Foreword

From Hematology Analyzers to Clinical Test Systems

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The basic parameters for complete blood cell counts (CBC) contains the number of White blood cells (WBC), number and size of Red blood cells (RBC), the concentration of hemoglobin (Hgb) contained in the RBC, and the number of platelets (PLT). The clinical importance of the CBC is to diagnose and detect inflammation, anemia, hemostasis and many other disorders. For a long time, blood cells were counted manually using hemocytometer, thick glass microscope slide engraved with grooves creating a grid of perpendicular lines, and an optical microscope. In 1956, the Coulter Corporation developed an impedance method that dramatically improved the accuracy of these measurements. The basic concept of impedance method is to measure the voltage across an aperture in a constant electrical current. When a blood cell floating in saline solution passes through the aperture, the cell resistivity affects the voltage across the aperture, which enables to detect the existence of the cell. Additionally, the potential differences are proportional to the blood cell volume, both cell size and cell volume could be obtained from the signals. This impedance method is very accurate for measuring targeted particle sizes, and volume can also be measured. This became the current standardized international reference method for measuring blood cell count.

Technological innovations in digital signal processing, such as improvement of amplifier performance has significantly contributed to the impedance method. Originally, this method had trouble distinguishing between signals and noise, made it difficult to count different cell type at the same time. As the development of operational amplifier IC has significantly reduced the noise. Additional to the development of high-speed AD converter, it is now possible to measure the RBC and PLT counts at the same time. In recent years, analyzing the pulse signal using digital signal processing and statistical calculation enabled to improve the accuracy of the cell counting. In addition to these technologies, simple differentiation of WBCs using changes in cell contraction that rely on a special reagent and the differentiation by combining cell dyeing technology and optical analysis became possible. Currently, hematology analyzers with this WBC differentiation function are standard. In terms of sampling, the accuracy of the control mechanism has improved and units have become more compact, which has resulted in significantly small volume of blood (a few dozen μL) is required for measurements, and the instrument size has also become smaller.

The HORIBA Group has developed these technologies while continuing to develop instrument to meet the needs of medical institutions. The small hematology analyzers was developed to meet the need for a limited installation area, and to be easy to operate so that it does not require a dedicated operator. HORIBA has installed the highest number of small hematology analyzers. Also, by developing a hematology analyzer that incorporates the inflammation marker C-reactive protein (CRP) for immunity, the WBC count and CRP value can now be obtained at the same time. This helps medical personnel to understand the patient’s condition and determine dosage. Currently 20% of the pediatricians in operation are using this model, and many doctors have said that the unit was very useful in diagnosing changes in children’s conditions that could change rapidly. HORIBA is developing new clinical test device by always trying to find out what medical institution really need, putting the hematology analyzer as main product.

Nowadays, the evolution of information technology is proceeding at a rapid pace, many useful tools such as electronic medical records have been installed in various clinical sites. The need for clinical test devices to be connected to networks is also increasing. To meet this requirement, HORIBA did not just incorporate a simple data connection, but began to develop a better system for clinical test devices to give users and patients peace of mind. In the future, HORIBA aims to continuously develop stable, high-accuracy medical devices, and to develop high-accuracy, high-quality clinical system supported by information technology. As this paper draws to a close, HORIBA would like to thank the medical institutions using our products, every sales companies for their constructive feedback that has helped HORIBA get where it is today.