

We will thrive by manufacturing the best IVD products



To : Dear our valuable customers

C.C : -

Subject : Software update of STANDARD™ F200 Analyzer (Version: V001.067.004)

1. We, SD Biosensor, Inc., wish you happiness and success.

2. We, SD Biosensor, Inc., complies with the requirements of the international standards ISO 13485:2016, MDSAP (Medical Device Single Audit Program) and KGMP (Korean Good Manufacturing Practice) for Quality management system of design, development, production and distribution for all products.

3. The purpose of this document is to claim that SD Biosensor validation studies were performed for the new SW Version following internal referenced procedures under the SD Biosensor Quality Management System. As a result of validation, the SW version verified that there was no problem and satisfied the internal quality standard.

4. Product information

- Product Name : STANDARD™ F200 Analyzer
- Reference No. : F200
- Catalog No. : 10FA20

5. Software information

Version	Effective date	Update details
V001.067.004	25.Apr.2025	<p>1. Fixed issue in unit settings screen</p> <ul style="list-style-type: none"> - Added NGSP / IFCC units in addition to the existing 9 units 1.1 HbA1c(07) <p>2. Separated OBX.3 (Observation Identifier) values in HL7 transmission</p> <ul style="list-style-type: none"> - Rota → LOINC code for Rota - Adeno → LOINC code for Adeno 2.1 Rota/Adeno(29) <p>3. Assigned strip LOT identification numbers</p> <ul style="list-style-type: none"> 3.1 Tnl / NT-proBNP(87) <ul style="list-style-type: none"> 1) Assigned strip lot number 697 3.2 hsTnl(89) <ul style="list-style-type: none"> 1) Assigned strip lot number 60H 3.3 hsTnT(91) <ul style="list-style-type: none"> 1) Assigned strip lot number 698 <p>4. Fixed special character encoding issue in qualitative results</p> <ul style="list-style-type: none"> - Resolved character corruption when values are out of normal

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		range
		5. India SW – Code restoration 5.1 Dengue IgM/IgG(15) 1) Restored code to reduce IgG result by 25% 5.2 TSH(25) 1) Restored code to reduce result by 90% 5.3 TSH2(54) 1) Restored code to reduce result by 90% 5.4 FSH(88) 1) Restored code to reduce result by 75%

6. Before using the analyzer, please update and check the most up-to-date software version from your distributor and SD Biosensor.

7. This letter needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please transfer this change letter to other organizations or users on which this action has an impact.

8. If you have any questions about the analyzer, please contact your local distributor and SD biosensor. You can also visit "www.sdbiosensor.com" for product information.

9. We will continue our efforts to comply with high quality management standards and to maintain a consistent high quality management system to ensure customer's satisfaction and product safety.

Sincerely,

SD Biosensor, Inc.



Writer	: Jee-Won Kim	Reviewer	: Jin-Hyung Lee	QMR	: Jong-Kwan Ko	Factory Manager	: Yeon-Seok Jin
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