

- To: Engineering Team
- From: Paul Proudy
- Re: Welcome to Parck

Dear Transition Team:

Jan Johanson, VP of Business Development for Essex, asked me to provide information and guidance related to the engineering function at Parck. I have attached a number of documents that will help you begin to understand the product and its performance characteristics. Those documents are as follows:

- 1. <u>Technical Paper</u> A technical paper presented at the ASME convention describing how to calculate the performance of any TTBA.
- 2. <u>Engineering Drawings for the R50</u> A set of engineering drawings for our R50 TTBA. These drawings include options for components and their associated performance criteria.
- 3. <u>Design Data Manual</u> Parck's own details regarding specific elements of the performance calculation for the R50.

In your initial research, I suggest you attempt to answer the following questions:

- 1. How does the R50 work? What are the basic parts and what are their functions?
- 2. What are the current values of the main CTQs of the R50 (accuracy, functionality, processing time, and reliability)?
- 3. What NPIs do you envision hitting the factory during the next year?

I hope this information is helpful.

Sincerely,

Paul Poudy

Paul Proudy, Manager of Engineering

Performance Calculations for Top Blood Analyzers

presented at the ASME annual meeting Orlando, FL; August 2014

A tabletop blood analyzer (TTBA) is a diagnostic instrument designed to identify indicators in a patient's blood (e.g. uric acid, potassium, carbon dioxide, etc.) Until the late 1990s, these tests were performed by large machines only available in medical labs. Much simpler tabletop blood analyzers were made possible by two key enabling technologies: a patented combination of chemical reagents and a light sensitive conductive optical coating. Mixing reagents with a blood sample results in extremely small color variations that can be detected by the light sensitive coating. These materials were developed by research scientists at Harvard during the early 1990s. In addition to reagents and coating, TTBAs were made possible by a specialized light source, a multi-chambered spinning rotor, a precision index positioning motor, and patented signal processing algorithms. The combination of these technological innovations allow the TTBA to resolve a tremendous amount of data very quickly, providing blood analysis in a fraction of the time it would take if sent to a lab.

Harvard chose to license its innovations in 1999. Saluki Medical of Sunnyvale, CA was the first company to develop a product based on the work at Harvard and introduced the first TTBA in 2001. The Saluki unit was about the size of a large toaster oven, performed many of the tests of the larger units, and gave doctors and small labs the ability to perform rapid blood analysis. Since then, a number of manufacturers of larger blood analyzers introduced their own version of the tabletop unit. However, competition in this market space became quite heated during the 90's and today only four major companies remain.



Figure 1 Schematic of Tabletop Blood Analyzer

How it Works

Figure 1 is a schematic of a typical TTBA. It is composed of eight basic components: a high speed rotor, power supply, drive motor, detector, cooling coils, coolant pump and tank, electronic processing unit (EPU), and light source.

The fundamental principles of operation are relatively simple. A few drops of the patient's blood are placed in the center of the rotor that is spun up to 2,000 rpm. Centrifugal force distributes the blood into the 24 small chambers in the rotor, which contain previously loaded chemical reagents.

As the blood interacts with the unique reagent formulation in each chamber it changes color. An intense light is shown through the blood and reflected by small mirrors in the rotor cap onto an optically sensitive detector. The electrical conductivity of the specialized detector coating is changed slightly as reflected light from the multiple rotor chambers pass across the surface of the detector. The slight changes in conductivity are measured and processed by the electronic processing unit that combines signal processing circuits with detection algorithms. Light shines through several chambers at the same time, and by taking multiple samples, with a precisely indexed rotor position, the EPU is able to synthesize precise chemical compositions in each of the chambers. Special cooling is provided to the detector to enhance the optical sensitivity of the coating and allow for faster processing times. Although the basic underlying technology is shared by all competitors, each company differentiates their product by how they apply adjacent technologies in support of the basic reagent and conductive coating technology.

Performance Criteria

Tabletop blood analyzers were originally used in doctors' offices and small independent laboratories, but today Hospitals and larger labs are purchasing TTBAs. These analyzers allow quick and cheap point-of-care analysis of a patient's blood, avoiding a long wait and expense to transport a sample to a large lab. For tabletop blood analyzers, there are four basic performance criteria important to the doctor and/or lab technician.

- **Processing Time.** Most commercial units process samples in the 16-22 minute range. Speed of processing has obvious benefits for the doctor or lab. The current design of TTBAs provide a processing time of approximately 20 minutes.
- **Functionality.** Functionality refers to the number of tests performed by the analyzer. All tabletop blood analyzers have a rotor with 24 test chambers. However, through clever signal processing, additional readings can be taken by combining readings from the chemical reaction in multiple chambers. With a more sophisticated processors, current technology

allows a TTBA to offer functionality of up to 150 tests. At present most TTBAs in the market only perform 24 tests.

- Accuracy. Obviously an important feature, accuracy refers to the number of misdiagnosis per million tests. Because of variability in human blood chemistry, no unit has achieved an accuracy rating of 100%. Accuracy ratings for most commercial blood analyzers range from 280 to 300 errors per million tests (epm).
- **Reliability.** Reliability is a critical factor because downtime inconveniences patients and represents lost revenue for the doctor or lab. The number of failures measures blood analyzer reliability during 10,000 hours of operation. Measured in this way, reliability is determined by adding the failure rates of the various components as well as failures of the overall system. A failure rate of 13-15 fph*10⁴ is the current industry average. This is a critical measure of quality in the customer's eyes, and is an area of high variability in the industry.

Governing Design Equations

Designing a blood analyzer is principally a series of tradeoffs between processing time, functionality, accuracy, reliability, and cost. Of course manufacturing capability of critical components has to be factored into any design and performance calculation.

You will see in many of the equations that follow factors called "Manufacturing Losses." This reflects the variability of the manufacturing process and represents the difference between performance achieved by a single unit built by highly trained technicians in the lab versus typical performance achieved by thousands of units built in the factory. The following design equations govern the four performance measures of a tabletop blood analyzer:







Functionality

Functionality is defined rather than calculated. Designers decide how many tests they want the TTBA to perform and purchase an EPU with appropriate processing power and algorithms. Increasing functionality has a negative impact on both accuracy and processing time. These penalties can be seen in the performance equations for those performance criteria.



Manufacturing Losses:

TTBAs produced in the engineering lab perform noticeably better than those produced in the factory. This is normal for most products. However, for many firms in the TTBA Industry Manufacturing Losses have a significant negative effect on the performance of the analyzer. Estimated values for the various Manufacturing Losses are shown in the table below:

Factor	Tested Value
Processing Time	4 minutes
Accuracy	100 epm
Reliability	12 fph
Functionality	N/A

Power Considerations

In addition to design equations, engineers must account for overall power usage of the unit and specify an appropriate power supply. The primary users of power are the drive motor and the light source, with the coolant pump requiring the next largest electrical load. All components must be taken into consideration to avoid overloading the power supply. When power demands exceed the rating of the power supply, the unit will still function, but the life of the power supply is significantly decreased.

Rotor Sterilization

A key feature of the tabletop blood analyzer is a rotor that can be sterilized after each use. After each cycle (cycle = analysis of one patient's blood sample) the rotor is sterilized and reloaded with chemical reagents using a device designed specifically for this purpose and manufactured by Dow Chemical. After a blood test, the operator inserts the used rotor into the cleaner/loader, closes the lid, presses a button, and the rotor is washed and each channel is reloaded with reagents specified by TTBA manufacturer. Each line of Dow Chemical optical reagents consists of 24 different formulations so that each rotor channel is loaded with a unique reagent that highlights the blood sample differently. The entire clean/load process takes less than five minutes.

Detector Wear

Detector wear is an important design consideration for all blood analyzers. The chemical coating on the detector is relatively soft and friction caused by air driven by the spinning rotor wears away the coating. Coating wear is small, and not perceptible to the naked eye, but it affects the overall electrical conductivity of the detector and, therefore, test accuracy. At present detectors must be replaced after approximately 1000 hours of operation. For a typical customer this replacement occurs shortly after the unit is out of warranty. This is a key source of customer complaints, so much so that some firms are considering extending the warranty for detector replacement to two years at no cost to the customer.

Printer/Controller

An important component of the TTBA is the printer/controller. The printer/controller not only provides hardcopy of test results (an FDA requirement), it is the user interface with the TTBA (control buttons and LED screen) and, most importantly, controls the flow of information between the motor, detector, and EPU. The printer/controller is a second computer completing the overall system of information processing that allows the TTBA to perform blood tests.

Engineering Drawings Parck R50

Engineering Design Specification

Components and Settings

Product Name:	R50
Drive Motor	GE-50
EPU	EC-24-1
Coolant Pump	C1005
Coolant Tank	C156A
Power Supply	BC600
Chemical Reagents	D-220
Printer/Controller	BE3170
Tubing	Alloy 1602
Light Source	AS46-1
Detector Coating	SM-02X2
Coolant Velocity	5
Number of Tests	24
BPM	2,000
Coating Thickness	0.03125
Base Plate	BP33352
Support Dish	SD34532
Hardware	H-101

















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	-	Drive	Motors	T 1	
Name	Watts	IA	min rpm	Reliability	Cost
GE-50	200	1	2000	1.0	\$36
GE-53	200	3	2000	0.7	\$54
GE-57	250	5	1000	0.3	\$68
GE-78	300	10	1000	0.1	\$127
		rs supplied b	ov General		

	Powe	er Supply	
Name	Watts	Reliability	Cost
BC600	600	1.1	\$31
BC700	700	0.8	\$40
BC800	800	0.6	\$52
BC900	900	0.4	\$60
BCS600	600	0.3	\$77
BCS800	800	0.2	\$91
BCS1000	1000	0.1	\$105
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D - 220 32.8 0.1153 \$5.01 D - 230 36.9 0.1267 \$6.53 D - 300 41.7 0.1345 \$7.85 5000S 52.3 0.1023 \$12.13 Do not specify without prior approval of manager of engineering. Do not specify without prior approval of manager of engineering.	Series #	Sensitivity	Flow Coeficient	Cost**	
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Chemical (203) 712-4435. **Cost is for 3.4 fl. oz. (24 tests) Chemical Reagent Specification SI Drawn by: RM Issued: 6/6				100	

		1/4"	Tubing	
	Material	Cost per foot	Tensil Strength	Cost per TTBA (5 feet)
	Alloy 1602	\$3.00	101	\$15.00
	Alloy 1807	\$5.00	78	\$25.00
	Alloy 261H5	\$12.00	68	\$60.00
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iviodel	Output	Reliability	Watts	Price
AS46-1	5600	0.8	100	<u> </u>
AS46-2	6000	0.8	200	ig fe
AS46-3	6400	0.8	300	urcir
AS47-1	5600	0.5	50	- Sou Pric
AS47-2	6000	0.5	150	lusul†
AS47-3	6400	0.5	250	Cor
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Announcing Dow Chemical's New Optical Reagent Line

Take a look at our new families of optical reagent chemicals. Cheaper, faster, and more reliable. See back for specific sensitivities and flow coefficients.



Dow's Nev	Dow's New Reagents (adjusted 3.4 fl. Oz.)								
D1	28.3	0.1168	\$3.23						
D2	30.2	0.1168	\$4.32						
D3	31.5	0.1168	\$4.78						
D4	34.1	0.1201	\$5.25						
D5	36.1	0.1201	\$6.53						
D6	38.5	0.1201	\$6.99						
D7	40.1	0.1201	\$7.12						
D8	44.6	0.1257	\$8.02						
D9	47.0	0.1257	\$10.45						
D10	50.2	0.1257	\$11.00						
D11	52.9	0.1257	\$12.16						
D12	61.9	0.1298	\$13.44						
D13	65.3	0.1298	\$14.32						
D14	69.4	0.1298	\$15.67						
D15	72.6	0.1298	\$16.54						

Note: All reagents guaranteed to perform at or above spec on a 99.995% RRS test.

Dow Chemical welcomes all questions and inquiries. You can reach a technical sales representative at (201) 546-8724.

Engineering Design Data

(R50 Design Data)

Parck R50 Design Data version 1.5; 4/1/2015

Engineering Design Data

Contents

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Heat Transfer Coeficients for Various Cooling Coil Materials



Rev 32; 4/8/99

Calculation of Detector Temperature based on Cooling Coil Heat Transfer

Heat transfer of cooling coils touching the Detector is governeed by the following equation:

$$q = h*A*(T_1-T_0)$$
 (equation 1)

Where,

q = detector heat load (W) h = overall heat transfer coefficient (W/m² $^{\circ}$ C) A = total outside area of tubing (m²) T₁ = Detector Temp ($^{\circ}$ C)

Knowing that the typical heat load generated by the detector is 5 Watts, and that coolant temp after leaving the expansion orifice is 0° C, and that only half of the coils actually contact the detector we develop the equation:

 $T_0 = Coolant temperature (°C)$

$$T_1 = q/(h^*(A/2)) + T_0$$
 (equation 2)

With this equation, design temperature for the detector is obtained by varying the area (number of loops of cooling coils) and/or the convective heat transfer coefficient (by adjusting coolant velocity and/or material selection).

<u>Note</u>: Area of cooling coils is 48 square inches. Convert this to square meters for use in equations. <u>Note</u>: As coolant velocity increases, power utilization of the pump increases. Consult sheet 5 of Design Data when making changes to coolant velocities. For heat transfer coefficients, consult Design Data, sheet 3.

Rev 18; 2/5/00

Power Usage of Coolant Pump



Rev 3; 1/9/01

Optical Factors and Costs for Available Detector Coatings**

Optical Coatings Strong Materials								
Coating	Optical Factor	Hardness	Maleability					
SM-O2X2	900	80	2					
SM-O2X4	1500	120	4					

* Optical Factor Units = $(deci-volts)^{\circ}(C)(inches^{1/4})$ /lume:

*Coatings supplied by the Strong Materials Co.

Rev 17; 4/23/00

Parck R50 Design Data version 1.5; 4/1/2015

Experience Curve Cooling Coil Reliability vs. Coolant Velocity*



*Note: Only one test has been performed at 20 m/s. Reliability was 5 fph*10^4 $\,$

Rev 2; 10/9/99

Design Specs for the R50 Blood Analyzer

The following are design specs for our R50 Blood Analyzer:

Light Source: Avery Schwartz AS46-1 Power Source: Barrett-Craft model BC600 EPU Power Usage: 9.6 Watts Optical Coating: O_2X_2 Coating Thickness: .03125" Cooling Coil Material: Alloy 1602 Cooling Coil Tube Diameter: 1/4" Number of Cooling Coil turns: 6 Coolant Velocity: 5 m/s

Rev 39; 1/12/02



Reaction Time for Chemical Reagents

Time Calculation:

Time (minutes) = (32.5/X) + Flow Coefficient*5.23

Rev 12; 3/12/01



Rev 11; 3/2/00



Rev 2; 5/18/2013



Mfg. Variability Factor vs. Standard Deviation of Coating Thickness

Rev 6; 5/12/99



Experience Curves to analyze Detector Life Effects of Detector Coating Wear on R50 Accuracy

Rev 1; 2/3/01



Test Penalty Factor (effect on accuracy)

Rev 1, 3/12/00