

# Comparative Study of the Instrument Robustness of Automated Blood Culture Devices: BD BACTEC™ versus bioMérieux BacT/Alert™

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## ABSTRACT

Instrument robustness of the Becton Dickinson (Sparks, MD) BACTEC™ and the bioMérieux (Durham, NC) BacT/Alert™ automated blood culture devices was assessed by interviewing 278 laboratory managers and senior lab technicians in 5 European countries over a period of less than one month. The main question was “When was the last time you had to call the company for a repair or technical problem (not including normal maintenance).” 101 or 36,3% of the interviewees reported at least one technical intervention since the year of installation of their device. Specific attention was paid to comparability of the test population for both systems. Based on these data it can be concluded that the BacT/Alert™ device requires significantly more interventions than the BD BACTEC™ device. Also the time since last call to the supplier for a technical intervention was significantly shorter for the BacT/Alert™ device than for the BACTEC™ device. When intervention was needed the BacT/Alert™ device was “completely down” just as much time as the BACTEC™ device. The most common problems with automated blood culture devices are hardware related. However, these problems have little impact on patient care because of the availability of back-up and data-retrieval systems.

**KEY WORDS:** Instrument robustness, BACTEC™, BacT/ALERT™

## INTRODUCTION

Bloodstream infections (BSIs) cause substantial morbidity and mortality, with up to one quarter of affected patients dying as a result of their infection.<sup>1,2</sup> On the basis of data from death certificates, these infections are the 10th leading cause of death in the United States,<sup>5</sup> and the age-adjusted death rate has risen by 78% over the past 2 decades.<sup>6</sup> The rapid and reliable detection of bloodstream infections, including characterization of the bacterial microorganism to the species level and determination of its susceptibility pattern, is one of the most important tasks of clinical biologists.<sup>4</sup>

Prompt detection of bloodstream infection, accurate microbial identification and susceptibility testing, and appropriate reporting of results are also important patient care contributors.<sup>3</sup> Over the past decade, developments in blood culturing techniques have resulted in improved detection of bloodstream infections. These developments have included refinements in both blood culture media and detection methods.<sup>7,8</sup> Over the last decades, automated systems capable of monitoring microbial growth in a continuous manner have become available. Among these, the BacT/Alert™ and the BACTEC™ are widely employed.<sup>9</sup> In addition to other types of blood culture bottles, the BACTEC™ system offers bottles supplemented with resin particles capable of counteracting the activity of antimicrobial drugs that frequently (28-63%)<sup>1</sup> are administered to patients before blood culturing. BacT/Alert™ media are supplemented with activated charcoal and Fuller's earth. Both systems are designed to monitor the growth of organisms as a function of metabolic CO<sub>2</sub> production. To this end, the BacT/Alert™ uses a colorimetric sensor and the BACTEC™ a fluorimetric one.<sup>9</sup>

Most publications on blood culture systems look at differences in biological performance between blood culture devices, mostly focusing on Time-to-Detection (TTD) and recovery of bacteria as the main criteria.<sup>9, 10, 11</sup> One study has been done on the effects of rapid detection of bloodstream infections on the length of hospitalization and hospital charges.<sup>12</sup> However, none have considered the technical reliability of the instruments which can impact lab workflow, overall cost and time to report and as such, patient outcome. This study evaluates the instrument robustness of BACTEC™ and BacT/Alert™ automated blood culture devices and its impact on the sample used, the results reporting and the patient.

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## METHODS

**Study Design.** During the month of September 2006, 350 laboratory managers and senior lab technicians in 6 major European countries (Belgium, The Netherlands, France, UK, Germany and Italy) were asked to participate in this study. As a first screening criterion all respondents had to be lab managers. Secondly, the respondents were asked which kind of automated instrument they use to process blood cultures. Since the goal of this study is to compare BACTEC™ to BacT/Alert™, only users of these instruments\* were retained from the original sample. Total sample size of this study is 278 respondents (response rate of 79%).

The respondents were contacted by telephone and addressed in their native language. Each interview took approximately 5 to 10 minutes. In order to obtain reliable conclusions on the differences between both instrument brands, both samples were made as comparable as possible. The age of the instrument (year of installation)

and the number of vials processed through the instrument were used as indicators to assess comparability between groups.

**Assessment of Robustness.** Assessment of robustness was done by registering/analyzing the last and second last time the lab manager and lab technicians had to call the instrument supplier for a technical intervention, excluding normal maintenance visits. Secondly, the lab manager was asked if the instrument was “completely down” (unable to continue working). Finally, the impact of down-time of the instrument was assessed by examining the consequences of technical failure with respect to the blood culture sample used, the reporting of the results and the patient.

\*BACTEC™ (BD), BacT/Alert™ or Classic BTA™ (bioMérieux) and BacT/Alert 3D™ or BTA 3D™ (bioMérieux)

## DATA-ANALYSIS & RESULTS

**Quantitative Synthesis.** All statistical significance tests are performed in SPSS under the conditions of  $\alpha = .05$ , power level = .80 and a medium effect size (Chi-square:  $w=.3$ ; T-test:  $d=.5$ ). The chosen standards for the power level and effect size are based on the recommendations of Cohen.<sup>13,14</sup>

In total, the sample consisted of 176 BACTEC™ users (63,3%) and 102 BacT/Alert™ users (36,7%). 62,3% were laboratory managers in public non-academic hospitals, 21,8% in public academic hospitals and 15,9% in private labs. Table 1 gives an overview per country of the distribution of BD BACTEC™ and bioMérieux BacT/Alert™ users who participated in this study.

Table 1. Average number of blood culture vials and average year of installation of the automated blood culture devices in this study.

Country		Blood culture vials		Year of installation		
		Number of respondents	Mean	Standard Error of Mean	Mean	Standard Error of Mean
Benelux	BD	29	5708,80	663,46	1999,48	,81
	bioMérieux	16	8390,00	1909,10	2002,13	,82
France	BD	38	7607,89	1304,95	1998,00	,61
	bioMérieux	22	13614,55	3739,58	2001,59	,71
Germany	BD	49	5102,38	897,09	1999,17	,52
	bioMérieux	8	3525,00	1054,65	2003,14	1,16
Italy	BD	42	5625,50	1885,76	2001,24	,47
	bioMérieux	32	4801,20	1959,16	2002,72	,32
UK	BD	18	12411,11	2822,33	2001,83	,60
	bioMérieux	24	10811,75	1276,38	2002,38	,65

The average number of blood culture vials tested per year for the BACTEC™ devices is 7518, while for the BacT/Alert™ it is 10384. After performing a t-test, no significant difference was found between both averages ( $t = -1,954$  with  $p = 0,052$ ). For nuanced interpretation of these numbers, it should be taken into account that 81,4% of the bioMérieux users in this study apply the BacT/Alert 3D™ device which can process high quantities of vials at once, which explains the higher (though not significantly) number of vials tested per year. Moreover, when looking at the average number of vials tested since the installation of the devices, both brands are very comparable. This was evaluated by multiplying the number of vials tested per year by the age of the device ( $t = 0,178$  with  $p = 0,859$ ).

Regarding the year of installation of the studied instruments, the average age of a BD BACTEC™ device in this study is about 7 years with a range from 1991 to 2006. For a BacT/Alert™ device the average age is about 4 years with a range from 1993 to 2006.

A t-test shows a statistically significant difference ( $t = - 5,979$  with  $p = 0,000$ ). In this study, the BacT/Alert™ devices are more recently installed than the BACTEC™ devices.

Based on the question “When was the last time you had to call the company for a repair or technical problem?” it can be inferred if a certain instrument ever had any technical failure. This resulted in a binominal score, being “yes” or “no”. Out of the 176 BACTEC™ users, 111 (or 63,1%) reported that they had never experienced any technical failure since the installation of the device, while 47 (or 46,1%) of the 102 BacT/Alert™ users reported no technical failure. Using a Chi-square test comparing both observed frequencies it can be concluded that lab managers need significantly more technical interventions for bioMérieux devices than for the BD devices ( $\chi^2=7,598$  with  $p=0,006$ ).

Secondly, 120 respondents (= 43,2%) reported at least one technical failure since the year of installation of their device. Table 2 shows the incidence of technical failure per country, brand and age category of the devices.

Table 2. Incidence of technical failure for the BD BACTEC™ and the bioMérieux BacT/Alert™ device per age category.

Country	Device	Age category											
		< 3 years				3-6 years				> 6 years			
		Ever had any problems?				Ever had any problems?				Ever had any problems?			
		No		Yes		No		Yes		No		Yes	
Count	Row N %	Count	Row N %	Count	Row N %	Count	Row N %	Count	Row N %	Count	Row N %		
Benelux	BD	8	100,0%	0	,0%	4	50,0%	4	50,0%	10	76,9%	3	23,1%
	bioMérieux	5	71,4%	2	28,6%	1	20,0%	4	80,0%	1	25,0%	3	75,0%
France	BD	2	66,7%	1	33,3%	4	40,0%	6	60,0%	21	84,0%	4	16,0%
	bioMérieux	4	50,0%	4	50,0%	5	62,5%	3	37,5%	3	50,0%	3	50,0%
Germany	BD	5	100,0%	0	,0%	15	93,8%	1	6,3%	18	90,0%	2	10,0%
	bioMérieux	4	100,0%	0	,0%	1	50,0%	1	50,0%	1	100,0%	0	,0%
Italy	BD	5	45,5%	6	54,5%	6	30,0%	14	70,0%	1	9,1%	10	90,9%
	bioMérieux	5	50,0%	5	50,0%	8	38,1%	13	61,9%	1	100,0%	0	,0%
UK	BD	1	16,7%	5	83,3%	3	33,3%	6	66,7%	0	,0%	3	100,0%
	bioMérieux	5	45,5%	6	54,5%	1	11,1%	8	88,9%	1	25,0%	3	75,0%
Total	BD	21	63,6%	12	36,4%	32	50,8%	31	49,2%	50	69,4%	22	30,6%
	bioMérieux	23	57,5%	17	42,5%	16	35,6%	29	64,4%	7	43,8%	9	56,3%

To assess the difference in mean time since the last and second last intervention between BD and bioMérieux automated blood culture devices, a t-test on independent samples was performed. Average time since last call for BACTEC™ was 363 days, while for BacT/Alert™ it was 203 days. This is a difference of 160 days. Again, a significant difference was found in favor of BD BACTEC™ (t= 2,586 with p= 0,011). To conclude, BD BACTEC™ needs fewer technical interventions than the bioMérieux BacT/Alert™. Regarding to the time to the second last call, average time lapsed for BACTEC™ was 639 days while for BacT/Alert™ it was 383 days. Even though this suggests an advantage for BACTEC™, there were not enough data points to conclude a significant difference.

Thirdly, this study also focused on the difference between BD and bioMérieux regarding the question as to whether the device was completely down when a technical failure occurred. In 7,3% of the cases the BacT/Alert™ was completely down, while for BACTEC™ this was in 14,7% of the occasions. However, after performing a Chi-square test, the difference between both brands cannot be presumed as significant (x²=1,666 with p=0,197). If you take into account the less frequent interventions for the BACTEC™ system (only 37.9% of laboratories versus 53.9% for the BacT/Alert™ system), the overall percentage of cases where a system was completely down was quite comparable for both systems.

**Qualitative Synthesis.** Most of the technical failures are hardware related, both for BACTEC™ and for BacT/Alert™. Software related problems occur approximately half as often. Practically all these failures are quickly fixed and have minor impact on the workflow process. Hardware failures are commonly related to the screen of the device, to the bearings or racks of the device and other small replacements (e.g. barcode reader, power surge, battery, etc.). Software problems mostly cause data-processing flaws, which have minor impact on the system because of the quick repair, professional support and basic robustness of these devices.

Generally speaking, technical failures have a marginal impact on the blood culture sample taken, the reporting of results and the patient. Regarding the sample, subcultures are used within the same device after repair, or another blood culture device is applied. In 2 cases of the 120 respondents who actually had at least one technical failure since the installation of their device, detection of false positives was reported. Only 7 cases mentioned a longer time to result. Impact on the patient seems limited. When respondents reported no impact, they were asked why they called the supplier. Answers to this question were very straight forward. Any minor problem is very quickly repaired by both suppliers. There is rapid intervention, good follow-up and regular maintenance visits. Because both devices are provided with emergency batteries and back-up systems, acquired data rarely gets lost.

### CONCLUSION

- This study shows that the BD BACTEC™ device requires fewer technical interventions than the bioMérieux BacT/Alert™ device. Moreover, the BD BACTEC™ devices in this study were significantly older than the BacT/Alert™ devices, which possibly endorses this conclusion even more. Technical failure is mainly associated with hardware problems, which get repaired very quickly. However each technical failure will have some impact on the lab workflow. For those laboratories that do not have a full service contract which covers all needed interventions, there can also be a financial cost associated with the repair of the system. The impact of technical failure on the patient sample, the reporting of results and on the patient seems to be minor.

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