Achieve even more with the enhanced

## BD MAX<sup>TM</sup> System

The enhanced PCR benchtop platform that's just right for your lab.



Performance



Efficiency



Versatility





### Introducing the enhanced BD MAX™ System

Like you, we have a passion for advancing the world of health<sup>TM</sup> and we believe in healthcare innovation that leads to better patient management.

You have trusted BD to provide rapid, easyto-use diagnostic solutions that deliver the accurate results clinicians need to improve patient care.

You are continuously looking for ways to further optimize workflow efficiency, turnaround time and quality of results.

We heard you.

We have built for you an enhanced BD MAX $^{\text{\tiny M}}$  System to take your lab's efficiency to the next level.

With hardware and software innovations, the improved BD MAX™ System is designed to be easy-to-use, enhance the quality of testing, and improve laboratory efficiency.¹



Enhance the quality of testing, and streamline your lab's workflow with our latest hardware and product updates.\*1

**PCR Tray** 



The re-engineered PCR tray is designed to improve stability and pipetting precision into the PCR wells. This allows for more even pressure which is designed to offer better heat transfer and alignment with the pipette tips, and may reduce bubbles in the PCR cartridge.

Fixed Magnet Assembly



The BD MAX™ assays use magnetic affinity beads as part of the nucleic acid extraction process. The additional **Fixed Magnet Assembly** minimizes magnetic bead carry over during the pipetting process, which is designed to reduce the risk of non-reportable results and the need for sample re-runs for viscous samples.\*

Pierceable Cap<sup>†</sup>



The **Pierceable Cap** is a new design for the cap on the Sample Buffer Tube, which eliminates changing the blue septum cap for specimen prep or storage. Because the Pierceable Cap contains a septum that recloses after sample processing, evaporation of the sample is minimized — extending sample storage retention time from 5 hours at room temperature to 4 days for BD MAX<sup>TM</sup> Vaginal Panel.<sup>2,3</sup>

\*Bench Test results may not necessarily be indicative of clinical performance.

<sup>†</sup>Available for all models of the BD MAX™ System.



### Efficiency

Innovative enhancement that takes your lab's efficiency to the next level.

#### Streamlined sample prep and disposal

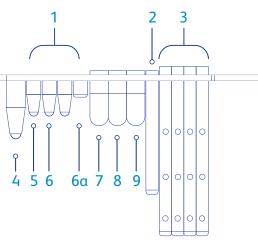
The compact and self-contained Unitized Reagent Strip is designed to be efficient for your lab:

- All your PCR and extraction chemistries and pipette tips are contained in one Unitized Reagent Strip, making it easy to run anywhere from 1 to 24 samples at a time.
- Reagents are room-temperature stable, making inventory management more flexible and convenient.
- With less than 1.5 minutes hands-on time per specimen, sample preparation is quick.<sup>1,4</sup>
- After the run, all waste from the extraction process is contained within the strip and can be discarded per your laboratory's standards, simplifying waste management.



#### **Unitized Reagent Strips:**

- 1 Snap-in Tubes
- 6 Master Mix 1
- 2 Waste Reservoir
- 60 Master Mix 2 if required
- 3 Pipette Tips
- 7 Wash Buffer
- 4 Lysis Tube
- 8 Elution Buffer
- 5 Extraction Tube
- 9 Neutralization Buffer



### Microfluidic PCR technology designed to standardize your workflow

Our patented PCR cartridge technology utilizes microfluidics to have 24 independent PCR reaction chambers:

- Different assays with unique temperature profiles can be run together, because each of the reaction chambers is heated by an independently-controlled set of heaters.
- > Contamination is minimized as wax valves seal off each chamber that holds the PCR amplification reaction.
- > The size and geometry of the chambers allow for rapid thermal cycling.





6 / Efficiency

### Efficiency

A streamlined and flexible workflow to help maximize your lab's throughput.

#### Streamlined workflow

Flexible batching workflow allows your lab to group multiple assays in a run, providing you walk-away time to perform other tasks in your busy lab.1

Interleave runs and the ability to mix-and-match assays help you to maximize your lab's throughput and efficiency.1

#### Ample throughput with fast results

#### Mix-and-match assays

The unique design of the Unitized Reagent Strip allows different assays to be processed together on the same run.

With an average turnaround time of 2 to 3 hours for most assays, the BD MAX<sup>™</sup> System runs up to 96 samples in an 8-hour shift.<sup>1,5</sup>

#### Ergonomic design for more efficiency

The updated All-in-One (AIO) computer offers:

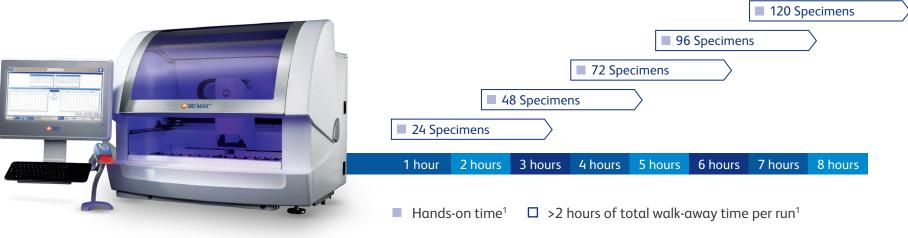
- High-resolution LED panel with a wide-viewing angle
- Four times more memory than the previous generation of AIO computers, which helps to improve processor speed and screen refresh rates
- Antimicrobial glass and housing, along with a front bezel that is IP65rated for dust and liquid protection
- Solid state hard drive and double the capacity, which is designed to improve system reliability

#### GCX® variable height arm mount and keyboard tray provide users:

- Additional benchtop space underneath by elevating the AIO computer with the wireless keyboard with touchpad
- Easier access to ports and control buttons, helpful during service and maintenance
- Ability to move the arm mount up and down and tilt for optimal viewing and positioning

#### HD barcode scanner and holder offers:

#### BD MAX™ System automated workflow



Automatic or manual scanning of the Sample Buffer Tubes Scanner holder to help keep your benchtop clean and orderly Efficiency / 7



### Versatility

Consolidate your molecular testing to the improved BD MAX™ platform



Get the best out of the broad and clinically relevant suite of BD MAX™ molecular assays and adapt quickly to your lab's evolving needs.\*

Reagents can be stored at room-temperature. making inventory and storage more convenient for you.

#### **Enteric solutions**

Simplify gastroenteritis testing with focused panels.

#### Enteric bacteria

BD MAX™ Enteric Bacterial Panel ( SKU: 442963)

Salmonella spp.

Campylobacter spp. (C. jejuni and C. coli)

Shigella spp. (including Enteroinvasive Escherichia coli [EIEC])

Shiga toxin 1 (stx1) / Shiga toxin 2 genes (stx2) genes

BD MAX™ Extended Enteric Bacterial Panel ( SKU: 443812) Plesiomonas shigelloides

Vibrio spp. (V. vulnuficus, V. parahaemolyticus, V. cholerae)

Enterotoxigenic *E. coli* (ETEC)

Yersina enterocolitica

#### **Enteric viruses**

BD MAX™ Enteric Viral Panel ( SKU: 443985)

Norovirus GI & GII

Rotavirus A

Adenovirus F40/41

Sapovirus (genogroups I, II, IV, V)

Human Astrovirus (hAstro)

#### **Enteric parasites**

BD MAX™ Enteric Parasite Panel ( SKU: 442960)

Giardia lamblia

Cryptosporidium (C. hominis and C. parvum)

Entamoeba histolytica

#### Respiratory infections

Help address and contain the spread of respiratory infections with accurate and timely testing.

#### SARS-CoV-2

BD SARS-CoV-2 Reagents for BD MAX™ System\*\* ( SKU: 445003-01) SARS-CoV-2 (N1 + N2)

BD Respiratory Viral Panel BD MAX™ System\*\* ( SKU: 445215)\*\*\* SARS-CoV-2 (N1+N2), Influenza A, Influenza B,

Respiratory Syncytial Virus

#### Healthcare-associated infections

Proper infection control and prevention requires active. timely surveillance and testing.

Clostridioides difficile

BD MAX™ Cdiff ( SKU: 443418)

Clostridioides difficile toxin B gene (tcdB)

#### Staphylococcus aureus

BD MAX™ MRSA XT ( SKU: 443461)

Methicillin-resistant Staphylococcus aureus (MRSA) (11 MREJ types including *mecA* and *mecC* resistance)

**BD MAX™ StαphSR (** SKU: 443419)

Staphylococcus aureus

Methicillin-resistant Staphylococcus aureus (MRSA) (11 MREJ types including *mecA* and *mecC* resistance)

#### Carbapenemase-producing organisms (CPO)

BD MAX™ CPO ( SKU: 445262)

KPC NDM

OXA-48 (OXA-48 and OXA-48 like)

VIM/IMP

#### Women's health & STIs

The right treatment starts with the right diagnosis.

#### Vaginitis

BD MAX™ Vaginal Panel ( SKU: 443712)

Bacterial vaginosis markers (Individual markers not reported):

- Lactobacillus spp. (L. crispatus and L. jensenii)
- Gardnerella vaginalis
- Atopobium vaginae
- Bacterial Vaginosis Associated Bacteria-2 (BVAB-2)
- Megasphaera-1

Candida spp. (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis)

Candida glabrata

Candida krusei

Trichomonas vaginalis

#### Antepartum

BD MAX™ GBS ( SKU: 441772)

Group B Streptococcus

#### Sexually transmitted infections (STIs)

BD CTGCTV2 for BD MAX™ System ( SKU: 443904)

Chlamydia trachomatis Neisseria gonorrhoeae Trichomonas vaainalis

\*Compatible with all models of the BD MAX™ System.\*\* This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized aboratories; · This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and · The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorization is revoked sooner. \*\*\*This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under EUA for use by authorized laboratories; This product has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus, not for any other viruses or pathogens; The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of CÓVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

BD MAX™ Open-System Reagents: embrace flexibility with open system and partner assays.

The BD MAX™ Open-System Reagents allow you to create your own labdeveloped tests or run third-party assays to address emerging diagnostic demands and meet local healthcare needs.

The BD MAX™ System is cleared, market

authorized or approved by the FDA only

have been cleared, market authorized

or approved by the FDA. IVD assays,

research use only (RUO) assays and

combined in the same rack.

user-defined protocols (UDP) cannot be

when used with BD MAX IVD assays that

		DNA Extraction Kits: Allows for extraction of DNA							TNA Extraction Kits: Allows for extraction of DNA & RNA	
	Sample Type	Ex	O MAX <sup>™</sup> IK <sup>™</sup> DNA-1 2817 / 442818		BD MAX <sup>™</sup> ExK <sup>™</sup> DNA-2 442819 / 442820		BD MAX <sup>™</sup> ExK <sup>™</sup> DNA-3 442821 / 442822		BD MAX <sup>™</sup> ExK <sup>™</sup> TNA-2 442825 / 442826	BD MAX <sup>™</sup> ExK <sup>™</sup> TNA-3 442827 / 442828
Extraction	Plasma			:		:		:		
	Serum	:	•	i				:		
	Urine		•	:			•	:		
	Cerebral Spinal Fluid			:	•			:		
	Dry Swab			-	•			1		
	Swab in UTM						•	:		•

#### **DNA Master Mix Kits:**

A complete PCR reagent mix for amplification of DNA

Amplification	BD MAX <sup>™</sup> DNA MMK (SPC) 442829	Contains primers and probes to detec BD sample processing control	
	BD MAX <sup>™</sup> DNA MMK 442848	Does not contain primers and probes t detect BD sample processing control	

TNA Master Mix Kits: A complete PCR reagent mix for amplification of total nucleic acids (DNA & RNA)

ct	<b>BD MAX™ TNA</b> <b>MMK (SPC)</b> 442830	Contains primers and probes to detect BD sample processing control
s to		

#### Seal In-house Reagents with the Axygen™ PlateMax™ Semi-Automated Plate Sealer

BD MAX<sup>™</sup> Barcoded

48 sheets per pack

(2592 tests)

Seal Sheets, 3 Codes

Holds 54 tubes

**Tube Holder** 

443412\*

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666666	

BD MAX<sup>™</sup> Conical : BD MAX<sup>™</sup> 5-Color

Seal Sheets

50 sheets per pack

(2700 tests)

443413\*







50 sheets per pack

(2700 tests)

BD MAX™ Barcoded

444160\*

Seal Sheets, 5 Codes



BD MAX<sup>™</sup> Bulk

Conical Tubes

437016

100 tubes per box

5000 tubes per

BD MAX™ Bulk

Conical Tubes

\*443412, 443413, 444159, and 444160 are designed to fit with the Axygen™ PlateMax™ Semi-Automated Plate Sealer (VWR 89203-178, Fisher 14-223-203)



## Enhancing diagnostics with informatics solutions

BD Synapsys<sup>™</sup> Informatics Solution enables secure connectivity and on-demand analytics for users of the BD MAX<sup>™</sup> System.

This initial release sets the groundwork for future features and capabilities for the BD MAX™ System, with more updates every six months.\*



Bi-directional Laboratory Information System (LIS) integration



Review results in BD Synapsys<sup>™</sup> Informatics Solution for an expanding list of BD MAX<sup>™</sup> System IVD molecular assays



Secure, browser-based technology enables anytime, anywhere access for multiple users and instruments



Robust cybersecurity with data security and privacy controls: UL CAP and SOC2 compliant

#### BD Synapsys™ Informatics Solution

is designed to provide near real-time analytics for quality control, administrative needs, infection prevention and physician requests.\*



#### Molecular Details Page: anytime, anywhere results access via a web browser

- > Access specimen test results and patient demographics anytime, anywhere
- > Get a consolidated view of a specimen run on both BD MAX™ System and BD COR™ System

#### Order Utilization Analytic: assay type and usage volume tracking

- > Track assay usage at quarterly, monthly, and weekly level
- > Assess usage of assays to aid in resource planning

#### Turnaround Time Analytic: near real-time monitoring of turnaround time (TAT)

- > Review average TAT from specimen collection to result reporting
- > Track TAT over time to help drive workflow changes to impact lab performance
- > May help increase efficiency and improve quality of service

#### Statistic Banner Analytic: at-a-glance dashboard

- > Customize dashboard with key testing metrics
- > Monitor prevalence trends and other key testing metrics in near real-time

#### Drill Down Analytic: in-depth analysis of positive results

- Understand the distribution of infection within the population
- > Analyze positive specimens broken down by patient or specimen demographics, allowing further data analysis

\*New software updates are released approximately every 6 months.

BD Synapsys™ Informatics Solution / 11



Upgrade your molecular capabilities today and achieve even more with the enhanced BD MAX™ System.



#### Choose the full BD MAX™ System

SKU	Description
441916	BD MAX™ System Includes instrument, 4 BD MAX™ Racks, printer, vortexer, and vial holder
445284	BD MAX™ Starter Kit Includes Touch Pad Keyboard, AIO computer, USB cable, USB key, and HD Barcode Scanner and Stand
445268	BD MAX™ Monitor Arm Installation Kit Includes GCX® Arm Mount, GCX® Keyboard Tray, and Monitor Arm Installation Bracket
444934	BD Synapsys™ Lab Conn - MAX Term (Connectivity & Workflow Management license)
444937	BD Synapsys™ Advanced – Molecular (Advanced Analytics license)



### Enhance your current BD MAX™ System with our latest innovations



SKU: 445268, 445275, 443686, 445277

#### BD MAX™ Accessories Upgrade Kit\*

Includes AIO computer, Monitor Arm Installation Kit, HD Barcode Scanner and Stand, and Wireless Touch Pad Keyboard

\*Components also available separately



SKU: 443686

BD MAX™ All-in-One (AIO) Computer



SKU: 445268

#### BD MAX™ Monitor Arm Installation Kit\*

Includes GCX® Arm Mount, GCX® Keyboard Tray, and Arm Mount Bracket Assembly \*Requires new AIO & Touch Pad Keyboard (sold

separately)



SKU: 445277

Wireless Touchpad Keyboard Accessory



SKU: 445219

BD MAX™ Fixed Magnet Assembly



SKU: 435120

Standard Optical USB Mouse



SKU: 445275

HD Barcode Scanner Stand Kit
Includes HD Barcode Scanner and Stand



**SKU: 444808** 

BD MAX™ Rack (4 EA)

SKU: 444807

BD MAX™ Rack (1 EA)

12 / Molecular capabilities / 13

### Technical specifications



#### BD MAX<sup>™</sup> System

**Height:** 72.4 cm x 94.0 cm x 75.4 cm (H,W,D)

Weight: 125 kg

Input Voltage: 100–240 VAC

Input Current: 10 A

Input Line Frequency: 50–60 Hz Maximum Power Input: 300 VA

Operating conditions

Temperature: 18–30 °C

Humidity: 20–80% R.H. (non-condensing) Altitude: Evaluated for safety to 2,000 m

**Non-Operating conditions** 

Temperature: -25–45 °C

Humidity: 10–85% R.H. (non-condensing) Thermocycling: Temperature Adjustment

**Range:** 50.3-110 °C

**Temperature Accuracy:** ± 0.1 °C

Fluid is ± 2.0 °C; control system is ± 0.25 °C Temperature Dwell Time Range ± 1 sec



#### **HD Barcode Scanner & Stand**

Optical system: 752 X 480 CMOS sensor Resolution 1D: 4 mil (0.102 mm) min Resolution 2D: 6.7 mil (0.17 mm) min Ambient LUX: Total darkness to 100.000

lux (full sunlight)

Scanning angle: plusmn40deg Field of View: HD version 38.4deaH and

24.9degV

**Focal distance:** HD version 6.9 cm/2.7 in Interface: RS-232, USB HID, USB Virtual

Supply Voltage Range: 3.7 to 5.5 VDC Power Consumption: Max 300 mA@5V

operating RS232 mode Max 300 mA@5V operating USB-HID mode

60mA (idle)

Regulatory listings: FCC BSMI CE

Indicator: LED and adjustable beep sound



#### All-in-One (AIO) Computer

Resolution: 1600 x 900

Screen: 20 in Medical Grade PCAP Multi Touch LED Panel

**Dimensions:** 20.35 in x 14.37 in x 1.95 in

Specifications: IP65 Sealed Front Bezel,

IP54 Back Cover Intel HD Graphics 520

Dual 1 Gigabit Ethernet ports Intel® Core™ 6th generation i5 vPro Processor, 2.4 GHz

16GB DDR4-2400MHz SO-DIMM

512GB 2.5 in SSD Drive

PCAP Touchscreen Stylus Pen for Medical

Security Cable Management Cover Skylake Series TPM Module

Antimicrobial Base Stand: included with all AIOs



#### GCX® Variable Height Arm Mount

**Specifications:** Bolt-Down Interface Small profile—space saving design Smooth continuous surface with minimal seams for easy cleaning Tilt/swivel adjustment 7–20 lb / 3.2–9.1 kg Weight limit 100/75 mm VESA compatible

7 in / 17.8 cm angled extension for optimal 20 in / 50.8 cm maximum reach

Flush fold-over ability for minimal foot print

**Weight:** 7 lb / 3.2 kg

**Dimensions:** 4 x 4 in / 10.2 x 10.2 cm base with 3 in / 7.6 cm square hole pattern

#### Requirements for the Application Server:

> Quad Core Processor CPU to 3.2GHz or higher

It is recommended to use two virtual or physical servers installed on site (on the institution's internal IT infrastructure), one as

the application server and one as the

> 32GB RAM

BD Synapsys<sup>™</sup> Informatics

Management of the last of the

Solution

> 50GB Disk Storage

database server.

- > Internet Access
- > Windows Server 2016
- > .NET 4.6
- > PowerShell
- > IIS v10
- .NET Core Windows Server Hosting bundle
- > Google Chrome
- > IE 11.0 with Silverlight installed\*\*

#### Requirements for the Database Server:

- Ouad Core Processor
- > CPU to 3.2GHz or higher
- > 32GB RAM
- > 1TB Disk Storage, SSD recommended > Windows Server 2016
- > PowerShell
- > MS SQL 2016 SP2 Enterprise or Standard with Mixed Mode Authentication enabled
- > SQL Server Management Studio
- > IIS v10
- > .NET Core Windows Server Hosting bundle

Minimum Required Configuration for use of a single virtual machine for both the application and database:

- > Intel® i5 or higher Quad Core Processor
- > 32GB RAM minimum
- > CPU to 3.2GHz or higher
- > 1TB Disk Storage, SSD recommended
- Internet Access
- > Windows Server 2016
- MS SQL 2016 SP2 Enterprise or Standard with Mixed Mode Authentication enabled
- > SQL Server Management Studio
- > .NET 4.6
- > PowerShell
- > IIS v10
- > .NET Core Windows Server Hosting bundle
- > Google Chrome
- > IE 11.0 with Silverlight installed\*\*

#### Note:

Amazon's AWS RDS service cannot be utilized for BD Synapsys™ Informatics Solution SQL database.

Specifications / 15



\*\*Note: IE 11.0 is not used as part of BD Synapsys™ Informatics Solution. It is only required by the tool used to configure LIS/EMR messaging or review message logs. 14 / Specifications

# BD MAX™ System with enhancements continues to support your laboratory with a simplified, efficient and streamlined workflow

BD MAX™ System offers you a fully integrated, automated real-time PCR platform with a broad menu of molecular IVD and open-system tests.<sup>6</sup>

- > Less than 1.5 minutes hands-on time per sample<sup>1,4</sup>
- > 24 patient results in 2 to 3 hours, on average 1,5
- > 96 samples per 8 hour shift1

### Snap



Assemble unitized reagent strips with extraction and PCR reagents.

#### Load



Load the Sample Buffer Tubes, racks, and PCR cartridges.

#### Go



Come back in an average of 2 to 3 hours for results.\*.1,5

\*Assay times may vary.

#### For more information about BD MAX™ System, please visit: bd.com/BDMAX

AIO, all-in-one; FDA, Food and Drug Administration; IVD, in vitro diagnostic; MMK, Master Mix Kit; PCR, polymerase chain reaction; RUO, research use only; UDP, user-defined protocols.

References: 1. Felder RA et al. J Lab Autom. 2014;19(5):468–73. 2. BD MAX™ Vaginal Panel. [Instructions for Use]. Becton, Dickinson and Company: Franklin Lakes, NJ; 2021. P0223. 3. BD MAX™ Vaginal Panel. [Instructions for Use]. Becton, Dickinson and Company: Franklin Lakes, NJ; 2022. P0258. 4. Hirvonen JJ et al. Eur J Clin Microbiol Infect Dis. 2015;34(5):1005–9. 5. BD MAX™ Enteric Bacterial Panel [Instructions for Use]. Becton, Dickinson and Company: System User's Manual. Becton, Dickinson and Company:

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