should ensure that its contents are disclosed solely in compliance with any nondisclosure obligations between our organizations. The information provided in this InterSystems Product Alert or Service Bulletin is provided "as is" and without additional warranty. Except as provided for in a mutually executed agreement between you and InterSystems Corporation, its subsidiaries, and affiliates, InterSystems disclaims all warranties, either express or implied, including the warranties of merchantability and fitness for a particular purpose.

End of Alert HS2020-04-03

– End of Alerts –

The information provided in this message is proprietary information being shared with you on the basis of your identification as a contact for product updates from InterSystems. This message may contain confidential information, and you should ensure that its contents are disclosed solely in compliance with any nondisclosure obligations between our organizations. The information provided in this InterSystems Product Alert or Service Bulletin is provided "as is" and without additional warranty. Except as provided for in a mutually executed agreement between you and InterSystems Corporation, its subsidiaries, and affiliates, InterSystems disclaims all warranties, either express or implied, including the warranties of merchantability and fitness for a particular purpose.

Addendum

Clinical Risk Rating Process

InterSystems' clinical risk rating uses standard methodology to estimate the risk of a system hazard based on the most typical foreseeable adverse patient outcome, as opposed to the worst-case scenario. Experienced clinicians in our clinical safety team provide an estimate of the severity and likelihood using standard ordinal scales to derive the risk category.

Description of Outcome Severity

5	Catastrophic	Multiple patients	Death. Permanent life-changing incapacity. Severe injury or incapacity from which recovery is not expected in the short term.
4	Major	Single patient	Death. Permanent life-changing incapacity. Severe injury or incapacity from which recovery is not expected in the short term.
		Multiple patients	Severe injury or incapacity from which recovery is expected in the short term. Severe psychological trauma.
3	Moderate	Single patient	Severe injury or incapacity from which recovery is expected in the short term. Severe psychological trauma.
		Multiple patients	Minor injury from which recovery is not expected in the short term. Significant psychological trauma.
2	Minor	Single patient	Minor injury from which recovery is not expected in the short term. Significant psychological trauma.
		Multiple patients	Minor injury from which recovery is expected in the short term. Minor psychological upset. Inconvenience.
1	Minimal	Single patient	Minimal injury from which recovery is expected in the short term. Minor psychological upset. Inconvenience.

Description of Outcome Likelihood

5	Very High	Will undoubtedly happen/recur, possibly frequently	Expected to occur at least daily
4	High	Will probably happen/recur, but it is not a persisting issue/ circumstances	Expected to occur at least weekly
3	Medium	Might happen or recur occasionally	Expected to occur at least monthly
2	Low	Do not expect it to happen/recur but it is possible it may do so	Expected to occur at least annually
1	Very low	This will probably never happen/recur	Not expected to occur for years

Risk Score & Category

The combination of the Severity and Likelihood produce an overall Risk Score and Risk Category as follows:

Severity	5	3	4	4	5	5
	4	2	3	3	4	5
	3	2	2	3	3	4
	2	1	2	2	3	4
	1	1	1	2	2	3
		1	2	3	4	5
		Likelihood				

Risk Score	Risk Category
5	Very high risk
4	High risk
3	Medium risk
2	Low risk
1	Very low risk

The information provided in this message is proprietary information being shared with you on the basis of your identification as a contact for product updates from InterSystems. This message may contain confidential information, and you should ensure that its contents are disclosed solely in compliance with any nondisclosure obligations between our organizations. The information provided in this InterSystems Product Alert or Service Bulletin is provided "as is" and without additional warranty. Except as provided for in a mutually executed agreement between you and InterSystems Corporation, its subsidiaries, and affiliates, InterSystems disclaims all warranties, either express or implied, including the warranties of merchantability and fitness for a particular purpose.

Privacy Risk Rating Process

InterSystems’ risk rating uses standard methodology to estimate the risk to privacy based on the most typical foreseeable adverse outcomes, as opposed to the worst-case scenario, which is used to determine the impact and likelihood using standard ordinal scales to derive the risk rating.

Description of Impact Rating

5	Critical	Full public disclosure of confidential information, complete impact to data integrity, severe violation of legitimate basis for processing.
4	High	Disclosure to improper and unauthorized parties, operational impact to data integrity, elevated violation of legitimate basis for processing
3	Moderate	Limited disclosure to improper or unauthorized parties, limited impact to data integrity, existing violation of legitimate basis for processing
2	Low	Restricted disclosure to improper parties, restricted impact to data integrity, marginal violation of legitimate basis for processing
1	Minimal	No disclosure to improper or unauthorized parties, no discernable impact to data integrity, trivial or technical violation of legitimate basis for processing

Description of Outcome Likelihood

5	Critical	Will undoubtedly happen/recur, possibly frequently	Expected to occur at every operational or use or with all processing
4	High	Will probably happen/recur, but it is not a persisting issue/ circumstances	Expected to occur regularly or with most processing
3	Moderate	Might happen or recur occasionally	Expected to occur occasionally or with some processing
2	Low	Do not expect it to happen/recur but it is possible it may do so	Expected to occur a few times or with limited processing
1	Minimal	Unlikely happen/recur	Not expected to occur over time of normal operation

Risk Score & Category

The combination of the Impact and Likelihood produce an overall Risk Score and Risk Category as follows:

Severity	5	3	4	4	5	5
	4	2	3	3	4	5
	3	2	2	3	3	4
	2	1	2	2	3	4
	1	1	1	2	2	3
		1	2	3	4	5
		Likelihood				

Risk Score	Risk Category
5	Critical risk
4	High risk
3	Moderate risk
2	Low risk
1	Minimal risk

Security Risk Rating Process

InterSystems’ risk rating uses standard methodology to estimate the risk to security based on the most typical foreseeable adverse outcomes, as opposed to the worst-case scenario, which is used to determine the impact and likelihood using standard ordinal scales to derive the risk rating.

Description of Impact Rating

5	Critical	Full failure of safeguard(s) (administrative, physical, or technical) relating to confidentiality, integrity, and/or availability
4	High	Major (majority) failure of safeguard(s) (administrative, physical, or technical) relating to confidentiality, integrity, and/or availability
3	Moderate	Limited failure of safeguard(s) (administrative, physical, or technical) relating to confidentiality, integrity, and/or availability
2	Low	Marginal failure of safeguard(s) (administrative, physical, or technical) relating to confidentiality, integrity, and/or availability
1	Minimal	Incomplete (or intermittent) failure of safeguard(s) (administrative, physical, or technical) relating to confidentiality, integrity, and/or availability

Description of Outcome Likelihood

5	Critical	Will undoubtedly happen/recur, possibly frequently	Expected to occur at every operational or use or with all processing
4	High	Will probably happen/recur, but it is not a persisting issue/ circumstances	Expected to occur regularly or with most processing
3	Moderate	Might happen or recur occasionally	Expected to occur occasionally or with some processing
2	Low	Do not expect it to happen/recur but it is possible it may do so	Expected to occur a few times or with limited processing
1	Minimal	Unlikely happen/recur	Not expected to occur over time of normal operation

Risk Score & Category

The combination of the Impact and Likelihood produce an overall Risk Score and Risk Rating as follows:

Impact	5	3	4	4	5	5
	4	2	3	3	4	5
	3	2	2	3	3	4
	2	1	2	2	3	4
	1	1	1	2	2	3
		1	2	3	4	5
		Likelihood				

Risk Score	Risk Category
5	Critical risk
4	High risk
3	Moderate risk
2	Low risk
1	Minimal risk

The information provided in this message is proprietary information being shared with you on the basis of your identification as a contact for product updates from InterSystems. This message may contain confidential information, and you should ensure that its contents are disclosed solely in compliance with any nondisclosure obligations between our organizations. The information provided in this InterSystems Product Alert or Service Bulletin is provided "as is" and without additional warranty. Except as provided for in a mutually executed agreement between you and InterSystems Corporation, its subsidiaries, and affiliates, InterSystems disclaims all warranties, either express or implied, including the warranties of merchantability and fitness for a particular purpose.

Operational Risk Rating Process

InterSystems’ risk rating uses standard methodology to estimate the risk to operations based on the most typical foreseeable adverse outcomes, as opposed to the worst-case scenario, which is used to determine the impact and likelihood using standard ordinal scales to derive the risk rating. Operational Risk is the failure of the operational system (application, O/S, database, etc.) relating to:

- **System Performance:** the system performs with the expected functionality, throughput, and utilization.
- **Data Quality:** the system can provide assurance of the accuracy and consistency of data over the entire life-cycle of the data, including recording the data exactly as intended and, upon later retrieval, ensuring the data are the same as when data were originally recorded.
- **System Availability:** the system responds to operations in a time better than the calculated or estimated Mean Time Between Failures (MTBF) and continues to operate without noticeable (based upon expected performance) interruption or delay.

Description of Impact Rating

5	Very high risk	Full failure of safeguard(s) (administrative, physical, or technical) relating to performance, quality or availability
4	High risk	Major (majority) failure of safeguard(s) (administrative, physical, or technical) relating to performance, quality or availability
3	Medium risk	Limited failure of safeguard(s) (administrative, physical, or technical) relating to performance, quality or availability
2	Low risk	Marginal failure of safeguard(s) (administrative, physical, or technical) relating to performance, quality or availability
1	Very low risk	Incomplete (or intermittent) failure of safeguard(s) (administrative, physical, or technical) relating to performance, quality or availability

Description of Outcome Likelihood

5	Very high risk	Will undoubtedly happen/recur, possibly frequently	Expected to occur at every operational or use or with all processing
4	High risk	Will probably happen/recur, but it is not a persisting issue/ circumstances	Expected to occur regularly or with most processing
3	Medium risk	Might happen or recur occasionally	Expected to occur occasionally or with some processing
2	Low risk	Do not expect it to happen/recur but it is possible it may do so	Expected to occur a few times or with limited processing
1	Very low risk	Unlikely happen/recur	Not expected to occur over time of normal operation

Risk Score & Category

The combination of the Impact and Likelihood produce an overall Risk Score and Risk Rating as follows:

Impact	5	3	4	4	5	5
	4	2	3	3	4	5
	3	2	2	3	3	4
	2	1	2	2	3	4
	1	1	1	2	2	3
		1	2	3	4	5
		Likelihood				

Risk Score	Risk Category
5	Very high risk
4	High risk
3	Medium risk
2	Low risk
1	Very low risk

– End of HS2020-04 Alert Communication –

The information provided in this message is proprietary information being shared with you on the basis of your identification as a contact for product updates from InterSystems. This message may contain confidential information, and you should ensure that its contents are disclosed solely in compliance with any nondisclosure obligations between our organizations. The information provided in this InterSystems Product Alert or Service Bulletin is provided "as is" and without additional warranty. Except as provided for in a mutually executed agreement between you and InterSystems Corporation, its subsidiaries, and affiliates, InterSystems disclaims all warranties, either express or implied, including the warranties of merchantability and fitness for a particular purpose.