# Reflotron® Plus

# Information Booklet


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# Contents



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# Reflotron®

## Applications

The outstanding features of the Reflotron® System for running single tests and short series of clinical-chemical parameters are its ease of use and fast operation. Sample collection is often the only preparatory step needed, and results are available within minutes.

## The Reflotron® System

Reflotron® Plus is a compact reflectance photometer for fully automatic evaluation of Reflotron® Tests. The instrument takes charge of all functions such as heating, automatic calibration, test execution and evaluation, and calculation of results.

Reflotron® Tests are reagent strips for specific testing of important clinical-chemistry parameters directly from whole blood, plasma or serum. The direct use of whole blood is made possible through an integrated plasma separation pad. Various tests can also be run using urine.

Other Reflotron® supplies include control substances, pipettes and systems for keeping the tests, lancets and dispensing aids neatly together.

## Easy to use

Tests are performed with a minimum of human intervention. Steps such as calibration, sample pre-treatment and calculation of results are all taken care of in this low-maintenance system. The three key steps in a Reflotron® test are:

- collect blood and apply sample to the reagent strip
- insert the reagent strip in the instrument
- read the result after about 3 minutes

## Reliable results

Reflotron® has its own separate keyboard through which the sample is assigned to the patient. The instrument saves the result together with the patient data. It can use its own onboard printer to print the result along with date, time and patient name or number. Data downloading to a practice computer or laboratory information management system is also possible, enabling fast and reliable results documentation.

**The Reflotron® system is now well-established in thousands of hospitals and doctors' practices as well as in the primary care sector.**

### In the practice

Reflotron® brings the following benefits to the doctor's office:

The immediate availability of laboratory results means doctors can diagnose the problem faster or confirm a suspected diagnosis without delay.

- Test results available for immediate discussion with the patient
- 17 different laboratory parameters covering most routine clinicalchemical diagnoses in doctors' practice
- The immediacy with which the patient's condition can be diagnosed and therapy can be implemented increases patient compliance and motivates patients with a good state of health to continue their healthy way of living
- Acute parameter testing (Table 1) makes routine out-of-hours diagnosis possible, too. The immediate availability of structured diagnostic capability allows the appropriate therapy to be instituted immediately.

### In the laboratory

Reflotron® supports doctors and laboratory personnel:

- Through immediate availability of urgently needed laboratory results
- When a plausibility control is needed
- As a reliable, low-maintenance system that can be used at night and at weekends, and as an adjunct to automatic analysers
- As an aid to fast decision-making concerning appropriate treatment
- In organizational emergencies

### For screening

A robust, portable system with a broad spectrum of parameters, Reflotron® can be used to detect metabolic disorders and organ damage:

- Recognition of high lipid, glucose or uric acid values and for screening out patients who need to see a doctor
- For early disease recognition when a patient who feels well would not normally visit a doctor

**Fast, reliable diagnostic support with a large number of relevant indications**

Reflotron®, with the large number of parameters it offers, enables diagnostic tests to be performed for numerous indications

**Table 1:**

**Reflotron® Tests and Indications**

**Acute Parameters**

- Potassium
- CK
- Haemoglobin
- Glucose
- Creatinine
- α-Amylase
- Pancreatic Amylase
- AST/GOT

**Kidney diseases**
- Urea
- Creatinine
- Potassium
- Uric Acid
- Haemoglobin

**Liver diseases**
- AST/GOT
- ALT/GPT
- γ-GT
- Bilirubin
- Alkaline Phosphatase

**Lipid disorders**
- Cholesterol
- Triglycerides
- HDL Cholesterol
- LDL Cholesterol
- Glucose

**Diabetes**
- Glucose
- Triglycerides
- HDL Choesterol
- Creatinine

**Anaemia**
- Haemoglobin
- Bilirubin

**Gout**
- Uric Acid
- Urea
- Creatinine
- Glucose
- Cholesterol
- Triglycerides

**Pancreatitis**
- Pancreatic Amylase
- Amylase

**Muscle disease (myocardial infarction)**
- CK

# Reflotron® reagent strip

The reagent strip has four functions:

**Top of the reagent strip**

1. Plasma separation and pre-incubation
2. Plasma transport
3. Reaction and dye formation

**Underside of the reagent strip**

4. Transfer of test- and lot-specific information to the photometer (magnetic stripe)

The following illustration depicts a typical Reflotron® reagent strip.

**Figure 1**
Reagent strip for Reflotron®; top and underside

Figure 2 is a schematic representation of the principal components of a Reflotron® reagent strip. On the upper side of the carrier strip is the test zone consisting of several discrete areas in which various processes and reactions take place.

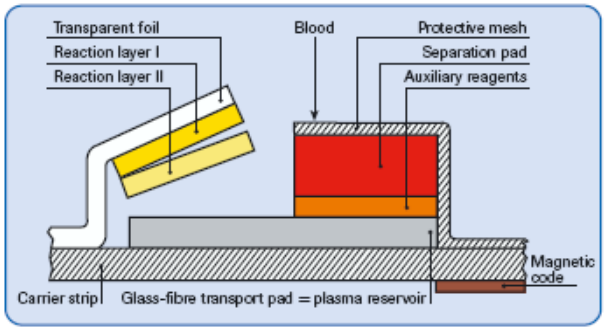



**Figure 2**
Schematic diagram of a reagent strip

The sample undergoing analysis is placed on the protective mesh. Below this is the separation pad in which plasma separation occurs when whole blood is taken as sample material. One or more prereaction reagent papers may be located upstream or downstream of this. The transport pad allows plasma to travel to the reaction zone and, additionally, acts as plasma reservoir. The reaction zone consists of a reagent layer, an indicator layer and a transparent foil, though its structure may differ from one parameter to another.
On the underside of the carrier strip is a magnetic stripe that is encoded with lot-specific data.

# Processes occurring on the reagent strip

## Integrated plasma collection

A Reflotron® or capillary pipette is used to apply 30 µL of sample (blood, serum or plasma) to the red mesh covering the separation pad. A yellow mesh is used for potassium and HDL cholesterol to indicate that serum or plasma is required as sample material.

The sample passes through the separation pad which, when blood is the sample material, separates out erythrocytes and other cellular components. The plasma or serum that is obtained passes (sometimes through an additional pre-reaction zone) to the transport pad and hence underneath the reaction zone.

Having arrived there the sample (more than is actually required) is available for the test reaction. The photometer starts the analyte determination reaction at a defined time by pushing the reaction zone onto the transport pad. The reaction layers absorb from the transport pad by capillary action the quantity of plasma or serum required for the reaction (Figure 3).

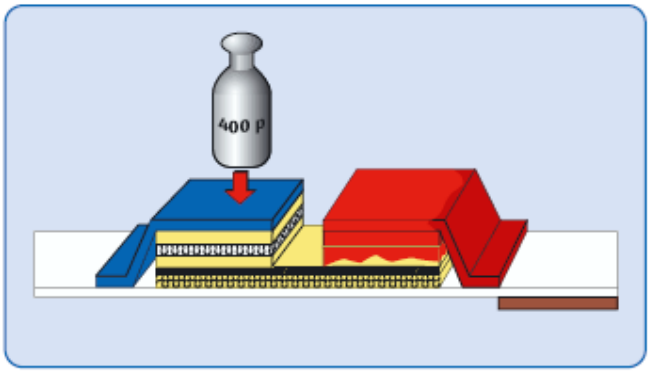



**Figure 3**
Schematic diagram of automatic sample dosing

This principle of automatic dosing by the reaction layers enables always the same volume of sample to be applied for blood, plasma or serum.

An exception to this is the Reflotron® Hemoglobin reagent strip. Instead of the glass-fibre pad it incorporates a material that has been saturated with saponin to induce erythrocyte haemolysis and also contains the reactive components for converting haemoglobin to methaemoglobin.

## Pre-reaction

Below the separation pad, all according to the parameter, is a prereaction reagent layer the composition of which differs for each test. The pre-reaction layer allows any interfering substances that may be present to be eliminated and/or the sample to be pre-incubated with special activators or auxiliary reagents.

For an HDL cholesterol determination, for example, chylomicrons, VLDL and LDL can be precipitated out beforehand with dextran sulphate/Mg2+ to stop them affecting the determination.

### Plasma transport

The transport pad is also a glass-fibre pad but has a different fibre composition and orientation, so the plasma is drawn into the transport pad. It behaves like a sponge and serves additionally as a reservoir for the plasma that is obtained. It thus evens out any differences in the plasma content due to different haematocrit values.

### Reaction zone

The reagents that are required for the analyte determination reaction are present on carriers. Reagents that would normally be unstable together on a single carrier can be placed on separate carriers. The reaction starts when the reaction zone is pushed onto the filled plasma reservoir.

### Principles of the tests

Because of the differences in the underlying requirements, the test principles and indicators used in the Reflotron® Tests cannot be the same as those applied in normal laboratory testing. All of the test components for the reaction must be capable of being fixed onto the reagent carrier and must exhibit long-term stability in this form. Also, where possible, they should allow the reagent strip to be stored at room temperature. Table 2 shows the principles of the individual tests.

Table 2: Reflotron® Tests: test principles

| Test | Test principle | Wavelength |
|---|---|---|
| **Glucose** | ß,D-glucose + $0_2$ + $H_2O$ $\xrightarrow{\text{glucose oxidase}}$ D-gluconolactone + $H_2O_2$<br>$H_2O_2$ + 2 $H^+$ + indicator $\xrightarrow{\text{peroxidase}}$ blue-green dye + 2 $H_2O$<br>Indicator: 3,3',5,5'-tetramethylbenzidine | 642 nm |
| **Cholesterol** | cholesterol ester + $H_2O$ $\xrightarrow{\text{cholesterol esterase}}$ cholesterol + RCOOH<br>cholesterol + $O_2$ $\xrightarrow{\text{cholesterol oxidase}}$ cholestenone + $H_2O_2$<br>$H_2O_2$ + indicator $\xrightarrow{\text{peroxidase}}$ dye + $H_2O$<br>Indicator: 3,3',5,5'-tetramethylbenzidine | 642 nm |
| **HDL cholesterol** | 1. Precipitation of chylomicrons, VLDL and LDL with dextran sulphate/$Mg^{2+}$<br>2. Determination of HDL cholesterol<br>cholesterol ester + $H_2O$ $\xrightarrow{\text{cholesterol esterase}}$ cholesterol + RCOOH<br>cholesterol + $O_2$ $\xrightarrow{\text{cholesterol oxidase}}$ cholestenone + $H_2O_2$<br>$H_2O_2$ + indicator $\xrightarrow{\text{peroxidase}}$ dye + $H_2O$<br>Indicator: 4-(4-dimethylaminophenyl)-5-methyl-2-(3,5-dimethoxy-4-hydroxyphenyl)imidazole dihydrochloride | 642 nm |

| Test | Test principle | Wavelength |
|---|---|---|
| **Triglycerides** | triglycerides + 3 $H_2O$ $\xrightarrow{\text{esterase}}$ glycerol + 3 RCOOH<br>glycerol + ATP $\xrightarrow{\text{glycerol kinase}}$ glycerol-3-phosphate + ADP<br>glycerol-3-phosphate + $O_2$ $\xrightarrow{\text{glycerol phosphate oxidase}}$ dihydroxyacetone phosphate + $H_2O_2$<br>$H_2O_2$ + indicator $\xrightarrow{\text{esterase}}$ dye + $H_2O$<br>Indicator: 4-(4-dimethylaminophenyl)-5-methyl-2-(3,5-dimethoxy-4-hydroxyphenyl)imidazole dihydrochloride | 642 nm |
| **Bilirubin** | Bilirubin + 2-methoxy-nitrophenyldiazoniumtetrafluoroborate ——> azobilirubin<br>Indirect bilirubin is released by means of dyphilline | 567 nm |
| **Creatinine** | creatinine + $H_2O$ $\xrightarrow{\text{creatinine iminohydrolase}}$ N-methylhydantoin + $NH_3$<br>N-methylhydantoin + 2 $H_2O$ + ATP $\xrightarrow{\text{N-methylhydantoinase}}$ N-carbamoylsarcosine + ADP + $P_i$<br>N-carbamoylsarcosine + $H_2O$ $\xrightarrow{\text{carbamoylsarcosine hydrolase}}$ sarcosine + $CO_2$ + $NH_3$<br>sarcosine + $H_2O$ + $O_2$ $\xrightarrow{\text{sarcosine oxidase}}$ glycine + HCHO + $H_2O_2$<br>$H_2O_2$ + indicator $\xrightarrow{\text{peroxidase}}$ dye + $H_2O$<br>Indicator: 2-(3,5-di-*tert*-butyl-4-hydroxyphenyl)-4-(5)-(9-julolidino)-5-(4)-methyl-(1H)-imidazole | 642 nm |
| **Haemoglobin** | haemoglobin + $K_3[Fe(CN)_6]$ ——> methaemoglobin | 567 nm |
| **Uric acid** | uric acid + $O_2$ + 2 $H_2O$ $\xrightarrow{\text{uricase}}$ allantoin + $H_2O_2$ + $CO_2$<br>$H_2O_2$ + indicator $\xrightarrow{\text{peroxidase}}$ dye + $H_2O$<br>Indicator: 4-(4-dimethylaminophenyl)-5-methyl-2-(3,5-dimethoxy-4-hydroxyphenyl)imidazole dihydrochloride | 642 nm |
| **Urea** | $(NH_2)_2CO$ + $H_2O$ $\xrightarrow{\text{urease}}$ 2 $NH_3$ + $CO_2$<br>$NH_3$ + indicator (yellow) ——> $NH_4^+$ + indicator (blue)<br>Indicator: tetrachlorphenoltetrabromosulphophthalein | 642 nm |
| **Potassium** | $K^+$ + valinomycin + indicator ——> dye<br>Indicator: 4-[(2,6-dibromo-4-nitrophenyl)azo]-2-octadecyloxy-1-naphthol; 2, 4, 6, 8,-tetranitro-S-octadecyloxy-1-napthol | 642 nm |

| Test | Test principle | Wavelength |
|---|---|---|
| **Alkaline Phosphatase** | o-cresolphthalein phosphate + methylglucamine $\xrightarrow{ALP}$ o-cresolphthalein + methylglucamine phosphat | 567 nm |
| **Amylase** | indolyl-α, D-maltoheptaoside $\xrightarrow{\alpha\text{-amylase/}\alpha\text{-glucosidase}}$ indoxyl + glucose<br>indoxyl + 2-methoxy-4-morpholinophenyldiazoniumtetrachlorozinkate ⟶ purple dye | 567 nm |
| **Pancreatic Amylase** | 1. Inhibition of salivary amylase with monoclonal antibodies<br>indolyl-α, D-maltoheptaoside $\xrightarrow{\alpha\text{-amylase/}\alpha\text{-glucosidase}}$ indoxyl + glucose<br>indoxyl + 2-methoxy-4-morpholinophenyldiazoniumtetrachlorozinkate ⟶ purple dye | 567 nm |
| **CK** | creatine phosphate + ADP $\xrightarrow{CK}$ creatine + ATP<br>glycerol + ATP $\xrightarrow{\text{glycerol kinase}}$ glycerol-3-phosphate + ADP<br>glycerol-3-phosphate + $O_2$ $\xrightarrow{\text{glycerol phosphate oxidase}}$ dihydroxyacetone phosphate + $H_2O_2$<br>$H_2O_2$ + indicator $\xrightarrow{\text{peroxidase}}$ indicator (ox.) + $H_2O$<br>Indicator: 2-(3,5-di-*tert*-butyl-4-hydroxyphenyl)-4-(5)-(9-julolidino)-5-(4)-methyl-(1H)-imidazole | 642 nm |
| **γ-GT** | glycylglycin + γ-glutamyl-3-carboxy-1,4-phenylene diamine $\xrightarrow{\gamma\text{-GT}}$ γ-glutamylglycyl-glycine + 3-carboxy-1,4-phenylene diamine<br>3-carboxy-1,4-phenylene diamine + N-methylanthranilic acid + 6 $[Fe(CN)_6]^{3-}$ ⟶ dye + 6 $[Fe(CN)_6]^{4-}$ | 642 nm |
| **GOT (AST)** | α-ketoglutarate + alanine sulphinate $\xrightarrow{GOT}$ glutamate + pyruvate + $SO_3^{2-}$<br>pyruvate + $PO_4^{3-}$ + $O_2$ + $H_2O$ $\xrightarrow{\text{pyruvate oxidase}}$ acetylphosphate + $H_2O_2$ + $CO_2$<br>$H_2O_2$ + indicator (red.) $\xrightarrow{\text{peroxidase}}$ indicator (ox.) + $H_2O$<br>Indicator: 4-(4-dimethylaminophenyl)-5-methyl-2-(3,5-di-*tert*-butyl-4 hydroxyphenyl)imidazole dihydrochloride | 567 nm |
| **GPT (ALT)** | α-ketoglutarate + alanine $\xrightarrow{GPT}$ glutamate + pyruvate<br>pyruvate + $PO_4^{3-}$ + $O_2$ + $H_2O$ $\xrightarrow{\text{pyruvate oxidase}}$ acetylphosphate + $H_2O_2$ + $CO_2$<br>$H_2O_2$ + indicator (red.) $\xrightarrow{\text{peroxidase}}$ indicator (ox.) + $H_2O$<br>Indicator: 4-(4-dimethylaminophenyl)-5-methyl-2-(3,5-di-*tert*-butyl-4-hydroxyphenyl)imidazole dihydrochloride | 567 nm |

# Transfer of test- and lot-specific information

### Magnetic Strip

On the underside of the Reflotron® reagent strip is a magnetic strip that is encoded with information relating to the test and to that particular lot of strips. The photometer reads the stripe immediately after the strip has been inserted. The strip contains all the information it needs to carry out the test:

- **Test parameter**
- **Time/process settings**
  - Plasma separation time
  - Rate at which the Ulbricht's sphere advances
  - Ventilation time
  - Reaction time
  - Number of measurements
  - Kinetic measurement
  - End-point measurement
- **LED configuration**
  - Measuring wavelength
  - Calculation factors
- **Evaluation constants**
  - Conversion factors for units of measurement (Con/SI)
  - Conversion factors for temperature (37°C; 30°C; 25°C)
  - Measuring range limits
- **Linearity limit values for enzyme determinations**

The photometer uses a checkcode to verify that it has correctly read the data from the magnetic strip. While most of the data remain constant for a given parameter, the characteristic data that are used to calculate the result from the reflectance readings are determined anew for each lot of reagent strips. This balances out the inevitable lot-to-lot differences that occur during production as a result of changing from one lot of raw material to another.
Calibration by the user is therefore unnecessary.

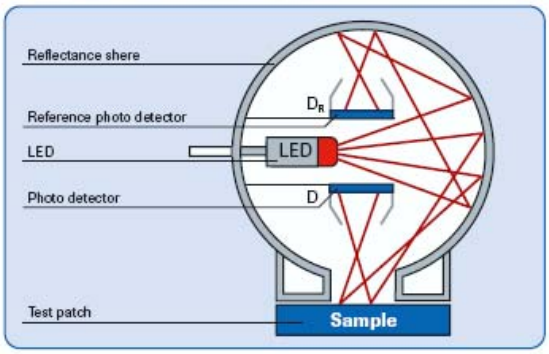
# The reflectance photometer

### Reflotron® Plus

The instrument, a microprocessor-controlled reflectance photometer, takes full charge of the test and automatically measures reflectance values as well as performing calculations. It receives the test- and lotspecific information from the magnetic stripe affixed to the underside of each Reflotron® reagent strip. In this way the microprocessor system is able to control and monitor all functions such as testing procedure, heating, automatic calibration and evaluation of reflectance values and calculation of results, specifically for each test. At the heart of the photometer is the Ulbricht's sphere in which the measurements actually take place (Figures 4 and 5)

**Figure 4**
The Ulbricht's sphere

**Figure 5**
Schematic diagram of the Ulbricht's sphere




# Testing procedure

## Very simple operation

The Reflotron® system, unlike other clinical-chemical systems, does not require calibration by the user, as the manufacturer calibrates the reagent strips lot by lot and encodes the data on the reagent strip, which the instrument reads.

A Reflotron® test thus starts immediately following the application of sample to the reagent strip.

The test strip is designed to make testing quick and simple. The silver foil is removed from the test strip and sample is applied. Since only a minute quantity of sample is required (30 µL), capillary blood can also be directly used. Just potassium and HDL cholesterol require the use of serum or plasma. Serum or plasma may be used for the other tests, too, of course, with the exception of the haemoglobin test.

Sample is applied to the reagent strip with an ordinary capillary or laboratory pipette, the reagent strip is placed in the photometer and testing is started by closing the measuring chamber flap.

**Figure 6**
Test procedure – simple and fast

### Fast test result

The time to result is approximately 2-3 minutes. Lipid results can be used directly for other calculations such as LDL cholesterol, myocardial infarction risk, and the cholesterol/HDL cholesterol quotient. If desired, creatinine values can be used to measure creatinine clearance. The formula for performing the calculation is programmed into the photometer.

## Measuring procedure

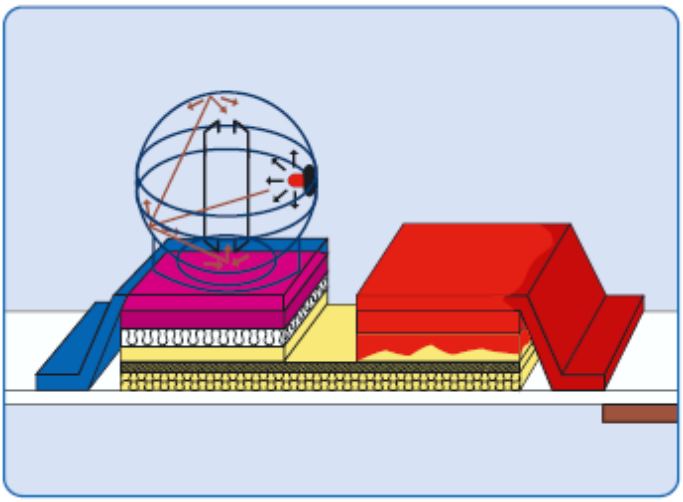
### Test reaction

Closing the measuring chamber flap moves the strip to the measuring position and automatically starts the measuring procedure. The photometer first reads, checks and saves the data encoded on the magnetic stripe on the underside of the reagent strip. Strip recognition is then complete and the instrument carries out the measurement strictly according to the data it has received from the strip.

Before the reaction starts, erythrocytes are separated out of the blood sample. During the incubation phase, the plasma reservoir fills and the photometer heats the reagent strip to 37°C.

The reaction commences when the reactive layers are pressed by the measuring head, an Ulbricht's sphere, into the plasma reservoir, so bringing the reagents into contact with the plasma or serum.

**Figure 7**
Measurement - schematic



Sample can now enter the layers carrying the reagents. The intensity of colour of the reaction product is measured at various times (kinetic measurement) or on completion of the reaction (end-point measurement) (Figure 7).

## Evaluation – the optical system

The Ulbricht's sphere measures reflectance, i.e. the intensity of the light directed onto the reagent strip and reflected all according to its depth of colour. The depth of colour is itself determined by the concentration of analyte in the sample being investigated. Figure 5 shows a cross-section through an Ulbricht's sphere. The light sources are rigorously selected light-emitting diodes (LEDs) emitting at the key wavelengths 567, 642 and 951 nm. Each test therefore can take place at the most favourable wavelength. The light receptors are two symmetrically arranged photodiodes, a reference photodiode DR and a measuring photodiode (D).

The light emitted by the LED is repeatedly reflected from the white inner surface of the sphere so that it is diffused uniformly within the sphere. The reference photo detector measures the intensity I0 of the diffuse light, while the measuring photo detector registers the amount of light I that is diffusely reflected from the test zone of the strip. I is reduced through light absorption by the indicator. The I0 /I quotient is proportional to the reflectance value R. The reflectance measured in the test is converted to a concentration or an activity value based on the test-specific function curve.

This reference procedure excludes the possibility of errors that are due to differences in component olerances or to ageing being incorporated into the result. In Reflotron® the electronics utilize a compensation procedure to ensure that mains-frequency interferences or series of zeroes, or steady sources of interference such as stray light and ultrasound or diathermic equipment located further than 4 metres away do not affect the result.

## Automatic calibration

Following measurement and data evaluation, the result appears on the display screen. Automatic calibration based on the data transferred from the magnetic stripe on the reagent strip to the photometer helps ensure that results obtained for human samples measured with Reflotron® agree closely with the results obtained using the reference or standard method. Owing to the fact that there are always slight differences in the characteristics of the biochemical starting materials, not only does each parameter have to be calibrated but also each lot of parameters. This process occurs within the factory and relieves the user of the need to perform separate, often edious and error-prone calibrations.

## Calibration values

All according to the particular test, between 6 and 18 calibrators are grouped by the factory into sets covering the required analyte concentration range; where necessary hrough addition of analyte in order to achieve the necessary concentration. These calibrators are the link between the standard method used in formal clinical chemistry analysis in the laboratory and the values obtained using the Reflotron® test. This means that, despite the different test principles utilized in the formal and the Reflotron® systems, the values obtained from human specimen material remain comparable.

Calibration of the tests is carried out using internationally applied reference methods so that comparability with these laboratory methods is assured (Table 3).

The reference method values for a calibrator set are determined in reference laboratories, and each alibrator thereby receives a value that relates to the standard method. These calibrators are then measured using fresh human specimen material in parallel by the reference method and on the Reflotron®. In this way concentrations can be matched with reflectance values as measured by the Reflotron®. This gives a reflectance/ concentration curve. Subsequently, the values measured using the calibrators are plotted on the fresh material curve. The calibrators therefore also have a defined reflectance/concentration relationship and, in subsequent calibrations of new batches, can be used for calibration instead of fresh human specimen material.

These human serum or plasma-based calibrators are kept at -20° C to -70° C in order to guarantee stability. The use of frozen samples has the advantage that stable specimen material is available over a prolonged period in order to guarantee and document the comparability of different reagent strip lots for the same parameter.

| **Test** | **Reference Method** |
|---|---|
| Alkaline Phosphatase | ALP IFCC liquid |
| Amylase | α-Amylase liquid (IFCC) |
| Pancreatic Amylase | Pancreatic- α-Amylase liquid |
| Bilirubin | DPD method |
| Cholesterol | CHOD-PAP method |
| CK | CK liquid |
| Creatinine | Creatinine plus |
| γ-GT | γ-GT liquid (IFCC) |
| Glucose | Hexokinase method |
| GOT (AST) | IFCC (without pyridoxal phosphate activation) |
| GPT (ALT) | IFCC (without pyridoxal phosphate activation) |
| HDL Cholesterol | Homogeneous HDL cholesterol plus method |
| Haemoglobin | SLS Haemoglobin method |
| Uric acid | Uric acid plus |
| Urea | Kinetic UV test |
| Potassium | Flame photometry |
| Triglycerides | GPO-PAP method |

**Table 3**
Reference methods for the Reflotron® Tests

The precision with which the concentration or activity can be measured depends on the slope of the function curve within the relevant concentration range. To reach a high level of precision, every effort must be made to achieve an optimum curve shape over the entire clinically relevant range.

Apart from choosing the correct indicator there are two main measures that are employed to achieve this desired sensitivity: addition of a reducing agent in the case of high analyte concentrations, and use of different film layers on the reagent strip and different types of layer arrangement.

### Measuring ranges

The measuring ranges cover the entire clinically relevant concentration or activity range. Table 4 is a ummary of measuring ranges of the Reflotron® Tests.

| | |
|---|---|
| Glucose | 0.56 – 33.3 mmol/l |
| Choesterol | 2.59 – 12.9 mmol/l |
| HDL Cholesterol | 0.26 – 2.59 mmol/l |
| Triglycerides | 0.80 – 6.86 mmol/l |
| Creatinine | 44.5 – 884 µmol/l |
| Urea | 3.33 – 50mmol/l |
| Uric aicd | 120 – 1190 µmol/l |
| Bilirubin | 8.5 – 204 µmol/l |
| Haemoglobin | 3.1 – 12.4 mmol/l |
| Potassium | 2.0 – 12.0 mmol/l |
| Alkaline Phosphatase | 20 – 1250 U/l (37°C) |
| GPT (ALT) | 5.0 – 2000 U/l (37°C) |
| GOT (AST) | 5.0 – 500 U/l (37°C) |
| γ-GT | 5.0 – 3500 U/l (37°C) |
| CK | 24.4 – 1400 U/l (37°C) |
| Amylase | 29 – 860 U/l (37°C) |
| Pancreatic Amylase | 14 – 850 U/l (37°C) |

**Table 4**

Measuring ranges for Reflotron® Tests

# Additional functions

### LDL cholesterol

A program integrated in the Reflotron® photometers can calculate LDL cholesterol easily from the measured cholesterol, triglycerides and HDL cholesterol values as follows: the user calls up the menu (the program is named on the keyboard) and enters the patient ID. The values are taken directly from memory and the calculation is performed automatically.

### Myocardial infarction risk calculator

Atherosclerotic cardiac and vascular disease is the most frequent cause of death and the principle cause of premature disability in the industrially developed world.

Numerous long-term studies have shown that, in the vast majority of cases, risk factors existed. When several risk factors coincide, morbidity rises cumulatively. Consequently, when looking at the clinical picture, it is important not to view individual risk factors in isolation. There is a linear or exponential relationship between most risk factors and the incidence of coronary heart disease. It is impossible, unfortunately, to specify clear limits for low and high individual risk.

Patients at risk of developing coronary heart disease who only exhibit one risk factor are extremely hard to identify, and information gathered from several simultaneously measured parameters is needed. If such information is not

obtained, the doctor finds it more difficult to decide whether the person is a high-risk CHD patient and whether therapy is necessary. This is where the MI risk calculator is useful.

The Reflotron® systems incorporate two MI risk calculators: one according to PROCAM, based on long-term studies in the prospective cardiovascular Münster study, and one based on the Framingham study. Cholesterol, triglycerides and HDL cholesterol values measured with Reflotron® can be directly included in the calculation along with the various risk-influencing factors such as blood pressure, age, smoking and history of myocardial events. The myocardial infarction risk result that is thus obtained can be determined again later to discover the change that has occurred since the suggested therapy was first implemented, an excellent means of encouraging patient compliance.

### Cholesterol/HDL cholesterol factor

The cholesterol/HDL cholesterol factor, which is often used for therapeutic decision-making, is also available. It is calculated and displayed automatically following appropriate data entry.

### Creatinine clearance calculation

Evaluation of kidney function in cases of suspected renal insufficiency can be undertaken more precisely based on creatinine clearance than by measuring just urea or creatinine in blood. The fact that the Reflotron® Creatinine Test can be performed on pre-diluted urine as well as blood enables it to be used for the creatinine clearance test, also.

The program for calculating creatinine clearance is available via the keyboard. The user enters the measured value and data on the urine collection period and volume along with the results, and the calculation is performed automatically.

## Quality Assurance

### Instrument checks

Reflotron® largely checks itself, monitoring around 50 different items to ensure that it maintains its full operating functionality. Reflotron® provides on-screen user guidance.

### Reflotron® Check

By using a Reflotron® Check quality control strip the user can check the function of the instrument's optical system easily and quickly. Depending on the laboratory's standing instructions, this check may be performed in addition to the overall system check with control sera or partly as a replacement for it, making it possible to perform total-system quality controls less frequently. Comparison of the on-screen result with the confidence interval printed on the tube indicates whether the optical system is functioning correctly.

**Figure 8**
Instrument checks with Reflotron® Check


## System Checks

The well-proven Precinorm® control sera are available in adapted form as Reflotron® Precinorm® U, Reflotron® Precinorm® HDL and Reflotron® Precinorm® HB for checking the Reflotron® system.
Precinorm® is a range of freeze-dried control sera that are reconstituted with distilled water.

**Figure 9**
Control sera


## Identifying quality controls

Tests run using Reflotron® Check quality control strips or with the control sera can be identified as such and kept separate from patients' results.

# Technical Data for Reflotron® Plus

| | |
|---|---|
| **Dimensions** | Approx. 30 x 35 x 21 cm |
| **Weight** | Approx. 5.3 kg |
| **Power supply** | 115 – 230 V AC (± 22 %); Frequency 47 Hz to 63 Hz, optional 10 – 30 V battery connection |
| **Power consumption** | 45 VA |
| **Transport conditions** | Temperature - 20° C to + 55° C. Relative humidity 5 % to 95 % |
| **User guidance** | Easy-to-follow on-screen text messages. Various language options |
| **Measuring principle** | Reflectance measurement with an Ulbricht's sphere using a reference beam |
| **Light sources** | Light-emitting diodes (LEDs) |
| **Wavelengths** | 567 nm, 642 nm, 951 nm |
| **Light detectors** | Photodiodes (2) |
| **Service life of the light source** | > 50 000 tests |
| **Automatic compensation** | For the zero point and changings in current frequency. |
| **Measuring range** | 2.5 % to 90 % diffuse reflectance |
| **Temperature** | 37° C ± 0,1° C |
| **Change over time between parameters** | None |
| **Accuracy of input** | The records are checked for plausibility |
| **Electronic memory Storage capacity (in KBytes)** | Microprocessors: 7<br>Master / Controller<br>EPROM 128 / 48<br>EEPROM 16 / 0.5<br>RAM 32 / 16 |
| **Process control** | On-screen text messages provide user guidance. Over 50 functions controls ensure the working saftey of the instrument |
| **Display** | Alphanumeric: 2 lines of 24 characters, liquid crystal display |
| **Clock** | Battery-buffered real-time clock |
| **Data interfaces** | RS 232 C serial, 1 keyboard interface |
| **Accuracy** | ± 0.5 % reflectance, with respect to the means for the instrument delivered |
| **Precision** | ≤ 0.2 % reflectance |
| **Linearity** | ± 0.05 variation deviation |
| **Required operating environment** | Temperature: 15° C to 34° C. Relative humidity max. 95 % |

# Reflotron® Plus Product List 2006

## Starter Packs

**Reflotron Plus Instrument** Cat. no. 278000

Includes:

- **Instrument**
- **Keyboard**
- **Manual**
- **Maintenance log book**

**QC Starter Pack** Cat. no. LIST0002

Includes:

- **Precinorm UR quality control material**
- **32µl pipette plus tips**
- **2ml pipette plus tips**
- **Clean and Check Strips**

**HDL Cholesterol Starter Pack** Cat. no. LIST0003

Includes:

- **Centrifuge**
- **Microvette tubes (EDTA)**
- **HDL cholesterol control material**

## Service & Repair Options

### Support Contract

Cat. no. 278075

Includes:

- **Comprehensive telephone support, 24 hours a day, 7 days a week**
- **Return-to-base service for instrument breakdowns – all labour charges included but parts are chargeable**
- **Loan instrument during repair if required**

### Workshop Repair (for customers not holding Support Contract)

Cat. no. 278060

Includes:

- **One-off return-to-base repair - all labour charges included but parts are chargeable**

# Consumables

| CAT. NO. | DESCRIPTION | PACK SIZE |
|---|---|---|
| **TEST STRIPS** | | |
| 278006 | Reflotron Glucose | 30 tests |
| 278007 | Reflotron Haemoglobin | 30 tests |
| 278008 | Reflotron Urea | 15 tests |
| 278009 | Reflotron Triglyceride | 30 tests |
| 278010 | Reflotron Cholesterol | 30 tests |
| 278011 | Reflotron Gamma GT | 30 tests |
| 278012 | Reflotron Uric Acid | 30 tests |
| 278013 | Reflotron AST | 30 tests |
| 278014 | Reflotron ALT | 30 tests |
| 278015 | Reflotron Bilirubin | 30 tests |
| 278016 | Reflotron Amylase | 15 tests |
| 278017 | Reflotron Creatinine | 30 tests |
| 278018 | Reflotron Pancreatic Amylase | 15 tests |
| 278019 | Reflotron CK | 15 tests |
| 278020 | Reflotron HDL Cholesterol * | 30 tests |
| 278021 | Reflotron Potassium * | 30 tests |
| 278022 | Reflotron Alkaline Phosphatase | 30 tests |
| **QUALITY CONTROLS** | | |
| 278026 | Reflotron Clean & Check | 15 tests |
| 278023 | Precinorm UR | 4 x 2ml |
| 278024 | Precinorm Hb | 4 x 2ml |
| 278025 | Precinorm HDL | 4 x 2ml |
| **CONSUMABLES** | | |
| 278003 | Reflotron – printer paper (large) | 1 roll |
| 278004 | Reflotron – printer ribbon | Pack of 5 |

| CAT. NO. | DESCRIPTION | PACK SIZE |
|---|---|---|
| **BLOOD COLLECTION** | | |
| 278027 | Softclix pro | Each |
| 278028 | Softclix pro lancets | Pack of 200 |
| 278029 | Alcohol Wipes | Pack of 100 |
| 278031 | Safe-T-Pro single use device | Pack of 200 |
| 278121 | Serum Capillary - 250µl | Pack of 100 |
| 278122 | Serum Tube – 2ml | Pack of 100 |
| 278123 | Lithium Heparin Capillary - 250µl | Pack of 100 |
| 278124 | Lithium Heparin Tube – 2ml | Pack of 100 |
| 278125 | EDTA Capillary - 250µl | Pack of 100 |
| 278126 | EDTA Tube – 2ml | Pack of 100 |
| 278045 | Microsafe® Blood Collection Tubes | Pack of 100 |
| 278205 | Reflotron Capillary Applicator - Grey | Each |
| 278206 | Capillary tubes for grey applicator | Pack of 100 |
| 278038 | Capillary tubes for original black applicator | Pack of 100 |
| **PIPETTES AND TIPS** | | |
| F123615 | P100 Pipette for application of material to test strip | Each |
| F161932 | Tips to fit P100 | 10 racks of 96 |
| F123603 | P5000 Pipette for reconstitution of quality control material | Each |
| F161370 | Tips to fit P5000 | 12 racks of 50 |
| **MISCELLANEOUS** | | |
| 278120 | Mini Centrifuge | Each |

*** PLEASE NOTE:**

HDL AND POTASSIUM TEST STRIPS CANNOT BE USED WITH WHOLE BLOOD – SAMPLES MUST BE CENTRIFUGED AND PLASMA APPLIED TO TEST STRIP.

| CAT NO | DESCRIPTION | PACK SIZE |
|---|---|---|
| **BLOOD COLLECTION** | | |
| 278027 | Softclix pro | Each |
| 278028 | Softclix pro lancets | Pack of 200 |
| 278029 | Alcohol Wipes | Pack of 100 |
| 278031 | Safe-T-Pro single use device | Pack of 200 |
| 278035 | Microvette Tubes (EDTA) | Pack of 50 |
| 278072 | Microvette Tubes (Lithium Heparin) | Pack of 50 |
| 278100 | Microvette 100 Tubes (Lithium Heparin) | Pack of 100 |
| 278045 | Microsafe® Blood Collection Tubes | Pack of 100 |
| 278205 | Reflotron Capillary Applicator - Grey | Each |
| 278206 | Capillary tubes for grey applicator | Pack of 100 |
| 278038 | Capillary tubes for original black applicator | Pack of 100 |
| **PIPETTES AND TIPS** | | |
| F123615 | P100 Pipette for application of material to test strip | Each |
| F161932 | Tips to fit P100 | 10 racks of 96 |
| F123603 | P5000 Pipette for reconstitution of quality control material | Each |
| F161370 | Tips to fit P5000 | 12 racks of 50 |
| **MISCELLANEOUS** | | |
| 278071 | Centrifuge MC6 | Each |

## Current Users of the Reflotron® Plus include:

- BUPA Wellness
- Leeds Metropolitan University
- GMC Fire Service
- Ninewells Hospital
- BMI, The Saxon Clinic
- Superdrug Health Screening
- BMW UK Ltd
- British International Rowing
- Well Woman Centre
- Cromwell Hospital
- Scottish Power
- British Nuclear Fuels PLC
- Sussex Police
- HMP Bedford
- The Fire Service, Birmingham
- West Midlands Police

# Health Screening with the Reflotron® Plus

Annie Smith and myself commenced our employment as screening nurses for West Midlands Police over 2 years ago.

Our role was described as 'diverse, busy and interesting' – a definite understatement! No-one mentioned life-style screening for all staff, which would involve looking at someone's life-style and offering dietary and fitness advice. We were also informed that part of this screen would be a cholesterol check using the Reflotron® Plus analyser – whatever that was!

We were introduced to the said Reflotron® but even after having read the manuals and spoken to the Occupational Health Advisors, we still had lots of questions about its use. In desperation we turned to the technical support team at Bio-Stat who were 'saints'. All our questions (some at best silly, at worst naïve) were answered, explained and talked through calmly. With Bio-Stat's help we began to understand the Reflotron, and gain confidence in its operation.

Now we make full use of the Reflotron in many areas of our everyday appointments and find Police Officers, and other Police Staff members, regularly refer others to our department for health screening / tests that involve the use of the Reflotron.

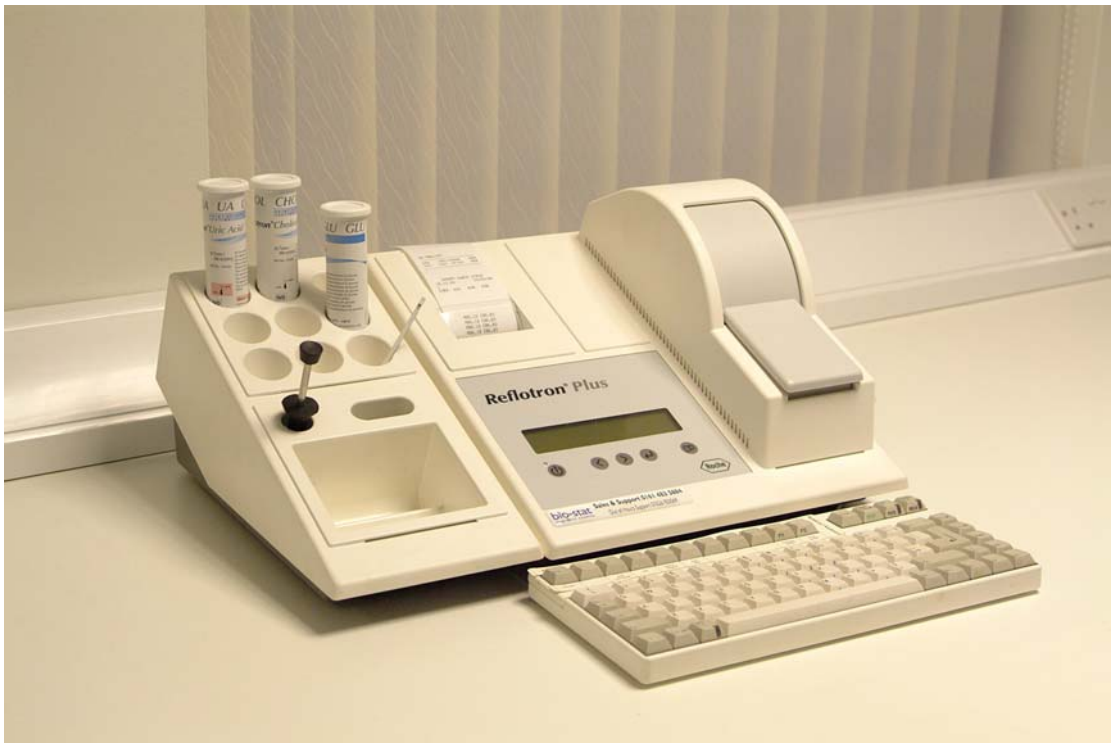
It is difficult to remember the times when we were slightly afraid, and in awe, of the little machine we now find so useful. With the support and guidance we have received from Bio-Stat we are now able to use the Reflotron, and interpret the results, with confidence.

**Sister Chris Fitzgerald**
***West Midlands Police***

# Reflotron® Plus and Sports Science

'At the Centre for Sport and Exercise Science, the Reflotron® is heavily used for teaching, research and consultancy purposes. Its range of applications and reliability makes the Reflotron a valuable piece of equipment.'

*Carl Wells*
*Senior Technician*
*Centre for Sport and Exercise Science*
*Sheffield Hallam University*



# Monitoring of cholesterol in a Diabetic Clinic

In 1994 a new combined Renal and Diabetic Unit was opened at Wrexham Maelor Hospital. Funding for both the building and equipment was via public donations including £30,000 for laboratory equipment from The Lion's Club of Great Britain. Now four Diabetic Clinics per week are run by the unit, with an additional Adolescent Clinic starting up in March 2005.

On arrival in clinic, patients have blood specimens taken and a Biomedical Scientist measures blood glucose (130 per week), HbA1c (130 per week), and Total Cholesterol (100 per week) prior to the patient seeing one of the Diabetologists. Initially, we were using a YSI 2300 to measure blood glucose, a Variant II to measure HbA1c, and a Spotchem I to measure Total Cholesterol.

Recently, a request was made by the Diabetologists for us to start measuring HDL Cholesterol, as well as Total Cholesterol (TC), on all patients being treated with statins and attending the Clinic for annual review. Although the Spotchem I can measure HDL, the pre-precipitation step needed prior to analysis would add 5 minutes to every sample analysed, and this was deemed to be unsuitable for the fast-tracking of samples in the Clinic situation.

We already had prior knowledge and experience of the Reflotron® Plus in a POCT setting and, following discussions with Bio-Stat, we decided to look at the use of the Reflotron as a replacement for the Spotchem I for the measurement of both TC and HDL Cholesterol. The Reflotron was evaluated in Clinic, and it was found that it took just 135 seconds to perform a TC and 135 seconds to perform a HDL. Sample volume is 32µl for each test, using plasma for the TC and for the HDL test. The measurement ranges are 2.6-12.9 mmol/l and 0.26-2.59 mmol/l respectively.

It was decided at an early stage that the preferred option would be to have two Reflotrons working side-by-side, using one analyser specifically for HDL and the other for TC. This would minimise the overall analysis time on those patients that required both tests. Also, in the case of breakdown, we could ensure continuation of the service to the Clinics.

Correlation of results with the main laboratory was deemed to be essential, so a study was performed to compare results from the Reflotron instruments with those generated by a Beckman LX-20 in the main laboratory. Statistical analysis in the laboratory confirmed a linear relationship between the two Beckman LX20 analyser and the Reflotron instruments.

Confidence was high that the proposed option could be put into routine operation.

The Reflotron instruments are now an established part of our diabetic clinic. We are currently only measuring TC, however the introduction of the HDL assay is just waiting for the funding to be finalised and is expected to begin soon.

Marge Everall
Pathology Department,
*Wrexham Maelor Hospital*