DS DILUENT

Liquid. Store at 2℃~30℃. For in Vitro Diagnostic Use (IVD). Do not freeze.

Ref No	Package
5950MN	1 x 20 L

Changes made in the instructions for use are marked as grey.

INTENDED USE
The DS DILUENT participates in the measurement of parameters related to RBC, PLT, WBC, RET and NRBC.

APPLICABLE INSTRUMENTS
This product applies to BC-6000 / BC-6200 / BC-6800Plus / BC-6800 / CAL6000 / CAL8000 / BC-7500[N] CRP / BC-7500[NR] CRP / BC-700[B] / BC-700[R] / BC-720[R] / BC-760[B] / BC-760[R] / BC-780[R] / BC-700[B] CS / BC-700[R] CS / BC-760[B] CS / BC-760[R] CS Auto Hematology Analyzer, SC-120 Auto Slide Maker & Stainer and CRP-M100 Specific Protein Analyzer produced by Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

TEST PRINCIPLE
The DS DILUENT is an electric conducting solution formulated to dilute samples and form sheath fluid in the process of blood cell measurement.

This product participates in cell differentiation, counting and HGB measurement which are accomplished by using the impedance method, colorimetric method and SF Cube cell analysis technology (3D analysis using information from scatter of laser light at two angles and fluorescence signals).

ACTIVE COMPOSITION
Compositions:
Tris Buffer.....≤0.5 %
Sodium Chloride.....≤0.1 %

PRODUCT SPECIFICATIONS
1. **Appearance:** Transparent liquid without deposits, suspended grains or flocks.
2. **Blank count results:** The blank count results of the reagent tested on the Mindray Auto Hematology Analyzer shall meet requirements of Table1.

Table 1. Blank Count Requirements

Parameter	Blank Count Requirements
WBC	$\leq 0.1\times10^{9}$/L
RBC	$\leq 0.02\times10^{12}$/L
HGB	≤1g/L
PLT	$\leq 5\times10^{9}$/L

REAGENT PREPARATION
Reagents are ready to use.

REAGENT STABILITY AND STORAGE
This product shall be stored in ventilated room free from corrosive gas at 2℃~30℃ with the humidity lower than 90%. The shelf life is 2 years.

The working temperature range of the product is consistent with that of its applicable instruments. The open-vial validity is 60 days.

SAMPLE REQUIREMENT
Fresh human whole blood anticoagulated. Do not use contaminated samples.

MATERIALS REQUIRED BUT NOT PROVIDED
The following materials are required but not provided with the product: Mindray-manufactured measurement instruments and matched reagents.

INSTRUCTIONS FOR USE
1. Restore the product to usage temperature.
2. Open the external packing and insert the pickup tube into the reagent container based on the matching color of the reagent cap and the connector of analyzer cap assembly.
3. Screw the cap assembly tight and replace the reagent according to the operator's manual of the analyzer,
4. Run a blank count and check the results. If the results meet the blank count requirements defined in the operator's manual of the analyzer, the newly installed reagent can be used for sample analysis. See the operator's manual of the analyzer for details.

CUT-OFF VALUE / REFERENCE INTERVALS
Not applicable.

RESULT ELABORATION
Not applicable.

LIMITATIONS
Not applicable.

NOTICE
1. Read the package insert carefully before using this product. It shall be used before expiration date and disposed of properly when expired.

2. Do not use the reagent if it is frozen.
3. If the blank count is abnormal after the reagent is transported, place is still for 24 hours at the room temperature before using it.
4. If the reagent is polluted or affected by other factors and becomes abnormal, stop using it and replace it with a normal one.
5. Dispose of the waste, residual and contaminated packing based on local regulations.
6. The following factors can affect the sample analysis: expired or ineffective reagent; reagent polluted by dust in the air; improper disposal of the sample; mixed with or used with newly-opened; used in condition other than specified.
7. Take the necessary precautions for the use of the product. Do not swallow. Avoid contact with skin and mucous membranes. If you accidentally take the reagent into your mouth, or the reagents accidentally spill on your skin or into your eyes, wash them off with plenty of water and go seek medical treatment if necessary.
8. Disposal of waste liquid and materials should be in accordance with local guidelines.
9. The Material Safety Data Sheet (SDS) is available upon request
10. All identified risks have been reduced as far as possible by generally acknowledged state of art, and the overall residual risk is acceptable.
11. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and / or the patient is established.

SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
GTIN	Global Trade Item Number
REF	Reference Number
FOR USE WITH	Identifies Products to Be Used Together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Humidity limitation
	Consult Instructions for Use

WARNINGS AND PRECAUTIONS

IVD: For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.

Precaution

P280 : Use protective gloves / clothes / glasses / mask.
P305+P351+ P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 If eye irritation persists: Get medical advice/attention.

REFERENCES

Not applicable.

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