
APPENDIX A3.2.1-21 (V2)

CHANGES

TABLE OF CHANGES

Document	Section	Summary of Changes to A3.2.1-21 (Original submission)
(b) (4)		
		3 minor changes added at the end of the Table of Secion 3.1
A3.2.1-21 (v2)	Section 3.2 Page 18 - 20	21 Minor changes made to the Holder, its specifications, and technical drawings.
A3.2.1-21 (v2)	Section 3.2 Page 20 - 21	13 Minor changes made to the Charger, its specifications and technical drawings
A3.2.1-21 (v2)	Section 3.3 Page 22	2 Changes made to Methods added at the end of the Table of Secion 3.3

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1. CHANGE MANAGEMENT BOARD

The Change Management Board (CMB) is the panel of experts, who govern the change control procedures ensuring that there are sufficient data generated to support decisions made regarding the impact of the change upon the quality, safety and performance of the final product.

Each change is classified either as Major or Minor, according to a internal procedure.

All changes classified as Major, with a potential to impact aerosol formation (performance), sensory perception (quality) or product safety are automatically escalated to the CMB, data are generated, the assessment is made to determine if the change results in a modification of the product. All assessments are performed with predefined acceptance criteria, using the established comparability model.

All other changes are considered Minor, with no potential to modify the product performance and are handled at local change committees, these are notified to the CMB through the change control forms for review to ensure a consistent assessment of changes across different entities and suppliers.

Some elements are not regarded as changes, but as maintenance – these are defined as “like for like”, e.g. replacements of machine parts, equipment and components. These maintenance elements are required to have the appropriate evidence in place to ensure no impact on the product. This is responsibility of the local change committees to ensure their process in adhered to and provide these as notifications to the Change Management Board.

2. MAJOR CHANGE NARRATIVES

(b) (4)

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Volatiles Method

Change rationale

In the context of improvement and revalidation of the methods used for the PMI-58, the volatiles and Semi-volatiles quantification in aerosol method review within PMI laboratories in Neuchâtel led to improvements that result in a different reporting levels of 1,3-butadiene and pyridine.

Change Impact Evaluation

The change had potential impact on some of the measured compounds using this method.

Summary and Conclusion

As a conclusion, the improved method was shown to be suitable for routine analysis for the quantification of volatile and semi-volatile compounds, according to results obtained during the validation. Whenever a comparison of results between averages obtained with the current and new method is needed, differences in absolute quantification (in µg/cig) are to be expected, in particular for 1,3-butadiene and pyridine compounds. (see Appendix A.3.2.1-25).

2.3. 2015

Carbonyls Method

Change rationale

In the context of improvement and revalidation of the methods used for the PMI-58, the Carbonyls method review within PMI laboratories in Neuchâtel led to improvements that

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result in a different quantification of some compounds when compared to the previous method.

Change Impact Evaluation

Potential impact on some of the measured compounds using this method.

Summary and Conclusion

New updated specifications for three compounds (Formaldehyde, Acetaldehyde and Butyraldehyde) were accepted based upon experimental studies using the new methods (see Appendix A3.2.1-22).

Metals Method

Change rationale

In the context of improvement and revalidation of the methods used for the PMI-58, the Metals in aerosol method review within PMI laboratories in Neuchâtel led to improvements that result in a different calculation of the Limit of Quantification (LOQ) for metals.

Change Impact Evaluation

The change had potential impact on some of the measured compounds using this method.

Summary and Conclusion

The measurement of some metals in aerosol is more accurate and representative of the whole process with the new proposed method. This new calculation of LOQs is fully in line with the approach used in external laboratories and is recognized by the scientific community (see Appendix A3.2.1-23).

2.4. 2016

Ammonia Method

Change rationale

In the context of improvement and revalidation of the methods used for the PMI-58, the ammonia method was subject to a change of technology from LC-MS/MS to Ion Chromatography within PMI laboratories in Neuchâtel.

Change Impact Evaluation

The change had potential impact on some of the measured compounds using this method.

Summary and Conclusion

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The use of the new method was introduced. The revision of the specifications (i.e. with a correction factor to apply to the current specifications), has also been introduced (see Appendix A3.2.1-24).

3. FURTHER PRODUCT CHANGES

Within this section are changes that were not escalated to the change management board according to internal process (post performance lock), or changes that were escalated as major and determined to be minor (Identified by original classification in the table), or not requiring additional testing.

3.1. Consumable

Change Classification	Change Description	Component	Change Part
Minor	Correction of menthol in filter value to match the menthol from thread value	Tobacco Stick	N/A
Minor	Correction of menthol value in 21 item code as it was not corrected in the DCR-00232 (design change request) and weight target as it was not updated from the save as from the high menthol filter	Tobacco Stick	N/A
(b) (4)			
Minor	Qualification of a new tow supplier for THS	Tobacco Stick	mouth-piece filter

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Change Classification	Change Description	Component	Change Part
Major	Final Batch Release Specifications for D1 Vinny Low	Tobacco Stick	Tobacco Substrate
Major	Performance Specifications for D1 Vinny Low	Tobacco Stick	Tobacco Substrate
Major	Performance Specifications for D1 Vinny High	Tobacco Stick	Tobacco Substrate
Minor	THS Stick: Change of HAT from [REDACTED] to Training center + correction of tipping length to typical value + comment on RTD specs on sampling point	RRP Consumable	HAT
Minor	THS Stick: Correction of Plug Wrap used.	RRP Consumable	Plug Wrap
Minor	Correction of specifications based on batch release and performance specifications report + replacement of "RD" parameters by "N" parameters	RRP Consumable	N/A

(b) (4)

Minor	Correction of rounding for Nicotine in smoke specification	RRP Consumable	Specifications
Minor	THS Mentholated Crimped filters: Blue Cay 20.A153 replaced by colorless Cay 20.A253.	RRP Consumable	Crimped-filter
Minor	Spec correction - Cigarette RTD Specification Type changed from Batch Release to Typical Value	RRP Consumable	Specifications

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Change Classification	Change Description	Component	Change Part
Minor	Update of temporary Specifications for DI - Vinny - Low Menthol products based on required number of batches. Remove tipping paper length from batch release specification. Align Specifications to system parameters	RRP Consumable	Specifications
Minor	Update of temporary Specifications for DII - Ron products based on required number of batches. Remove tipping paper length from batch release specification. Align Specifications to system parameters	RRP Consumable	Specifications
Minor	Introduction of a second cellulose fiber supplier with supplier specific fiber specifications	Tobacco Stick	Tobacco Substrate
Major	Performance Specifications for D1 Vinny Low	Tobacco Stick	Tobacco Substrate
Major	Performance Specifications for D1 Vinny High	Tobacco Stick	Tobacco Substrate

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Change Classification	Change Description	Component	Change Part
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(b) (4)

3.2. Device

Change Classification	Change Description	Component	Change
N/A	Change to software and device settings	Holder	Firmware
N/A	Contact PCB change	Holder	Assembly
N/A	PCB Change	Holder	Assembly
N/A	Add class III symbol to satisfy IEC60335 standard	Charger	Label
N/A	Replacement of machined parts with molded parts to accommodate new manufacturing process	Holder	Button + Light Guide Assembly
Major	FPD 4.2 Tobacco Stick Holder firmware v3.2.2	Holder	Firmware
Minor	Canoe Assembly	Holder	Assembly

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Change Classification	Change Description	Component	Change
Minor	Add [REDACTED] for heater blade and msc Add drawings and [REDACTED] for machined parts	Holder	Various
Minor	Change of [REDACTED] for assembly Add drawings and [REDACTED] for machined parts	Holder	Various
Minor	THS Charger Lid Spring improvement	Holder	Charger
Minor	Remove Fairchild transistor alternate type FDMA905P	Holder	Various

(b) (4)

Minor	Correction of the manufacturer part reference according to drawing revision: - ZRH7.05.0011 C => ZRH7.05.0011 D	Holder	Canoe
Minor	Drawing update: - Replace (b)(4) logo by PMI one - Use PMI standard title block format - Update manufacturer part number	Holder	Heater

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Change Classification	Change Description	Component	Change
Minor	Tobacco Stick Holder Battery specifications alignment for production This is including: - New batch codification (slurry reference week + additional number for the manufacturing days) - Relative position of the marking based on the tab - Tolerance for the dimension mentioned below	Holder	Battery
Minor	Add Kapton tape wrapping on canoe	Holder	Assembly

(b) (4)

Minor	Fixed HP QC defects: 523, 524, 525, 529, 531, 542, 551	Holder	Various
Major	Equivalence of THD 2.2 and THD 2.4	Various	Various
Minor	THS charger: component end of life – Change to proposed replacement	Charger	-
Minor	THS: Holder Connector in MU (THD 2.2 & 2.4)	Holder	-
Minor	Changes for THS V2.4 MU beta 1 to beta 2	Device	-
Minor	Changes for THS V2.4 TSH beta 1.1 to beta 1.2	Device	-
Minor	Changes for THS V2.4 TSH beta 1.2 to beta 2.1	Device	-
Minor	Changes for THS V2.4 TSH beta 2.1 to beta 2.2	Device	-

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Change Classification	Change Description	Component	Change
Minor	THS V2.4 White Matte holder housings from (b) (4) to (b) (4) paint	Holder	-
Major	(b) (4)	Holder	-
Minor	No function change, changes limited to an extension which allows the manufacturing of P1 THD 2.4 chargers with either an (b) (4)	Charger	Firmware
(b) (4)			
Minor	Approval of new suppliers for Battery of the holder and the charger	Device	Battery

(b) (4)

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Change Classification	Change Description	Component	Change
(b) (4)			
Minor	Updated design to Kambo2 AC Adaptor	Accesories	AC Adaptor
Minor	Heater tip tolerance change Heater length tolerance change	Holder	Heater
Minor	Additional approved vendors for 2 electronic components	Holder	-
Minor	Rebranding - New IQOS logo printed	Holder	Front housing
Minor	Lightguide design change	Holder	Light guide
Minor	Middle part tolerance change	Holder	Middle Part
Minor	Heater substrate (ceramic) – alternate sourcing	Holder	Heater
Minor	Heater overmold – D1 design	Holder	Overmolded Heater
Minor	Frame – design Flex B	Holder	Frame

(b) (4)

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Change Classification	Change Description	Component	Change
Minor	Relaxation of heater back side (Non-Printed) cosmetic specification	Holder	Heater
Minor	Additional approved vendor (b)	Holder	Resistor
Minor	(b) (4)	Holder	Contact PCB
Minor	Additional approved vendor (b) (4)	Holder	Contact PCB, Heater PCB
Minor	Top insulator design change for Fullriver battery	Holder	Battery
Minor	Correction of MPN for Electronic and Mechanical components	Holder	-
Minor	Correction quantity on ASM.000122 for PCB blank	Holder	-
Minor	Correction of MPN for Electronic components	Holder	-

(b) (4)

Minor	Change of MPN for Heater	Holder	Heater
Minor	Correction of MPN for Electronic and Mechanical components	Holder	-
Minor	Pocket Charger Technical drawing alignment	Charger	
Minor	TSH connector MPN change	Charger	

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Change Classification	Change Description	Component	Change
Minor	Additional approved vendors (b) (4)	Charger	Capacitors/ Resistors
Minor	Change artwork of Pocket Charger where EAC marking is added	Charger	
Minor	Additional approved vendor (b) (4) (b) (4)	Charger	Battery
Minor	Creation of additional MPN to allow tracking the manufacturing location	Charger	
Minor	Rebranding – New IQOS logo printed	Charger	
Minor	New design latch	Charger	Latch assembly Lid assembly
Minor	(b) (4)	Charger	Lid
Minor	Additional approved vendor (b) (4)	Charger	
Minor	Technical Drawing update	Charger	
Minor	Add additional MPN where the state of charge is specified	Charger	
Minor	MPN correction for (b) (4)	Charger	

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3.3. Methods

Change Classification	Change Description	Change Type	Change Component
Minor	Improved methods for Phenols and acetamide & acrylamide compounds	Methods	N/A
Minor	Method for the quantification of nitrosamines in aerosol	Methods	Ion source in the mass detector
Major	Improved method for Polycyclic Aromatic Hydrocarbons (PaHs) measurement	Methods	LOQ improved
Minor	Improved methods for Propylene oxide and Ethylene oxide & Vinyl Chloride	Methods	Method improvement
Minor	Switch to reduce inspection for batch release of Dorado II products	Process	N/A
Major	Review and re-validation of Metal method according internal guidelines with improved aerosol generation and inclusion of two additional elements (Tin, Beryllium)	Method	Method improvement
Minor	Exchange of ion source and re-validation of HCN method to improve robustness	Method	Ion source in the mass detector

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4. APPROVALS

	Name	Role	Signature	Date
Author	Klaus Buhlmann	Manager Specs & Change Management		28. Aug. 2017
Owner	Stefano Ceriali	Director Operational QA		28 Aug 2017
QA Review	Shelley Moores	QA Manager		29-AUG-2017

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