



BD Phoenix™ Update Data (PUD)
V6.91A Ex-US (Non-FDA) Release Notes
BALTRN0038(42) April 2021

Dear Customer:

The April 2021 update to the BD Phoenix™ Update Data (PUD) V6.91A provides system enhancements and/or modifications, as outlined in this document. Release notes for previous PUD releases are available at bd.com/e-labeling, key code BALTRN0038.

Instructions for use are available at bd.com/e-labeling:

- BD Phoenix™ M50 System User's Manual: 443575
- BD Phoenix™ 100 System User's Manual: 448021
- BDXpert System User's Manual: L009740, L009741

Summary of Changes

This update affects the following:

BD Phoenix™ and BD EpiCenter™ Systems for PUD V6.91A:

- [Attachment A: Phoenix Panel Format Additions](#)
- [Attachment B: Bruker MALDI Library Updates](#)
- [Attachment C: AST Reporting](#)
- [Attachment D: Organism Taxonomy Updates](#)
- [Attachment E: Organism Group Updates](#)
- [Attachment F: Organism Subgroup Updates](#)
- [Attachment G: BDXpert Updates](#)

Attachment A: Phoenix Panel Format Additions

The following BD Phoenix™ panel formats have been added to the PUD. These panel formats are also available through the installation of Panel Configuration Disk V725.

Catalog No.	Type	Panel Name	Format	CPO detect*	Standard	Minimum Required PUD
449485	GN	NMIC-472	EMERGE	CPO 9-well	EUCAST	V6.51A
449562	GN	NMIC-473	EMERGE	CPO 9-well	EUCAST	V6.51A
449569	GP	PMIC/ID-601	ID/AST	N/A	EUCAST	V5.71A
449726	GP	PMIC-601	AST	N/A	EUCAST	V5.71A
449580	GN	UNMIC/ID-471	ID/AST	CPO 6-well	EUCAST	V6.21A
449600	GN	UNMIC-471	AST	CPO 6-well	EUCAST	V6.21A
449724	GN	NMIC/ID-470	ID/AST	CPO 9-well	EUCAST	V6.31A
449723	GN	NMIC-470	AST	CPO 9-well	EUCAST	V6.31A

* **CPO 2-well:** panel contains substrates for detecting the presence of carbapenemase. No class determination is made.

* **CPO 6-well:** panel contains substrates for detecting the presence of carbapenemase plus additional substrates for determination of the Ambler class for *Enterobacteriales* isolates.

* **CPO 9-well:** panel contains substrates for detecting the presence of carbapenemase plus additional substrates for determination of the Ambler class for *Enterobacteriales*, *Acinetobacter baumannii* and *Pseudomonas aeruginosa* isolates.

Attachment B: Bruker MALDI Library Updates

The Mapping Table in the BD EpiCenter™ System has been updated to support the latest Non-FDA Bruker MALDI Reference Libraries as detailed below:

- MBT Compass (RUO) Library - Rev L (9607 MSP)
- MBT IVD Library - Rev K (9468 MSP)

Attachment C: AST Reporting

Reporting of AST results for *Acinetobacter* spp., *Pantoea* spp., *Shewanella* spp., *Sphingomonas* spp., *Staphylococcus* spp., and *Streptococcus* spp. includes the following additional species:

Organism Species
<i>Acinetobacter colistiniresistens</i>
<i>Acinetobacter pseudolwoffii</i>
<i>Pantoea brenneri</i>
<i>Pantoea conspicua</i>
<i>Pantoea eucrina</i>
<i>Shewanella xiamenensis</i>
<i>Sphingomonas aerolata</i>
<i>Staphylococcus massiliensis</i>
<i>Streptococcus thoralensis</i>

Attachment D: Organism Taxonomy Updates

Several BD EpiCenter-only organisms have been added to the BD EpiCenter™ System in support of MALDI. Additionally existing organism names within the BD Phoenix™/BD EpiCenter™ Systems have been updated as listed below. Note that the organism abbreviations have been updated to align with the current organism names.

Previous Organism Name	Previous Abbrev.	Current Organism Name	Current Abbrev.	System
<i>Actinomyces canis</i>	ACTMCAN	<i>Schaalia canis</i>	SCHACAN	Epi
<i>Actinomyces cardiffensis</i>	ACTMCAR	<i>Schaalia cardiffensis</i>	SCHACAR	Epi
<i>Actinomyces hominis</i>	ACTMHOM	<i>Gleimia hominis</i>	GLEHOM	Epi
<i>Actinomyces hongkongensis</i>	ACTMHON	<i>Pauljensenia hongkongensis</i>	PAULHON	Epi
<i>Actinomyces hordeovulneris</i>	ACTMHOR	<i>Buchananella hordeovulneris</i>	BUCHHOR	Epi
<i>Arthrobacter cumminsii</i>	ARTCUM	<i>Pseudoglutamicibacter cumminsii</i>	PSEGLCUM	Epi
<i>Atopobium parvulum</i>	ATOPAR	<i>Lancefieldella parvula</i>	LANPAR	Epi
<i>Atopobium rimae</i>	LACBRIM	<i>Lancefieldella rimae</i>	LANRIM	Epi
<i>Atopobium vaginae</i>	ATOVAG	<i>Fannyhessea vaginae</i>	FANVAG	Epi
<i>Aurantimonas altamirensis</i>	AURAALT	<i>Aureimonas altamirensis</i>	AUREALT	Epi
<i>Bacillus pasteurii</i>	BACIPAS	<i>Sporosarcina pasteurii</i>	SPOSPAS	Epi
<i>Candida catenulata</i>	CANCAT	<i>Diutina catenulata</i>	DIUCAT	Phx/Epi
<i>Candida ernobii</i>	CANERN	<i>Nakazawaea ernobii</i>	NAKERN	Epi
<i>Candida magnoliae</i>	CANMAG	<i>Starmarella magnoliae</i>	STARMAG	Phx/Epi
<i>Candida norvegensis</i>	CANNOR	<i>Pichia norvegensis</i>	PICNOR	Phx/Epi
<i>Candida pararugosa</i>	CANPARR	<i>Wickerhamiella pararugosa</i>	WICPARR	Phx/Epi
<i>Candida rugosa</i>	CANRUG	<i>Diutina rugosa</i>	DIURUG	Phx/Epi
<i>Candida tenuis</i>	CANTEN	<i>Yamadazyma tenuis</i>	YAMTEN	Epi
<i>Candida versatilis</i>	CANVER	<i>Wickerhamiella versatilis</i>	WICVER	Epi
<i>Clostridium aldenense</i>	CLOALD	<i>Enterocloster aldenensis</i>	ENTCLALD	Epi
<i>Cryptococcus albidus</i>	CRYALB	<i>Naganishia albida</i>	NAGALB	Phx/Epi
<i>Cryptococcus curvatus</i>	CRYCUR	<i>Cutaneotrichosporon curvatum</i>	CUTTCUR	Epi
<i>Cryptococcus diffluens</i>	CRYDIFF	<i>Naganishia diffluens</i>	NAGDIFF	Epi
<i>Cryptococcus laurentii</i>	CRYLAU	<i>Papiliotrema laurentii</i>	PAPLAU	Phx/Epi

Previous Organism Name	Previous Abbrev.	Current Organism Name	Current Abbrev.	System
<i>Cryptococcus terreus</i>	CRYTER	<i>Solicoccozyma terrea</i>	SOLITER	Phx/Epi
<i>Geotrichum clavatum</i>	GEOCLA	<i>Magnusiomyces clavatus</i>	MAGCLA	Epi
<i>Mycoplasma gallisepticum</i>	MYCPGAL	<i>Mycoplasma gallisepticum</i>	MYCDGAL	Epi
<i>Mycoplasma hominis</i>	MYCPHOM	<i>Metamycoplasma hominis</i>	METPHOM	Epi
<i>Pichia anomala</i>	HANANO	<i>Wickerhamomyces anomalus</i>	WICOANO	Epi
<i>Rhodotorula minuta</i>	RHOTMIN	<i>Cystobasidium minutum</i>	CYSBMIN	Phx/Epi
<i>Tatlockia maceachernii</i>	TATLMAC	<i>Legionella maceachernii</i>	LEGMAC	Epi
<i>Trichosporon cutaneum</i>	TRICUT	<i>Cutaneotrichosporon cutaneum</i>	CUTT CUT	Phx/Epi
<i>Trichosporon debeurmannianum</i>	TRIDEB	<i>Cutaneotrichosporon debeurmannianum</i>	CUTTDEB	Epi
<i>Trichosporon gracile</i>	TRIGRA	<i>Apiotrichum gracile</i>	APIGRA	Epi
<i>Trichosporon jirovecii</i>	TRIJIR	<i>Cutaneotrichosporon jirovecii</i>	CUTTJIR	Epi
<i>Trichosporon loubieri</i>	TRILOU	<i>Apiotrichum loubieri</i>	APILOU	Phx/Epi
<i>Trichosporon mucoides</i>	TRIMUC	<i>Cutaneotrichosporon mucoides</i>	CUTTMUC	Epi
<i>Trichosporon mucoides</i> group	TRIMUCGR	<i>Cutaneotrichosporon mucoides</i> group	CUTTMUCGR	Epi
<i>Trichosporon mycotoxinivorans</i>	TRIMYC	<i>Apiotrichum mycotoxinivorans</i>	APIMYC	Epi
<i>Yamadazyma guilliermondii</i>	YAMGUI	<i>Meyerozyma guilliermondii</i>	MEYGUI	Epi

Attachment E: Organism Group Updates

The organism group of the following organism species have been updated in the BD Phoenix™ and/or BD EpiCenter™ Systems.

Organism Species	Previous Group	Current Group	System
<i>Arcobacter butzleri</i>	–	Obligate anaerobe (ANA)	Epi
<i>Arcobacter cryaerophilus</i>	–	Obligate anaerobe (ANA)	Epi
<i>Arcobacter nitrofigilis</i>	–	Obligate anaerobe (ANA)	Epi
<i>Arcobacter skirrowii</i>	–	Obligate anaerobe (ANA)	Epi
<i>Arcobacter</i> species	–	Obligate anaerobe (ANA)	Epi
<i>Dietzia maris</i>	–	Gram-positive rods (GPR)	Epi
<i>Dietzia</i> species	–	Gram-positive rods (GPR)	Epi
<i>Lancefieldella rimae</i>	Gram-positive rods (GPR)	Obligate anaerobe (ANA)	Epi

Organism Species	Previous Group	Current Group	System
<i>Rothia aeria</i>	–	Gram-positive rods (GPR)	Epi
<i>Rothia dentocariosa</i>	–	Gram-positive rods (GPR)	Phx/Epi

Attachment F: Organism Subgroup Updates

The organism subgroup of the following organism species have been updated in the BD Phoenix™ and/or BD EpiCenter™ Systems.

Organism Species	Previous Subgroup	Current Subgroup	System
<i>Streptococcus acidominimus</i>	Streptococci, undefined	Viridans streptococci	Phx/Epi
<i>Streptococcus uberis</i>	Streptococci, undefined	Viridans streptococci	Phx/Epi

Attachment G: BDxpert Updates

1. CLSI

A. Overview

- **New Rules** : 2027, 2028
- **Modified Rules** : N/A
- **Obsoleted Rules** : N/A

B. Details

- Refer to the following pages for details.
- New rules are highlighted in **BLUE ACROSS**.

2. EUCAST

A. Overview

- **New Rules** : 2027, 2028
- **Modified Rules** : N/A
- **Obsoleted Rules** : N/A

B. Details

- Refer to the following page for details.
- New rules are highlighted in **BLUE ACROSS**.

CLSI/EUCAST Updates

Rule	IF	Organism/Group	AND	Drug(s)	AND	Logic Criteria	THEN	Action	AND	Message Chartable Text	Application	Reference
2027	–	Any Organism	–	Tigecycline	–	Source is UNS	–	Print message	–	Tigecycline is not routinely reported on isolates from the urinary tract.	EpiCenter, Phoenix	Tigecycline Package Insert
2028	–	Any Organism	–	Tigecycline	–	Source is URINE	–	Print message	–	Tigecycline is not routinely reported on isolates from the urinary tract.	EpiCenter	Tigecycline Package Insert

Impact of the Update

Installation of the BD Phoenix™ Update Data (PUD) V6.91A provides system enhancements and/or modifications, as outlined in this document, for BD Phoenix™ 100 software V6.31A or greater, BD Phoenix™ M50 software V1.1.20.0 or greater, and BD EpiCenter™ software V6.20A or greater.

Please evaluate the changes described above to determine if validation efforts are required per your laboratory protocols.

Update Preparation

Contact BD Technical Service and Support if you do not have these software versions loaded on your BD Phoenix™ and BD EpiCenter™ Systems. Your local BD Field Service Team will provide guidelines and information about required actions prior to, and after the update.

Software Verification and Validation Certification

Our software verification and validation process is compliant with IEC 62304. Each software version has a specific Software Development Plan and Software Verification and Validation Plan. All software development and verification activities were completed per the requirements in these plans. Each software version is tested to ensure it meets all of its specifications. PUD V6.91A passed all pre-established acceptance criteria. BD confirms that the software will not alter or modify previously obtained patient results.

If you have any additional questions, please contact your local BD representative.

Change History

Revision	Date	Change Summary
40	2020-04	Release Notes associated to PUD 6.71A
41	2020-08	Release Notes associated to PUD 6.81A
42	2021-04	Release Notes associated to PUD 6.91A

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