Document Revision History

Rev.	Effective Date	Section	Description
A	12/06/2021	All	Initial release

Purpose

The purpose of this memo is to provide the background, methods and rationale used to generate the Harms list for the LX100/200 system DHA (RM06-003-DHA).

Background

From its initial release until rev V, the LX100/200 system DHA did not include Hazardous Situations or Harms. The assumption made was that a Hazard would always lead to the Hazardous situation, and if the Hazardous situation were to occur, the Harm would also occur. Therefore the frequency of Hazard was equated to the frequency of the Harm. The Hazard severity was equated to the worst case Harm severity.

With the release of ISO 14971:2019 and IVDR regulation, remediation activities were planned to update Risk procedures in the Quality Management System and gap on-market Risk Management Files to the updated procedures. As part of these activities, Hazardous Situations and Harms will be added to the LX100/200 system DHA.

Instrument Harms Lists

Harms are given severity and probability (P2) scoring per tables 2 and 4 respectively, of the Risk Management Plan (RM06-003-RMP). Probability (P2) scoring is dependent on whether the Harm is Diagnostic or Non-Diagnostic.

Non-Diagnostic Harms

Non-Diagnostic Harms include any Harms that are not based on an incorrect or delayed result, including, but not limited to: Harms to end user (shock, burn, cut, etc.), environment, property, etc. Non-Diagnostic Harms do not have a second clinical sequence of events after the Hazardous situation that could lead to a Harm. Therefore, for the purposes of using the same template as diagnostic Harms, the P2 value for these Harms will be a 3, which will result in an overall probability value equal to P1.

Diagnostic Harms

Diagnostic Harms include Harms resulting from an incorrect or delayed result. For IVD instruments capable of running multiple assays, the specific diagnostic Harms that could occur with the device depend on the assay being used. The LX100/200 system Harms list was created based on a generalized worst case scenario approach of the possible Harms that could occur with any assay. Per the Risk

Management Plan (RM06-003-RMP, section 11), the Harms list in Table 1 below did not require consultant input or approval.

Process

Table 1 was generated by mapping the Harms list in the DHA template (02520) to the existing Hazards in the LX100/200 system DHA (Rev V). Based on the severity of the Hazard in the Rev V of the DHA, an appropriate Harm was selected from the DHA template Harms list to align with the severity scoring and outcome of the Hazard. In instances where the severity was changed from the severity listed in Rev V of the DHA, rationale is given. Rationale is also provided for the scoring of diagnostic Harms as these would typically depend on the assay used with the instrument. The rationale for these diagnostic Harms provides the reasoning behind the "generalized worst case approach".

Per the Risk Management Plan (RM06-003-RMP, section 11) for Hazards/Hazardous situations associated with multiple Harms, only the worst case Harm will be included in the DHA. Only the Hazard of "wrong results" is associated with multiple Harms. The worst case Harm was identified as "Patient Death or Life Threatening Complications". This Harm has the highest scoring of a severity 6 and a P2 of 2. The Harm of "Long Term Disease Complications" also shares the same scoring, however only one Harm is needed to represent worst case. The complete list of Harms associated with "Wrong results" in Table 1 demonstrates that all possible Harms resulting from the identified Hazard/Hazardous situations have been identified and acknowledged to be associated with the device.

Hazard 015 of rev V of the DHA, "System degradation or product degradation" is not included in Table 1, as the Hazard results in a damaged instrument, which has the same safety consequences as Delayed result. Therefore, in the DHA Analysis, Hazard 015 was changed to Hazard 006 (Results are Delayed or not obtained).

Hazard 017 of rev V of the DHA,"Labeling illegible/missing" was removed and changed to H018 (Hazardous Chemicals / Exposure to hazardous chemicals). Illegible labeling is not a hazard, but the related hazard would be exposure to chemical hazards.

Table 1: LX100/200 Instrument Harms list

Hazard from LX100/200 DHA, Rev V	Updated Hazard/Hazardous Situation wording in LX100/200 DHA, Rev W	Related Harm from DHA template 02520	Description	Severity of Hazard from LX100/200 DHA, Rev V	Severity of Harm in LX100/200 DHA, Rev W	P_2	Rationale
Non-Diagnostic Harms P2 will be scored at a 3 for all Harms listed below, as there is no subsequent clinical sequence of events to further mitigate the probability of the Harm							
H001 Operator injury caused by sharp edges, pinch points,stability/toppling,ejected parts	H001 Sharp edges, pinch points,stability/toppling,ejected parts / Operator comes into contact with to sharp edges, moving parts, tipping instrument	Minor localized trauma to soft tissue	Bruising, strain, and sprain; small contusions, non-sutured cuts, redness, blistering, or swelling due to mechanical interface / pressure of product on user.	2	2	3	N/A
H002 Operator injured by system leak/spill	H002 System leak/spill / Operator comes into contact with leaked/spilled fluid	Minor localized trauma to soft tissue	Bruising, strain, and sprain; small contusions, non-sutured cuts, redness, blistering, or swelling due to mechanical interface / pressure of product on user.	2	2	3	N/A
H003 Operator or bystander injured by biohazards	H003 Exposure to biohazards / operator or bystander exposed to biohazards.	Disease acquisition from handling biohazards	End user contracts infection due to handling biohazardous samples.	5	5	3	N/A
H005 Operator injured by exposure to laser	H005 Operator injured by exposure to laser	Irreversible damage to skin or eyes	Damage to skin or eyes as a result of exposure to lasers	2	5	3	Irreversible damage considered severity of 5.
H009 Operator receives electrical shock	H009 Hazardous electrical energy / exposure to hazardous electrical energy	Severe electrical shock	Electrical shock resulting in severe burns, cardiac arrest, and/or other lasting organ damage.	2	5	3	Severity of harm changed to 5 per template 02520 for the definition of severe electrical shock
H010 Operator or bystander adversely affected by electromagnetic fields	H010 Exposure to electromagnetic interference / Operator or bystander adversely affected by electromagnetic fields	Musculoskeletal injury, fracture, tissue loss and/or damage to internal organs	Injury due to electromagnetic interference with users electrical health devices	2	5	3	N/A
H012 Operator burned by the instrument	H012 Hot surfaces / Operator touches hot surfaces	Minor burn / scald	Burn / scald associated with a small area of the body (< 5% TBSA) and not affecting deep dermal structures (1st or 2nd degree). Is not likely to be life threatening requiring basic treatment.	2	2	3	N/A

Hazard from LX100/200 DHA, Rev V	Updated Hazard/Hazardous Situation wording in LX100/200 DHA, Rev W	Related Harm from DHA template 02520	Description	Severity of Hazard from LX100/200 DHA, Rev V	Severity of Harm in LX100/200 DHA, Rev W	P_2	Rationale
H013 Environmental Pollution	H013 Environmentally hazardous substances/ hazardous substances released into environment in harmful quantities	Environmental Pollution	Environment has been contaminated by hazardous waste products	2	2	3	N/A
H014 Operator injury/strain due to improper handling of sheath cubitainers	H014 Improper handling of sheath container / Operator injury/strain due to improper handling of sheath cubitainers	Minor localized trauma to soft tissue	Bruising, strain, and sprain; small contusions, non-sutured cuts, redness, blistering, or swelling due to mechanical interface / pressure of product on user. (e.g. lifting, tripping or sudden shift in load).	2	2	3	N/A
H015 System or product degradation	H015 Removed – Not used Covered by H006/C0158. System degradation results in failure that leads to delayed results.	N/A	N/A	2	Refer H006	Refer H006	N/A
H016 Explosion	H016 Explosion / Exposure to fire	Severe burn/scald	Burn / scald affecting a significant surface area of the body (>20% TBSA) and of deep partial thickness (3rd degree) or full thickness (4th degree). Could be life threatening and will require specialized treatment and hospitalization.	6	6	3	N/A
H017 Labeling illegible/missing	H017 Removed – Not used Replaced by H018. Exposure to Hazardous Chemicals.	N/A	N/A	1	Refer H018	Refer H018	N/A
H018 Chemical Hazard	H018 Hazardous chemicals / Exposure to hazardous chemicals	Allergic/sensitivity reaction to a chemical/toxin	Rash, irritation, redness, hives, swelling, itching, blistering, etc.	1	1	3	N/A
Diagnostic Harms							

Hazard from LX100/200 DHA, Rev V	Updated Hazard/Hazardous Situation wording in LX100/200 DHA, Rev W	Related Harm from DHA template 02520	Description	Severity of Hazard from LX100/200 DHA, Rev V	Severity of Harm in LX100/200 DHA, Rev W	P_2	Rationale
H006 Results are delayed or not obtained	H006 Results are delayed or not obtained / clinician receives delayed result	Prolongation of Symptoms	Treatment delayed (typically <4 hours) due to invalid call. Delay time may be different dues to instrument malfunction	1	2	3	Severity is 2. If assay is time sensitive, communication with clinician and backup methods of testing will be used to generate results in a timely manner. While waiting on results, clinicians will generally prescribe treatments or methods for alleviating symptoms. Probability 3: Symptoms expected to continue during delay
H011 System device adversely affects adjacent lab devices	H011 Generation of mechanical, electrical, electromagnetic, magnetic, radiation interference /System device adversely affects adjacent lab devices	Prolongation of symptoms	Other diagnostic lab devices malfunction due to effect of Luminex instrument. Treatment delayed (typically <4 hours) due to instrument malfunction.	1	2	3	Severity is 2. If assay is time sensitive, communication with clinician and backup methods of testing will be used to generate results in a timely manner. While waiting on results, clinicians will generally prescribe treatments or methods for alleviating symptoms. Probability 3: Symptoms expected to continue during delay
H008 Incorrect results reported	H008 Incorrect results reported / Clinician receives wrong results	Patient Death or Life threatening complications	Due to lack of treatment or possibly incorrect treatment given.	5	6	2	Severity was changed to a 6. Aligns with definition in severity scoring table of serious injury or death. Probability 2: Product is an aid to diagnosis. Other clinical practices will be relied upon to diagnose the condition, monitor patient status, treat symptomatically, etc.
H008 Incorrect results reported	H008 Incorrect results reported / Clinician receives wrong results	Long term disease complications	Infection results in long-term health effects due to false negative leading to absence of correct treatment.	5	6	2	Severity 6: because the injury is not reversible Probability 2: Product is an aid to diagnosis. Other clinical practices will be relied upon to diagnose the condition,

Hazard from LX100/200 DHA, Rev V	Updated Hazard/Hazardous Situation wording in LX100/200 DHA, Rev W	Related Harm from DHA template 02520	Description	Severity of Hazard from LX100/200 DHA, Rev V	Severity of Harm in LX100/200 DHA, Rev W	P_2	Rationale
							monitor patient status, treat symptomatically, etc.
H008 Incorrect results reported	H008 Incorrect results reported / Clinician receives wrong results	Disease transmission to others	Due to false negative and absence of correct treatment, disease spreads to others.	5	5	2	Severity 5: assuming the effects are severe when transmitted Probability 2: Aid to diagnostics, assumes that the patient is symptomatic. Patients experiencing symptoms are more likely to take precautions and will most likely be advised to do so by the clinician.
H008 Incorrect results reported	H008 Incorrect results reported / Clinician receives wrong results	Side effects due to unnecessary treatment	Due to false positive, incorrect treatment is given that has negative health consequences.	5	5	2	Severity 5: Assuming worst case side effects from common infectious disease treatment methods, severe, but reversible. Probability 2: Treatments of this nature do not typically result in severe symptoms for the entire population. Clinicians typically screen for drug reaction history and contraindicating conditions to reduce the probability of severe side effects.

References

Document Number	Title
RM06-003-RMP	LX100/200 Risk Management Plan
RM06-003-DHA	LX100/200 Device Hazard Analysis
02520	Device Hazard Analysis template

Document Number	Title
N/A	ISO 14971:2019, Medical devices. *Application of risk management to medical devices*
N/A	Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)