



# Myt-5D

## HEMATOLOGY CONTROLS

### **CONTROL**

#### INTENDED USE

**Myt-5D** is an assayed whole blood control designed to monitor values on Mythic™ 22 hematology cell counters.

#### SUMMARY AND PRINCIPLE

It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials that provide a means of monitoring the performance of hematology blood cell counters. It is sampled in the same manner as a patient specimen.

#### REAGENTS

**Myt-5D** is an *in vitro* diagnostic reagent composed of human erythrocytes, mammalian leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.



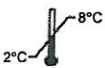
#### PRECAUTION

**Myt-5D** is intended for *in vitro* diagnostic use only by trained personnel.



#### WARNING:

**POTENTIAL BIOHAZARDOUS MATERIAL.** For *in vitro* diagnostic use. Each human donor/unit used in the preparation of this product has been tested by a FDA licensed method/test and found to be negative or non-reactive for the presence of HBsAg, Anti-HCV, NAT testing for HIV-1, HCV (RNA) and HIV-1/2. Each unit is also negative by a serological test for Syphilis (RPR or STS). Because no test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.



#### STABILITY AND STORAGE

Store **Myt-5D** upright at 2 - 8° C when not in use. **Protect tubes from overheating and freezing.** Unopened tubes are stable through the expiration date. Opened tubes are stable for 15 days, provided they are handled properly.

#### INDICATIONS OF DETERIORATION

After mixing, product should be similar in appearance to fresh whole blood. In unmixed tubes, the supernatant may appear cloudy and reddish; this is normal and does not indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration. **Do not use the product if deterioration is suspected.**



#### INSTRUCTIONS FOR USE

1. Remove tubes from the refrigerator and allow to warm to room temperature (15 - 30°C or 59 - 86°F) for 15 minutes before mixing.
2. To mix, hold a tube horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer.**
  - a) Roll the tube back and forth for 20 - 30 seconds; occasionally invert the tube. Mix vigorously, but do not shake.
  - b) Continue to mix in this manner until the red cells are completely suspended. Tubes stored for a long time may require extra mixing.
  - c) Gently invert the tube 8 - 10 times immediately before sampling.

3. Analyze the sample as instructed in the Quality Control section of the Operator's Manual for your instrument.
4. After sampling:
  - a) If tube has been open for sampling, clean residual material from the cap and tube rim with a lint-free tissue. Replace the cap tightly.
  - b) Return tubes to refrigerator within 30 minutes of use.

#### EXPECTED RESULTS

Verify that the lot number on the tube matches the lot number on the table of assay values. Assay values are determined on well-maintained, properly calibrated instruments using the instrument manufacturer's recommended reagents. Reagent differences, maintenance, operating technique, and calibration may contribute to inter-laboratory variation.

#### PERFORMANCE CHARACTERISTICS

Assigned values are presented as a Mean and Range. The Mean is derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. The Range is an estimate of variation between laboratories and also takes into account inherent imprecision of the method and expected biological variability of the control material.

Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range.

For greater control sensitivity each laboratory should establish its own mean and acceptable range and periodically reevaluate the mean. The laboratory range may include values outside of the assay range. The user may establish assay values not listed on the Assay Sheet, if the control is suitable for the method.

#### LIMITATIONS

The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

#### TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For assistance in resolving control recovery problems, please call your local Orphée representative or Orphée Technical Service at +41.22.884.90.90. For additional information on Orphée hematology controls and calibrators, or to place an order, call your local Orphée representative Customer Service or the Orphée's Customer Service at +41.22.884.90.90.

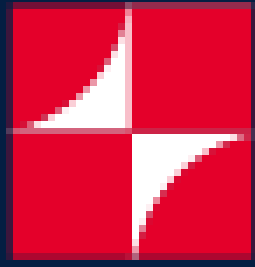
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ISO801-000 Rev 3/07







# CORMAY DIAGNOSTICS

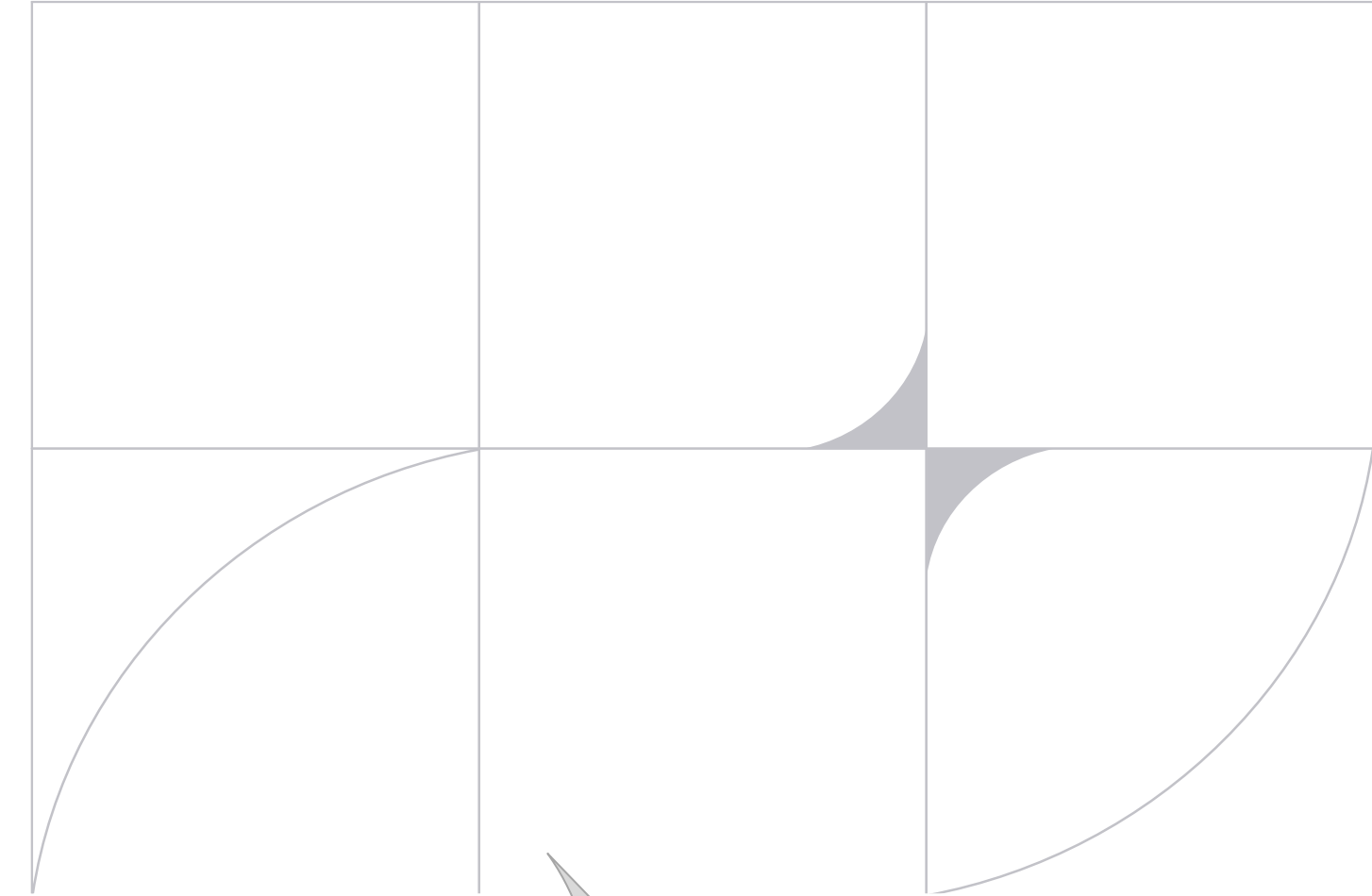
The Lifeline To Better Health

## A Partnership You Can Count On





# Hematology Technology Roadmap



**3 DIFF**

**3 DIFF + CRP**

**5 DIFF**

**VET**



## **MYTHIC X**

- 60 samples/hour
- 23 parameters



## **MYTHIC 3CRP**

- 60 samples/hour
- 22 parameters



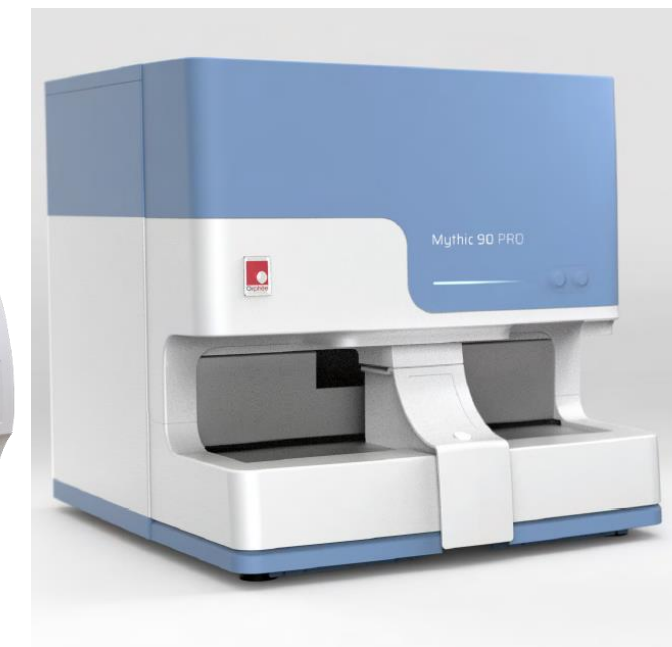
## **MYTHIC 60**

- 60 samples/hour
- 28 parameters



## **MYTHIC 70**

- 70 samples/hour
- 28 parameters



## **MYTHIC 90**

- 5-DIFF + RET + BF
- 90 samples/hour
- 49 parameters



## **MYTHIC 5VET PRO**

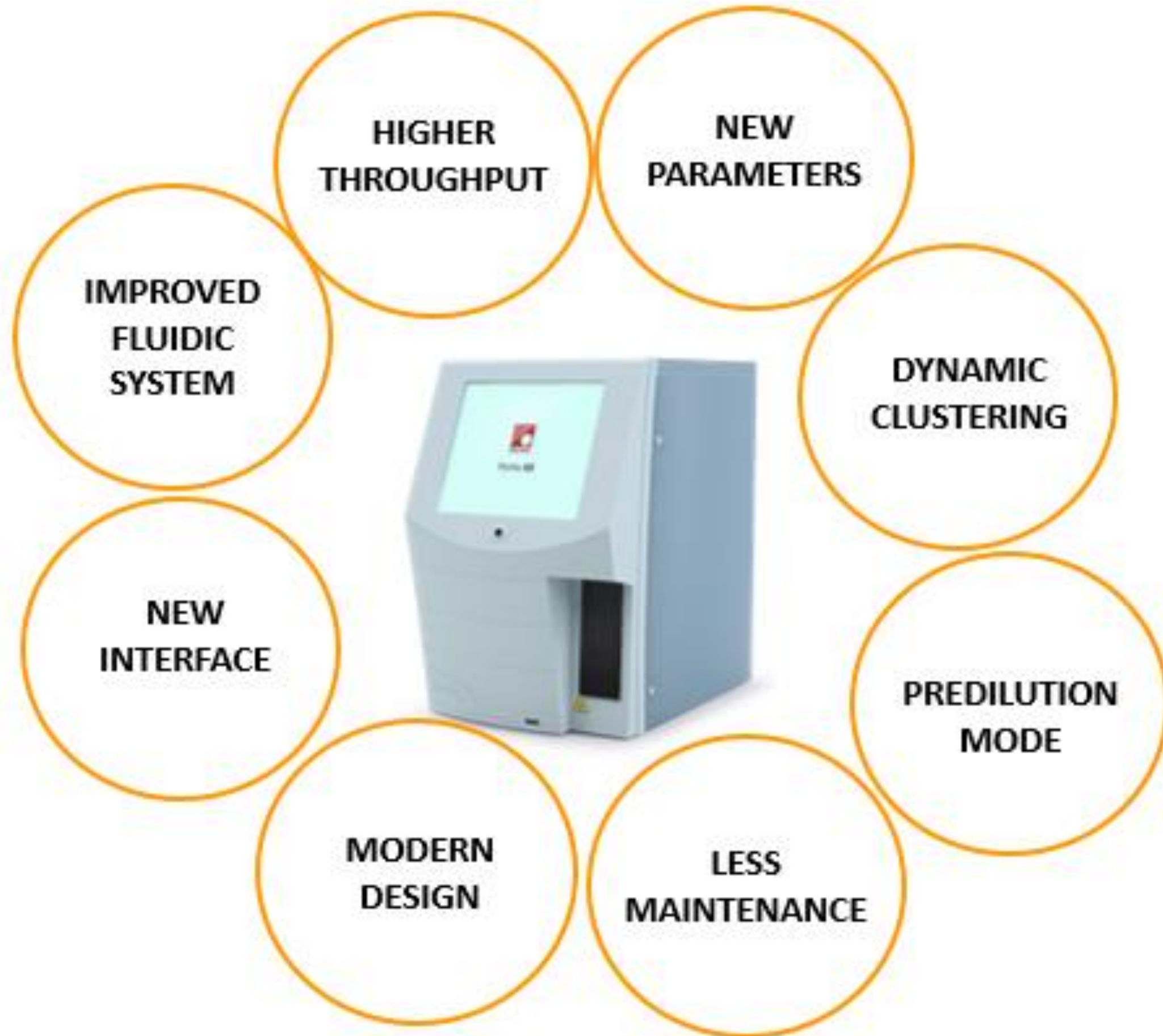
- 5-DIFF + RET
- 60 samples/hour
- 34 parameters

# MYTHIC 22 vs MYTHIC 60

Modern Design & More Capabilities



Features	Mythic 22	Mythic 60
Technology	Hydrofocusing Free Optical Flow Cytometry, True 5-DIFF	Patented “Hydrofocusing” Optical Flow Cytometry, True 5-DIFF, Dynamic Clustering
Throughput	50	60
Sample volume	15,7 µl	15,8 µl
Parameters	24	28
Size	250 x 340 x 350 mm (W x D x H), 11 kg	405 x 270 x 430 mm (W x D x H), 13 kg
Reagents	3	3
Testing After Collection	Up to 8 hours	Up to 24 hours
Dynamic Clustering	No	Yes
Prediluted Mode	No	Yes
Internal Memory	1.500 results	35.000 results



## NEW PARAMETERS

WBC:		RBC:		PLT:	
WBC #		RBC #		PLT #	
LYM %	LYM #	HGB		MPV	
NEU %	NEU #	HCT		PDW*	
MON %	MON #	MCV		PCT*	
EOS %	EOS #	MCH		P-LCR*	
BASO %	BASO #	MCHC			
<b>NEW</b>		RDW-CV			
ALY %*	ALY #*	RDW-SD			
IMM %*	IMM #*				

\* Research Use Only Parameters

**28**  
PARAMETERS

# MYTHIC 60

## New Interface & Updated Software

- New **Grafical User Interface**
- Mythic 60 features advanced algorithm classification of leucocytes – **Dynamic Clustering** that automatically defines the cell populations' areas at each run.
- New sampling modes: Whole Blood Dif (DIF WB) + Whole Blood CBC (CBC WB) + **Pre-diluted** Blood Dif (DIF PD) + Pre-diluted Blood CBC (CBC PD).
- Possibility to enter **more information** for each sample: name, PID, SID (can be entered with barcode reader), birth date, doctor's name, comments, mode (DIF WB / DIF PD / CBC WB / CBC PD) and gender (U/M/F).
- **Predefined reference ranges.** Are changed **automatically** accordingly to patient's age and sex.
- Patients, QC and calibration results have more **transparent design**.

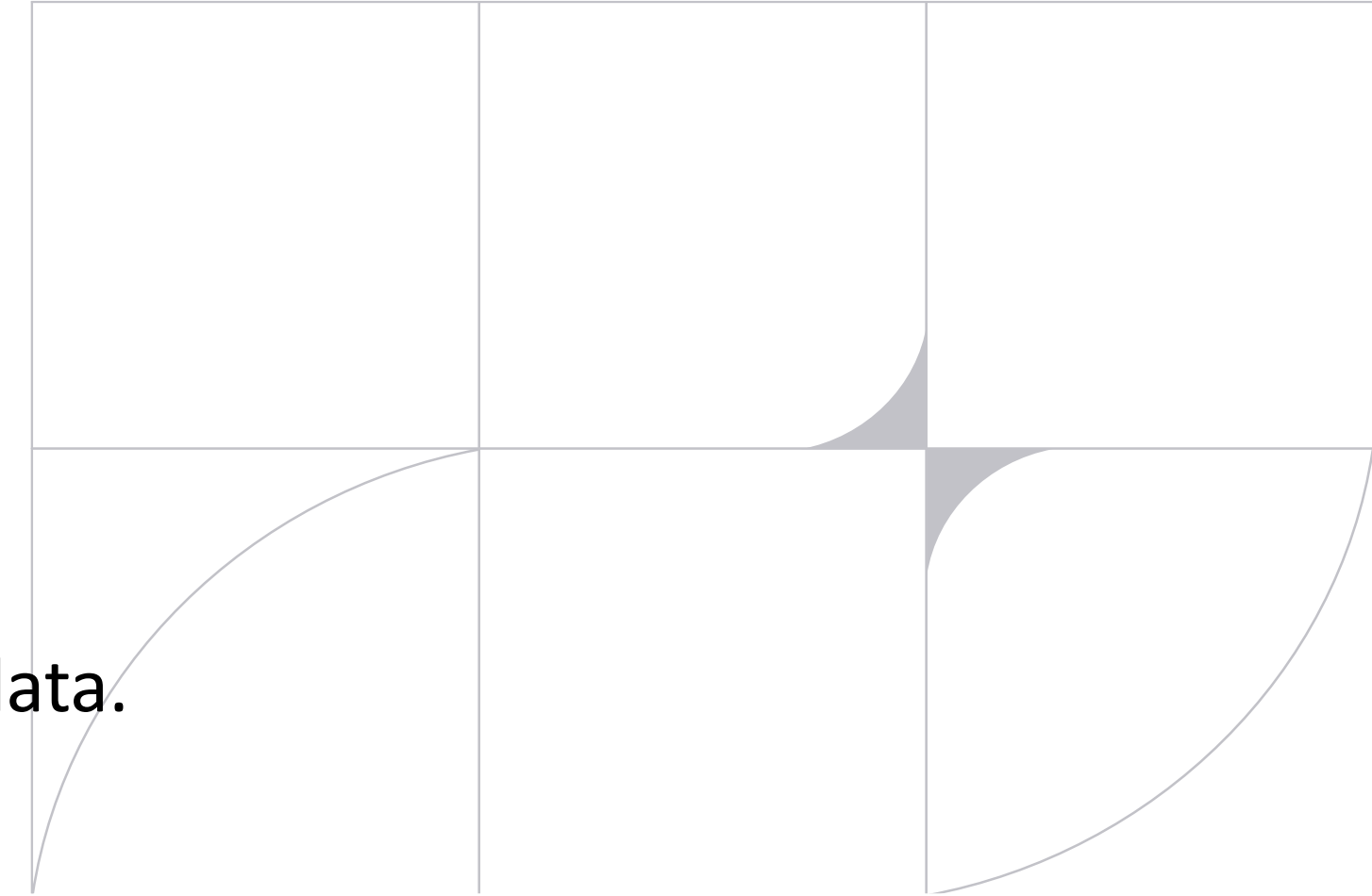




# MYTHIC 60

## New Interface & Updated Software

- Improved sample's **flagging** and **alarms** system.
- Up to **35 000** places in memory for patients results, qc and calibration data.
- USB barcode reader, keyboard and **printers options available**.
- New **reagent management system**. Close system.
  - Reagent expiry and onboard stability monitoring.
  - Checking the remain volume of reagents and counting remain samples.
  - Reagents LOTs log.
  - Open drain option for waste.
- Reagent and events log system collects more information for **more efficient troubleshooting** process.

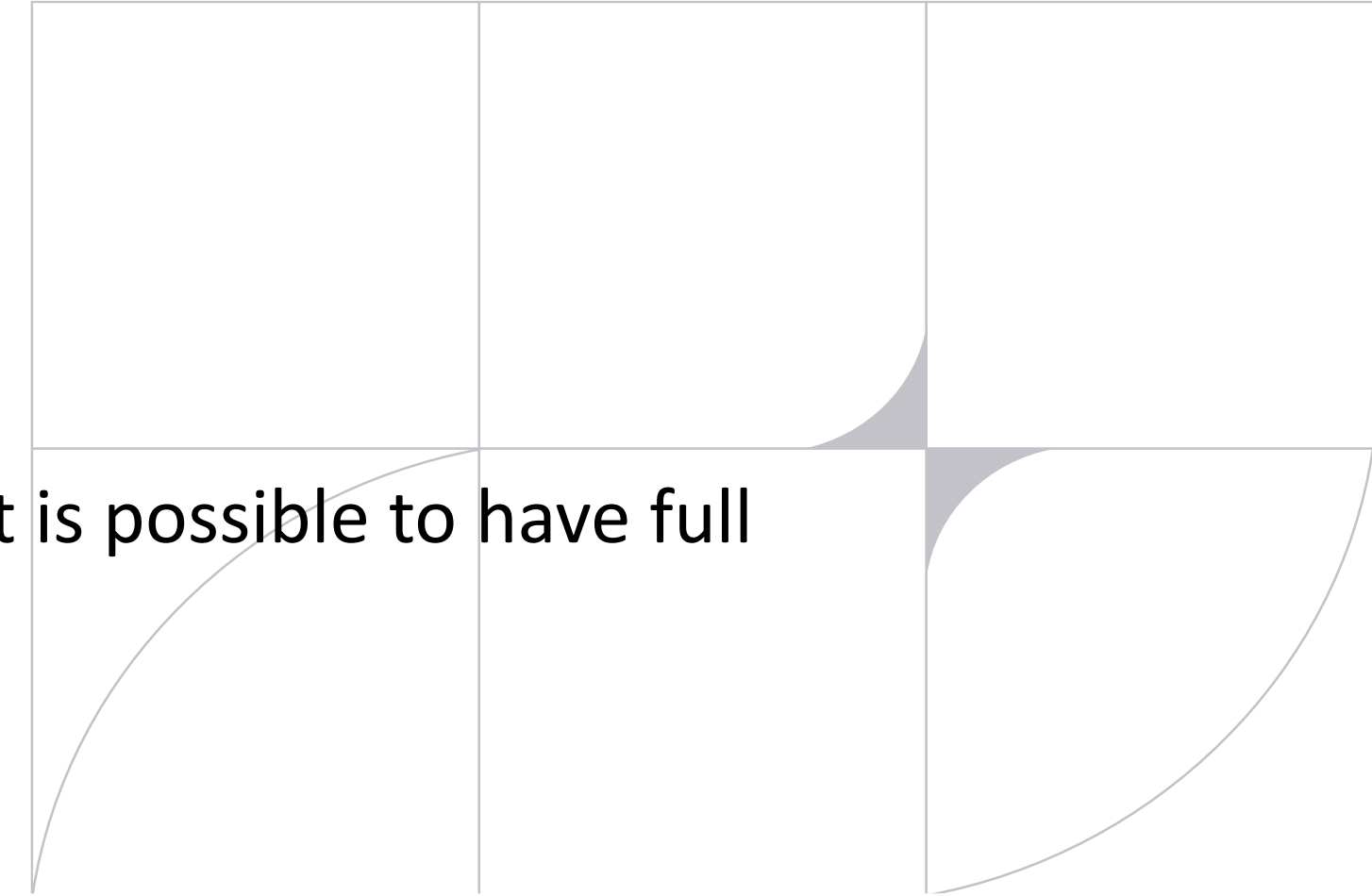




## MYTHIC 60

### New Interface & Updated Software

- Up to 100 results in 12 files for QC data. By pressing DETAILS in QC file it is possible to have full result's view. More **transparent design**.
- New **user management** system.
- Log-in by using password **increases data security**.
- **Automatic power up** can be defined for each day separately. **Shorter time of preparation** by running startup without login.

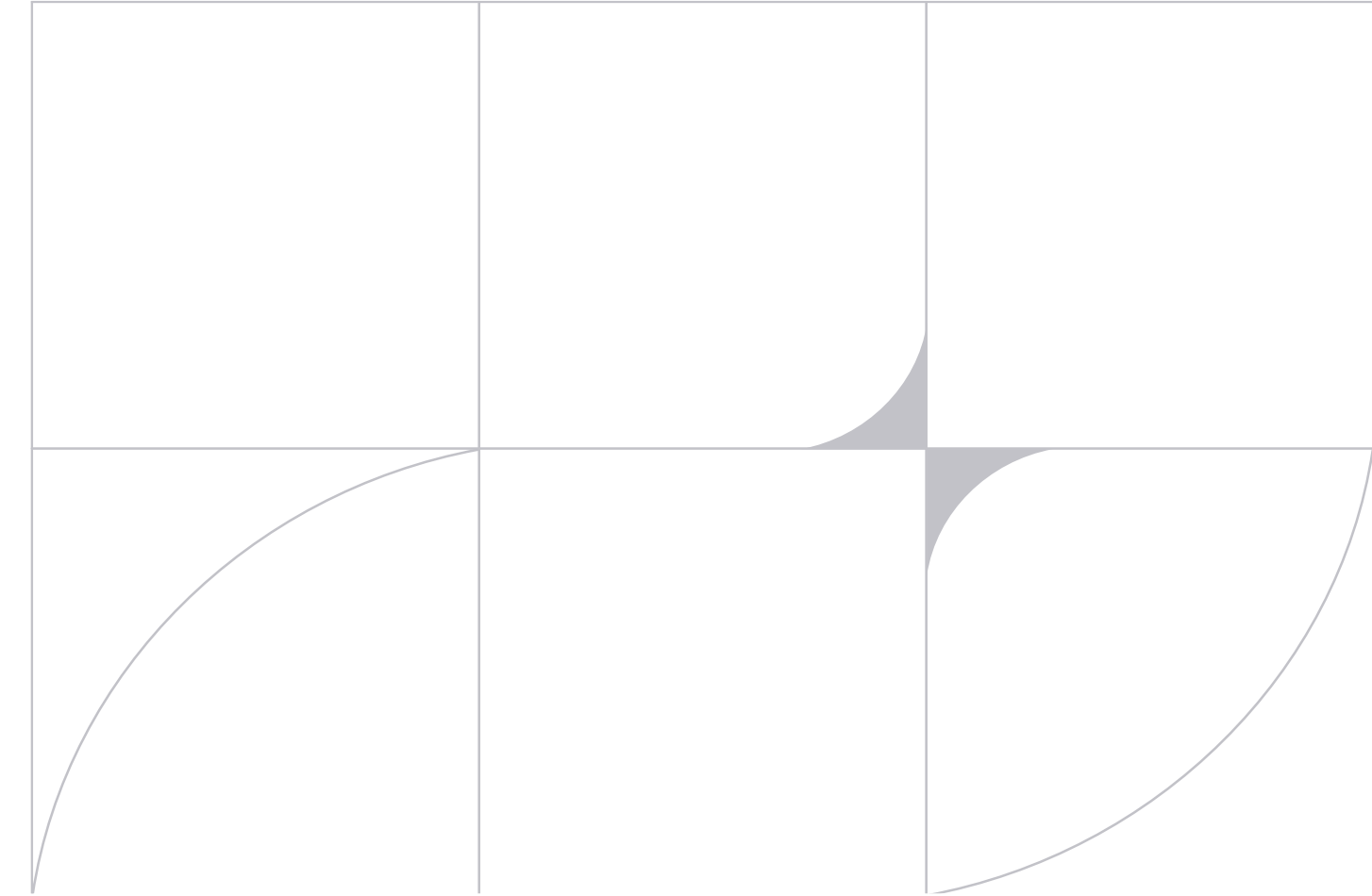




## MYTHIC 60

### Improved Electronic System

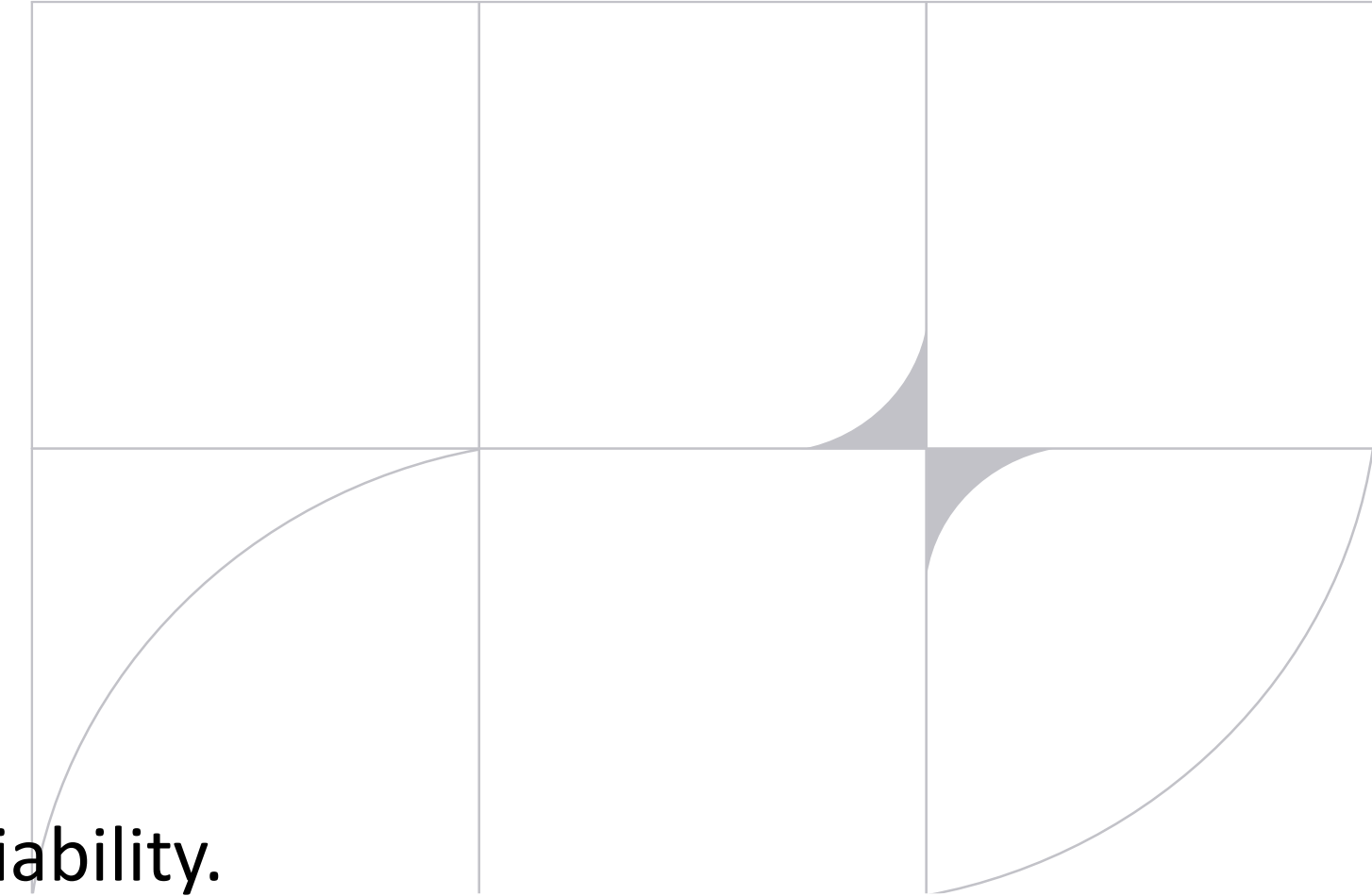
- CPU board is relocated to a front panel behind the screen.
- New big 8.4 inch (800x600) touch panel LCD.
- Mythic 60 uses same as Mythic 22 24V – 6.67 A – 160W power supply.
- New operating system – Linux.
- New design utilizes as much as possible parts present in MYTHIC 22 generation: valves, pumps, stepper motors, sensors and more.
- Impedance channel preamplifier is integrated with the CPU board. Low level signals are transmitted by coax cables.
- Valves electrical connections are kept separately from hydraulic connections.
- Counting chamber electrode can be replaced singly for each chambers.



## MYTHIC 60

### Improved Electronic System

- HGB LED and detector can be replaced **individually**.
- 5 USB universal ports, TCP/IP and RS-232 for LIS/HIS connection.
- No risk of CPU board or preamplifier flooding for higher instrument reliability.
- Analyzer has big touch panel LCD to easier control and more effective work.
- New counting chambers design fixes problems related to coax/electrodes and counting heads and allows faster service and **lower maintenance cost**.
- **Linux** provides **more** default settings for printers.
- Plenty of USB connectivity options: keyboard, barcode reader, printer and USB external storage.

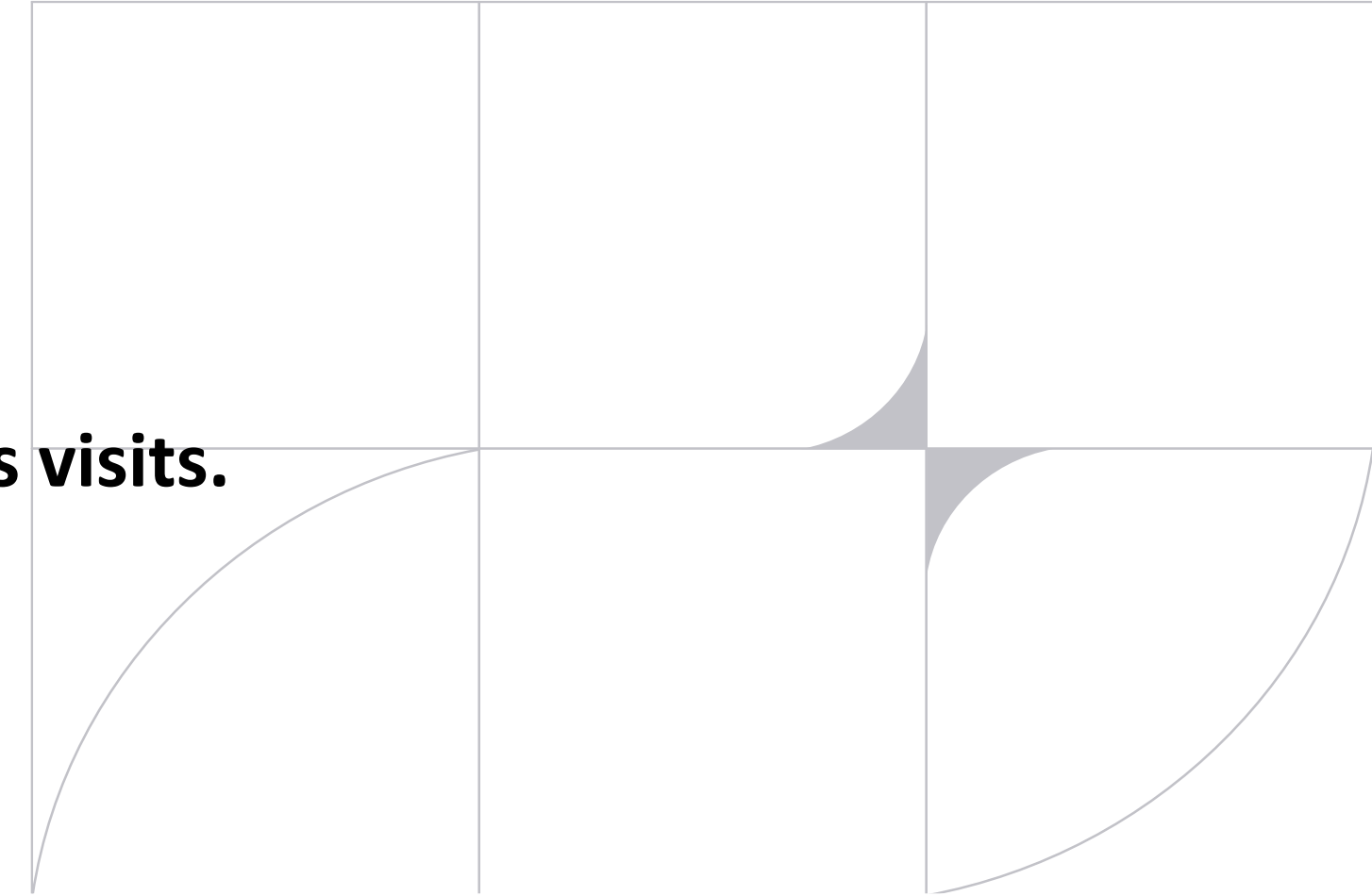




## MYTHIC 60

### Improved Fluidic System

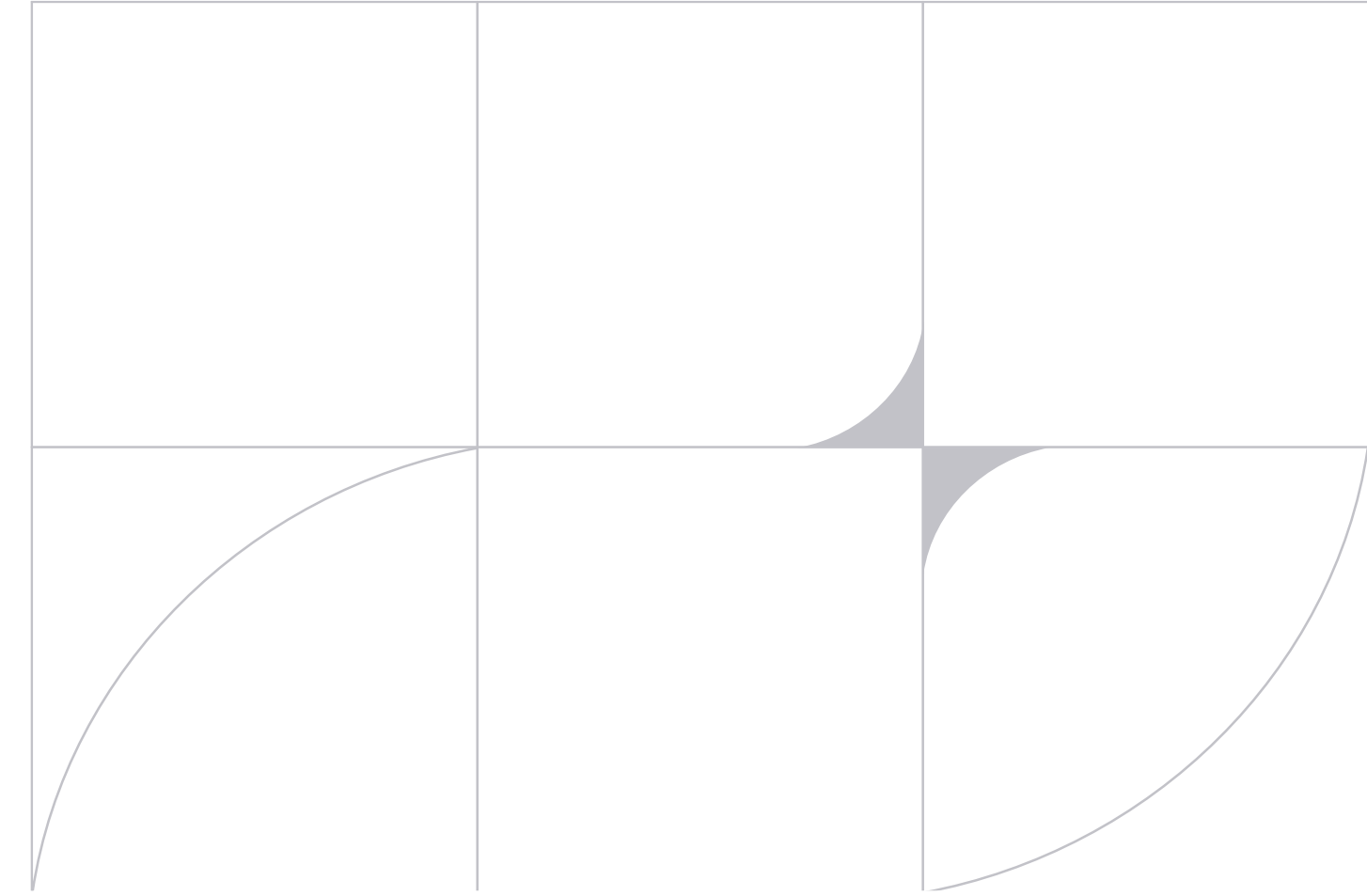
- Maintenance free tubing's connections for **less field service engineers visits.**
- Same molded fittings everywhere – **less spare parts SKUs and cost.**
- **Cheaper and more reliable** solution than an etched block.
- **No** risk of **reagents leaking.**
- **Very easy** dismantle and parts exchange.
- New counting chamber design **improves its reliability**, faulty electrode can be replaced instead of whole chamber.
- O-rings are uniform part of a syringe body, its replacement is **easier** than before.
- Only reagents are heated, analyzer reach operating temperature **faster.**
- Needle rinsing is improved due to dedicated pump.
- **Higher uptime** – 98,5 %.





## MYTHIC 60 Improved Optical System

- New concept of a patented flow cell.
- Increased size of flow cell injector from 80 to 200  $\mu\text{m}$ .
- Sample is shaped by “hydrofocusing” system.
- Flow cell built with very precise parts.
- Optical bench aligned in the same way as in Mythic 22.
- New LED blue light source to illuminate sample with better efficiency.
- Faster, providing greater precision, preamplifiers design.
- Additional 4 optical parameters.
- Dynamic Cells Clustering.





## MYTHIC 60

### Improved Optical System

- Higher throughput with 60 samples per hour due to increased cells flow speed.
- More cell can be recognized by the optical bench for more precise and accurate results.
- Lower pressure impact on white blood cells during sample's injection into flow cell. Higher resolution of 5-part diff separation for oncology samples.
- Bigger size of injector limits possibility of its clogging. Lower maintenance procedure, higher uptime.
- Hydrofocusing shapes and reduces a diameter of cell flow to 80  $\mu\text{m}$ - same as in previous generation, for single cell measurement.

## MYTHIC 60

### Improved Optical System

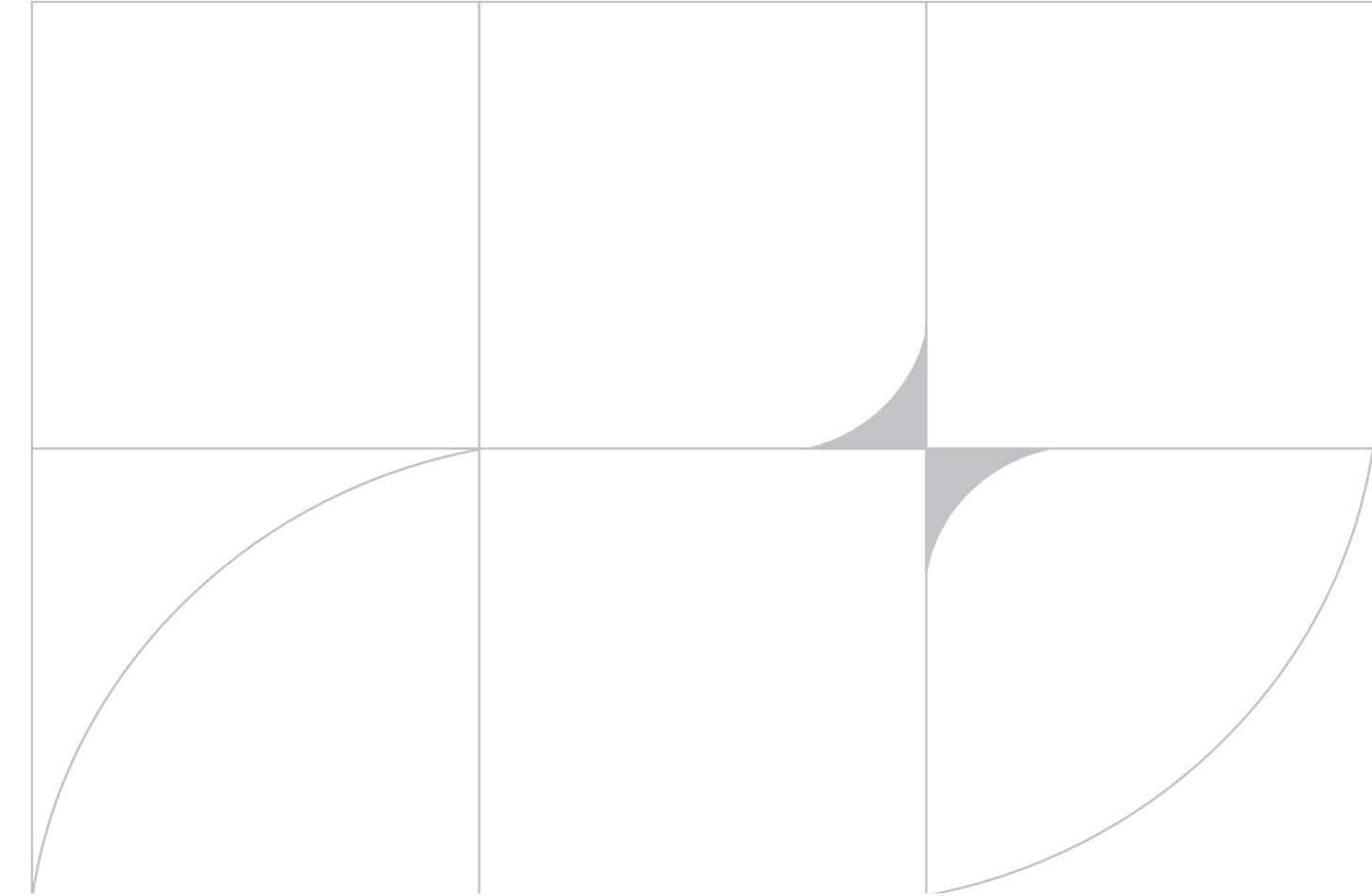
- Due to patented construction of the flow cell and propriety Dynamic Clustering algorithm Mythic 60 is enable to differentiate WBCs accurately even **after 24 hours** from blood collection.
- Use of blue wavelength, in conjunction with OnlyOne lytic reagent, enhances recognition of basophiles and allows to deliver **true 5-diff results** with measurement in one optical channel.
- Optical and impedance measurement can be performed with one dilution for **less reagent** consumption, **faster measurement** and more **accurate results**.
- All alignments are the same as in Mythic 22. Whole procedure can be made with same tools and calibration materials (WBC latex and G-CAL). **No extra cost** of spare parts and storage. Low time consuming procedure.



# MYTHIC 60

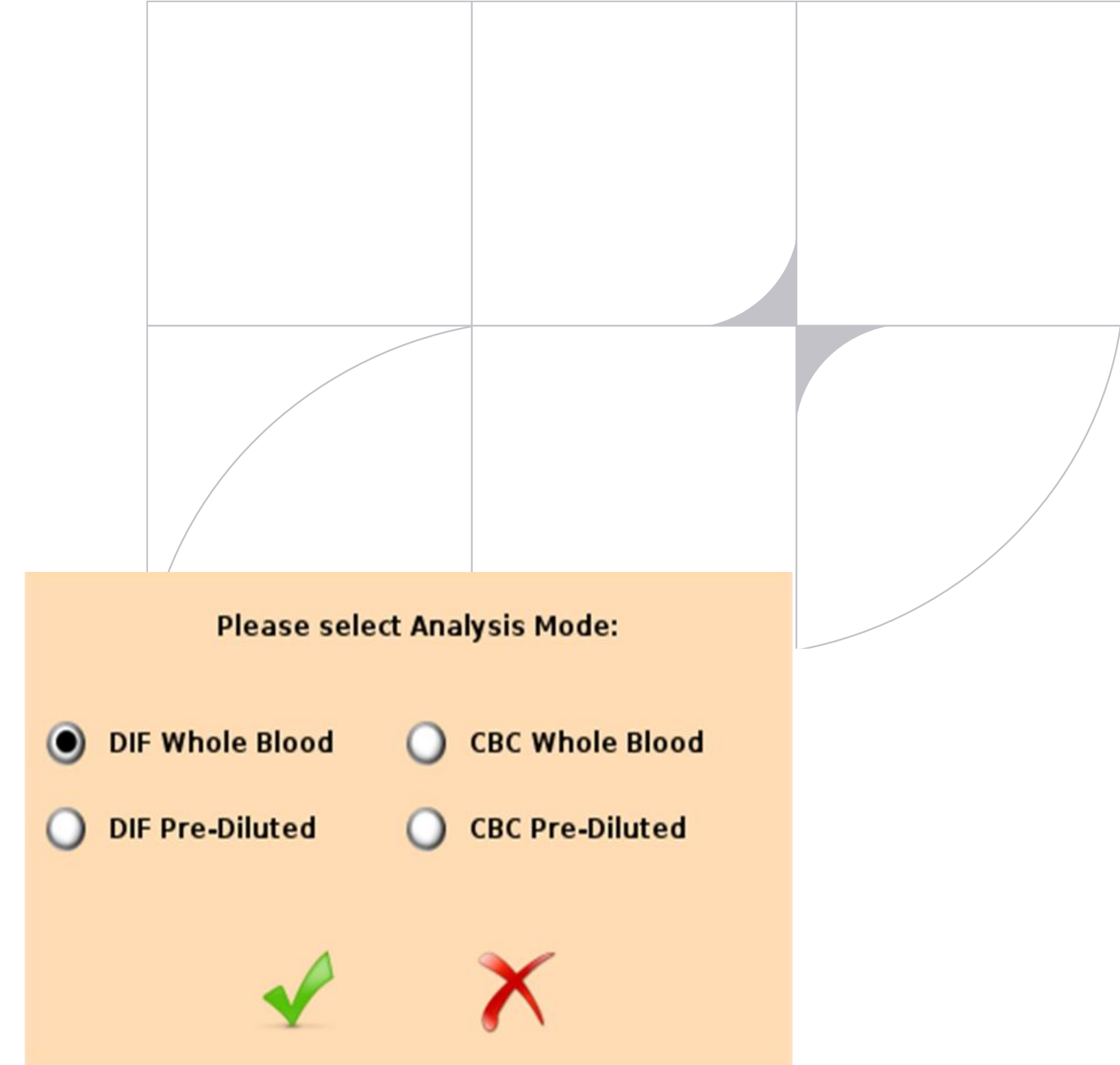
## Dynamic Clustering

- Automatically defines the cell populations areas at each run.
- Individualized results for each patient.
- The algorithm uses successive statistical analysis to compare the coordinates of elements and define the populations thresholds.
- Dynamic Clustering for WBC differentiation and improved flagging diagram help in diagnosing problematic oncology and hematology samples. Diseases can be recognize faster in more precise manner and risk of misdiagnosis decrease significantly.
- Challenging samples, 24 hours after collection.



## MYTHIC 60 Predilution Mode

- New sampling modes: Pre-diluted Blood Dif (DIF PD) + Pre-diluted Blood CBC (CBC PD).
- Faster preparation of prediluted samples due to automatic doze of diluent from a sampling needle.



# MYTHIC 60 Less Maintenance

- Tubbing connections patented solution.
- Lifetime tubing.
- New flowcell design.
- New chambers design.
- Separation fluidic and electrical parts.

		Startup	Shutdown	Flush Cleaning	Pistons greasing	Needle O-ring replacement	Motor screw greasing
Daily	U	→	→				
Weekly				→			
Semi annually					→		
Annually						→	→

- # tests countdown for maintenance actions. Flush cleaning every 5 days or every 200 samples



# MYTHIC 60



EXCELLENT  
PERFORMANCE

FAST  
PAYBACK

SMALL  
FOOTPRINT

MORE  
PROFIT

WIDE  
RANGE OF  
CUSTOMERS

COMPETTIVE  
OFFER

# TRUE 5-DIFF Technology

# MYTHIC 18 vs MYTHIC X

Modern Design & More Capabilities

AVAILABLE Q2 2022



## Features

### Mythic 18

### Mythic X

Features	Mythic 18	Mythic X
Technology	Hydrofocusing Free Optical Flow Cytometry,	Hydrofocusing Free Optical Flow Cytometry,
Throughput	60	60
Sample volume	10,0 µl	10,0 µl
Parameters	20	24
Size	250 x 340 x 350 mm (W x D x H), 9 kg	406 x 275x 415 mm (W x D x H), 18 kg
Reagents	3	3
Touchscreen	5,7 inch	10,4 inch
Prediluted Mode	No	Yes and capillary whole blood
Internal Memory	1.500 results	100.000 results
Thermal printer	No	built in
LIS connection	one way	bi-directional
Reagent ID	barcode	RFID technology and barcode

## MYTHIC 18 vs MYTHIC 3 CRP

Modern Design & More Capabilities

AVAILABLE Q2 2022



Feature	Mythic 18	Mythic 3CRP
Technology	Impedance, Spectrophotometry	Impedance, Spectrophotometry, Latex Immune Nephelometry
Throughput	60	60/45 (CRP)
Sample volume	9,6 µl	20 µl
Parameters	20	22
Prediluted Mode	No	Yes
Reagents	3	2
Built-in thermal printer	No	Yes
Connection	RS232	HL7
Touchscreen	5,7 inch	10,4 inch
Internal Memory	1.500 results	50.000 results



<b>Technology</b>	<b>Flow cytometry and Multi Angel Scatter Separation</b>
<b>Throughput</b>	<b>90 /h30 /h BodyFluid</b>
<b>Parameters</b>	<b>49 parameters(14 RUO, 7 BF) WBC, LYM%, MON%, NEU%, EOS%, BASO%, LYM#, MON#, NEU#, EOS#, BASO#, RBC, HGB, RETIC_ABS, RETIC%, IRF, HCT, MCV, MCH, MCHC, RDW_CV, RDW_SD, PLT, MPV, PDW, PCT, P_LCC, P_LCR, ALY#, ALY%, LIC#, LIC%, NRBC%, BLAST%, NRBC#, BLAST#, InR#, InR%</b>
<b>Sample volume blood</b>	<b>20uL</b>
<b>Sample volume BF</b>	<b>75uL</b>
<b>Linearity</b>	<b>WBC 0 - 400 x 10<sup>9</sup>/L RBC 0 - 8.60 x 10<sup>12</sup>/L HGB 0 - 300 g/L PLT 0 - 5 000 x 10<sup>9</sup>/L</b>
<b>Operation mode</b>	<b>CBC, CBC+DIFF, CBC+DIFF+RET, RET</b>
<b>No of reagents</b>	<b>4 reagents , 1 lyse</b>
<b>Autoloader</b>	<b>Autoloader for 50 samples</b>
<b>Internal Memory</b>	<b>500.000 Samples</b>

**AVAILABLE Q2 2022**





THANK  
YOU

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of satisfied customers

# Certificate of Approval

This is to certify that the Management System of:

## Orphée S.A.

chemin du Champ-des-Filles 19, 1228 Plan-Les-Ouates Geneva, Switzerland

has been approved by Lloyd's Register to the following standards:

**ISO 13485:2016, ISO 9001:2015**

Approval number(s): ISO 13485 – 0053001-001, ISO 9001 – 0053000-005

This certificate forms part of the approval identified by approval number: 0053001/0053000

**The scope of this approval is applicable to:**

Production and distribution of in vitro diagnostic reagents for in vitro diagnostics for medical, industrial and scientific laboratories and sales and maintenance of in vitro diagnostic medical devices.



**Paul Graaf**

Chief Operating Officer, Management Systems, MSIS

Issued by: Lloyd's Register Quality Assurance Limited

