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Date
2017-06-13

Safety Information regarding HL7 WorklistServer/Commander

Dear Sir or Madam,

we have become aware of a problem with the assignment of reports in our HL7 WorklistServer/Commander software which could pose a potential risk to patient safety. With the information sheet attached, we would like to inform you:

- what the actual problem is and under what circumstances it occurs,
- what you can do to avoid the problem, and
- what GETEMED plans to do to remove the problem altogether.

If your hospital information system uses the same numbering range for patient ID, visit ID and order ID, then it is possible that reports can be incorrectly assigned. This can only occur if the numbering ranges overlap.

GETEMED plans to resolve this problem with a software update as part of a field corrective action plan. The regulatory bodies have been informed of the situation accordingly.

In order to determine if your installation is affected, we kindly ask you to fill out the online questionnaire as soon as possible using the following link:

<http://www.getemed.de/WorklistServer>

We apologize for any inconvenience caused and thank you for your support in resolving this problem as quickly as possible. If you have any further questions, please do not hesitate to contact me directly or our technical support.

Yours sincerely,

Robert Downes
Medical Device Safety Officer

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Vorstand: Dipl.-Ing. Michael Scherf (Vorsitz) / Robert Downes M.Sc.
Aufsichtsratsvorsitzender: Dr.-Ing. Herwig Freiherr von Nettelhorst

Important Safety Information / Corrective Action

HL7 WorklistServer/Commander

Possibility of Incorrect Report Assignment

Affected product	HL7 WorklistServer Versions 1.1.0 to 1.3.2
Problem description	<p>The HL7-WorklistServer/Commander (WLS/C) receives reports from diagnostic tools (e.g. ECG analysis software) and assigns them to a patient or visit ID. This assignment is carried out based on the order ID, visit ID or patient ID transported with the report. When assigning a report, the HL7-WorklistServer software scans all three types and assigns the report to the first match found.</p> <p>If the numbering ranges for patient ID, visit ID and/or order ID overlap, then there exists the possibility that a report intended for patient ID <A> is assigned to another patient having the visit ID <A>.</p> <p>When overlapping numbering systems exist, the following situations are possible:</p> <ul style="list-style-type: none"> • Case 1: The patient ID is used to assign the report: In this case there exists the possibility that an identical visit ID is found first to which the report will be assigned to rather than to the intended patient ID. • Case 2: The patient ID or visit ID is used to assign the report and the numbering system used for order IDs overlaps: In this case there exists the possibility that the report is assigned to an incorrect order ID rather than the intended patient or visit ID. • Case 3: A visit ID is used to assign the report but the visit ID cannot be found in the HL7-WorklistServer's database: In this case there exists the possibility that an identical patient ID is found to which the report will be assigned to rather than to the intended visit ID
Potential risk	<p>Due to the incorrect report assignment, there exists a potential risk that a patient is diagnosed incorrectly.</p> <p>Note: The PDF report always contains the correct patient data. It is therefore always possible to detect the incorrect assignment and subsequently remedy it.</p>
What you can do to avoid occurrence	<p>To avoid occurrence of this problem, use numbering systems for patient IDs, visit IDs and orders in your hospital information system that do <u>not</u> overlap.</p> <p>If your numbering ranges do not overlap, then your installation is not affected.</p> <p>If this is not the case:</p> <ul style="list-style-type: none"> - Redefine the number ranges to avoid overlapping. - If this is not possible, then check the report assignment of each report and reassign it accordingly.

GETEMED actions	<p>GETEMED is currently informing all customers of this product about the potential risk and asking them to assist by filling out an online questionnaire.</p> <p>GETEMED is working to release an update of the HL7-WorklistServer software which mitigates the problem, even when the numbering ranges overlap.</p> <p>GETEMED will provide this update to all customers as part of a field corrective action plan.</p>
Further information	<p>If you need further technical information or support in this matter, please contact our technical service at: Hotline@getemed.de +49 3328 3942-200</p>