Module 3: Product Description

3.2.2.7 Product and Packaging Design Risks and Misuse Hazards

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As part of the development process, all the risks related to the intended use and foreseeable misuse of the product are identified and assessed in the Use-Hazard Analysis (UHA). Once the risks associated with the product use have been identified and evaluated, risk reduction measures are proposed depending on the risk criticality, which are also captured in the UHA.

1. USE-HAZARDS ANALYSIS FOR IQOS 3

For the preparation of the UHA the following information was considered:

- Product: *HeatSticks* and *IQOS* 3 System with essential accessories (dedicated AC adapter with USB cable and cleaning tool)
- (b) (4)
- Comparison with similar products: *IQOS* 3 System concept is very similar to previous versions of *IQOS* System.
- Compatibility with previous *IQOS* System: designed not to be compatible with previous *IQOS* Systems.

During the evaluation of the risks presented in Table 1, only safety risks related to the usage of the product only by the intended adult users were considered. UHA does not include the health risks related to the long-term usage of the product, nor the risks if the product is accessed by unintended users.

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Table 1: Risk Assessment for IQOS 3

Use scenarios	Use-Hazards	Final Effect	Risk Ranking			Control in Place	Comments
			Severity	Probability	Final Risk		
Charging/ Recharging the device (holder + charger)	Charging the charger with non-certified AC adaptor/ USB cable	Electrical shock from device while charging with non-certified adaptor due to high voltage delivered to charger	High	Low	Medium	1. USB Cable and AC Adaptor provided in the kit. (b) (4) (b) (4)	Holder/Charger Safety certificate - Certified IEC 62133 Device Electrical Safety Certificate (EN60335-1) AC Adaptor Electrical Safety Report (UL 1310).
		Risk of device battery explosion while charging with non-certified adaptor due to high voltage delivered to battery	High	Low	Medium	1. Charger, its Battery, USB cable and adaptor CE certified. (b) (4)	
	Charging with the holder inserted upside down	No safety impact	N/A	N/A	N/A	(b) (4)	N/A
	Charging for too long time the charger/ holder	Risk of explosion due to overcharging: case of damaged device	High	Low	Medium	3. Charger / Holder and their Batteries CE certified.	Holder/Charger Safety certificate - Certified IEC 62133 Device Electrical Safety Certificate (EN60335-1) AC Adaptor Electrical Safety Report (UL 1310) Point 1 - Tested at DV

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Use scenarios	Use-Hazards	Final Effect	Risk Ranking			Control in Place	Comments
			Severity	Probability	Final Risk		
	Charging a leaked device (battery leakage)	Chemical hazard due to battery leakage	Medium	Medium	Medium	(b) (4) 2. Charger / Holder and their Batteries CE certified.	Point 3 - Slurry leakage test at DV
	Charging holder with non PMI Power banks or non PMI chargers	Risk of fire	High	Low	Medium	(b) (4) (b) (4)	Point 2 - Tested at DV
	Puffing while holder performing thermal cleaning	Inappropriate aerosol generation	Medium	Low	Low	(b) (4)	N/A
	Device charged / used infrequently	No safety impact	N/A	N/A	N/A	N/A	N/A

(table continues)

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Use scenarios	Use-Hazards	Final Effect	Risk Ranking			Control in Place	Comments
			Severity	Probability	Final Risk		
Insertion / Pre-heating of the *HeatStick*	Over-insertion of the *HeatStick*	Overheating of HAT and transfer of other substances into aerosol	Medium	Medium	Medium	(b) (4) (b) (4)	N/A
	Puffing before the end of the pre-heating cycle	No safety impact	N/A	N/A	N/A	N/A	N/A
	Puffing long time after the end of the pre-heating cycle	No safety impact	N/A	N/A	N/A	N/A	N/A
	Abnormal (extreme) puffing pattern	Deliveries exceed specifications due to overheat as device has to heat up more often	Medium	Medium	Medium	(b) (4)	Tested at DV
	Pre-heating without front-housing	Finger burns as may touch the blade	Medium	Low	Low	(b) (4) (b) (4)	N/A
	Inserting the *HeatStick* after the pre-heating cycle	No safety impact	N/A	N/A	N/A	N/A	N/A
	Removal of the *HeatStick* during use (at operating temperature)	Fingers burns as the stick is hot	Low	Medium	Low	(b) (4)	N/A

(table continues)

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Use scenarios	Use-Hazards	Final Effect	Risk Ranking			Control in Place	Comments
			Severity	Probability	Final Risk		
Use/ Puffing experience	Reusing an already used *HeatStick* several times	No safety impact but low user acceptance	Low	Medium	Low	(b) (4)	N/A
	Lighting a *HeatStick* like a cigarette	Deliveries exceed specifications but comparable to 3R4F on a per puff basis	Medium	Medium	Medium		Point 2 - DAW-002360 Point 3 - Complementary Analyses to Sustain Non-Combustion Claim of P1 RLS - Scientific Report
		Lips/fingers burns	Medium	Medium	Medium	(b) (4)	
	Puffing / switch-off / puffing	No safety impact	N/A	N/A	N/A	(b) (4)	N/A
	Use with cigarettes	No safety impact as it will still be heated but low user acceptance	Low	Medium	Low	(b) (4)	N/A
	Puffing with a broken blade of the device	No safety impact	N/A	N/A	N/A	(b) (4)	N/A
						(b) (4)	
	Puffing after end of use experience	No safety impact	N/A	N/A	N/A	(b) (4)	N/A

(table continues)

(b) (4)

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Use scenarios	Use-Hazards	Final Effect	Risk Ranking			Control in Place	Comments
			Severity	Probability	Final Risk		
	Puffing without the front housing assembly	Fingers/ Lips burn	Medium	Medium	Medium	(b) (4) (b) (4)	Point 2 - Tested at DV
	Insert *HeatStick* upside down	Overheating of MPF/PLA/HAT and transfer of substances into aerosol	Medium	Low	Low	(b) (4) (b) (4)	N/A
No compatibility with previous IQOS 2.4 Plus[2]	*IQOS* 3 holder inserted in 2.4 Plus charger	*IQOS* 2.4 Plus charger pin short circuit	Low	Medium	Low	(b) (4) (b) (4)	Tested at DV of *IQOS* 2.4 Plus. No impact on *IQOS* 3 holder
	IQOS 2.4 Plus holder inserted in *IQOS* 3 Charger	*IQOS* 2.4 Plus holder may get mechanically stuck in *IQOS* 3 charger cradle	Low	Medium	Low		N/A
Disposal	Disposal of the holder and/or charger in a regular trash	Environmental impact only / No safety impact	N/A	N/A	N/A	2. Regulatory waste marking on Charger. 3. Device compliant with the Waste Electrical and Electronic Equipment (WEEE) directive.	N/A

(table continues)

[2] *IQOS* 2.4 Plus device was last version of the *IQOS* device before *IQOS* 3 device, which was launched on some international markets but not in the United States.

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Use scenarios	Use-Hazards	Final Effect	Risk Ranking			Control in Place	Comments
			Severity	Probability	Final Risk		
Maintenance/ Cleaning	Using the device after it was cleaned with cleaning agent	Transfer of other substances into aerosol	Medium	Medium	Medium	(b) (4)	N/A
		Risk of combustion if thermal cleaned	Medium	Medium	Medium		
	Thermal cleaning initiated while the holder / charger being charged	No safety impact	N/A	N/A	N/A	(b) (4)	N/A
	Insert *HeatStick* before end of thermal cleaning	No safety impact	N/A	N/A	N/A		N/A
	Clean holder while holder is still heating	Transfer of other substances in aerosol as cleaning unit / stick may melt	Medium	Medium	Medium	(b) (4)	Regulatory & Toxicological Assessment - SAR-03163
	Use the holder without cleaning	No safety impact	N/A	N/A	N/A	1. Confirmed by Robustness study on THS 2.2 that there is no impact on Aerosol Chemistry (b) (4) (b) (4)	Tested at DV
Environment	Use of a *HeatStick* after its "Best Used Before Date"	Deliveries exceed specifications due to degradation	Low	Medium	Low	Stability studies confirmed aerosol deliveries met specifications throughout 12 months.	N/A

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Use scenarios	Use-Hazards	Final Effect	Risk Ranking			Control in Place	Comments
			Severity	Probability	Final Risk		
	Storage of the holder and/or charger in extreme conditions	No safety impact / Device will not work	N/A	N/A	N/A	(b) (4) (b) (4)	Tested at DV
	Use of the device in hazardous environment (gas station, etc...)	Risk of explosion	High	Low	Medium	1. Report ATEX - **DAW-002670**. Test performed in explosive atmosphere, no risk identified.	N/A
	Devices soaked in water or in contact with water	Chemical hazard / risk of battery leakage due to short circuit	Medium	Medium	Medium	(b) (4)	Tested at DV
	Device cleaned with inappropriate non-PMI cleaning tool	Damage to blade or transfer of other substances in aerosol	Medium	Medium	Medium		N/A

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Use scenarios	Use-Hazards	Final Effect	Risk Ranking			Control in Place	Comments
			Severity	Probability	Final Risk		
	Use of device in non-recommended environment (cold, hot, wet, humid, extreme conditions)	Device will not work or permanent battery degradation	Low	Medium	Low	(b) (4) (b) (4)	N/A
	Interference with other electronic devices	Safety impact if interference with medical device like pacemakers, etc…	High	Low	Medium	Device CE Certified – compliant with EMC standards on Electromagnetic compatibility / immunity	N/A

(table continues)

(b) (4)

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Use scenarios	Use-Hazards	Final Effect	Risk Ranking			Control in Place	Comments
			Severity	Probability	Final Risk		
Misuse	*HeatStick* ingested by children (5-10 kg)	Choking / Intoxication	High	Low	Medium	(b) (4)	N/A
	Using device after unauthorized repairs	Battery explosion / deliveries exceed specifications	High	Low	Medium	(b) (4)	N/A

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Use scenarios	Use-Hazards	Final Effect	Risk Ranking			Control in Place	Comments
			Severity	Probability	Final Risk		
	Modify the Software / Firmware	Deliveries exceed specifications	Medium	Low	Low	(b) (4) (b) (4)	N/A

Note: In the use scenarios described in the table, the worst final effects are assessed (highest severity).

Conclusion

The risks identified have been mitigated as much as possible with design controls already implemented on the *IQOS* 3 product. The residual risks, which could not be reduced by design, have been mitigated either with warnings or instructions to the user in the User Guide. The intended users can use the product safely and effectively in actual conditions.

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