Product Security White Paper

Arctic Sun™ Stat Temperature Management System

BD is committed to providing secure products to our customers given the important benefits they provide to patient health. We value the confidentiality, integrity and availability of all information, including protected health and personally identifiable information (e.g. PHI, PII, and other types of personal data and sensitive data) and are committed to comply with applicable regional, federal and local privacy and security laws and regulations, including the Health Insurance Portability, Accountability Act (HIPAA), and the General Data Protection Regulation.

BD has implemented reasonable administrative, technical and physical safeguards to help protect against security incidents and privacy breaches involving a BD product, provided those products are used in accordance with BD's instructions for use. However, as systems and threats evolve, no system can be protected against all vulnerabilities and we consider our customers the most important partner in maintaining security and privacy safeguards. If you have any concerns, we ask that you bring them to our attention, and we will investigate. Where appropriate, we will address the issue with product changes, technical bulletins and/or responsible disclosures to customers and regulators. BD continuously strives to improve security and privacy throughout the product lifecycle using practices such as:

- Privacy and Security by Design
- Product and Supplier Risk Assessment
- Vulnerability and Patch Management
- Secure Coding Practices and Analysis
- Vulnerability Scanning and Third-Party Testing
- Access Controls appropriate to Customer Data
- Incident Response
- Clear paths for two-way communication between customers and BD

If you would like to report a potential product related privacy or security issue (incident, breach or vulnerability), please contact the BD Product Security team:

Site: http://www.bd.com/productsecurity/
Email: ProductSecurity@bd.com

Mail:

Becton, Dickinson and Company
Attn: Product Security
1 Becton Drive
Franklin Lakes, New Jersey 07417-1880

The purpose of this document is to detail how our security and privacy practices have been applied to the Arctic Sun™ Stat Temperature Management System, what you should know

about maintaining security of this product and how we can partner with you to ensure security throughout this product's lifecycle.

Contents

Product Description

The Arctic Sun™ Stat Temperature Management System Temperature Management System is a non-invasive, thermal regulating system, indicated for monitoring and controlling patient temperature. The system is composed of the Arctic Sun™ Stat Temperature Management System Control Module and disposable non-sterile ArcticGel Pads, which are adhered to areas of the patient's skin. The Control Module is the device that contains software. The ArcticGel Pads do not contain software or any sensors.

The Arctic Sun™ Stat Temperature Management System's Control Module re-circulates temperature-controlled water to the ArcticGel Pads. A commercially-available medical temperature probe, such as naso-pharyngeal, bladder, rectal, or esophageal, connected to the control module senses the patient's core temperature. Within the device, a control algorithm automatically adjusts the water temperature (automatic mode) or the clinician can adjust the water temperature (manual mode) to obtain the desired patient temperature.

Hardware Specifications

- 10.4" XGA/SVGA TFT LCD display with LED backlight
- Intel® Celeron® processor N3060
- USB 3.0

Operating Systems

Microsoft Windows 10 LTSC

Third-party Software

- Microsoft Windows 10 LTSC
- Veracrypt
- Cylance Protect

Network Ports and Services

- User settable; Full range output
- CCE connection (for Encrypted data transfer to EMR)

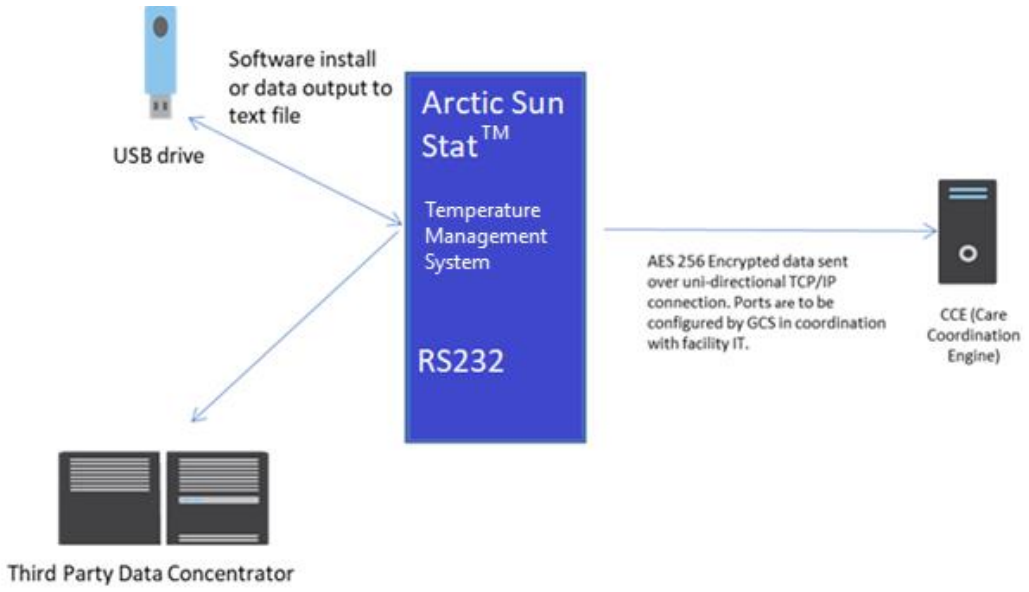
Sensitive Data Transmitted

There is no sensitive data in transit. Patient data in transit consists only of the patient's temperature with no additional identifiable information.

Sensitive Data Stored

No sensitive data is stored.

Network and Data Flow Diagram



Malware Protection
CylanceProtect is being used.

Patch Management
BD approved upgrades can be applied to the device. This requires BD personal to update at the site.

Authentication Authorization
None, the Arctic Sun™ Stat Temperature Management System is a local device only.

Network Controls
There are no network controls that need to be implemented by the user.

Encryption
No sensitive data is handled by application. If encryption on a USB software update fails, a failure symbol is displayed to the user.

Audit Logging
An internal log store can only be exported by developers; there is no concept of users with this system. Alarm logs can be viewed, however, there is no exportability. Error logs are limited in access to the same elevated mode needed to adjust calibration settings. Authorization is tied to authorization of product use

Remote Connectivity
There is no remote connectivity for the Arctic Sun™ Stat Temperature Management System.

Service Handling
Following installation and configuration Arctic Sun™ Stat Temperature Management System is designed to operate without service user interaction for up to 6 months of calendar time wherein calibration is required.

End-of-Life and End-of-Support
BD follows an internal process to provide end-of-life and end-of-support notifications directly to customers, where appropriate. Currently there is no plan for end-of-life or end-of-support for this device and/or service.

Secure Coding Standards
Secure coding standards have not been applied.

System Hardening Standards
Hardening standards have been applied to the operating system.

Risk Summary
A penetration test was performed on the Arctic Sun™ Stat Temperature Management System and was found to have a LOW CVSS rating. If a potential vulnerability is discovered or other potential security risk identified, BD will take all reasonable measures to address the issue and update this risk summary.

Third Party Soc2+ Reporting
Our commitment to ongoing Service Organization Control (SOC) Type II Plus reporting enhances the transparency of our relationship with customers. This reporting allows for visibility into the policies, procedures and processes governing the use of data gathered from customer environments.

Using an independent third party, we annually test and report on the operating effectiveness of controls in relation to the trust services principles & criteria for security and availability, as well as NIST800-66 (An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule). The third party firm completes their reporting in alignment with the American Institute of Certified Public Accountants (AICPA) over the suitability of the design and operating effectives of controls to meet the applicable criteria.

As part of this review, the following areas will be assessed:

1. Security Management Process
2. Security Official
3. Workforce Security
4. Information Access Management
5. Security Awareness and Training
6. Security Incident Procedures
7. Contingency Plan
8. Evaluation
9. Business Associate Contracts and Other Arrangements
10. Facility Access Controls
11. Workstation Use
12. Workstation Security
13. Device and Media Controls
14. Access Controls
15. Report Controls
16. Integrity
17. Person or Entity Authentication
18. Transmission Security
19. Business Associate Monitoring Process
20. Policies and Procedures

Manufacturer's Disclosure Statement for Medical Device Security

Otherwise known as the MDS2 form, this section provides an industry standard convention for security information.

Manufacturer Disclosure Statement for Medical Device Security – MDS²

DEVICE DESCRIPTION

Device Category Targeted Temperature Management	Manufacturer BD (Becton, Dickinson and Company)	Document ID DCS-28-5741-0061	Document Release Date 2020-05-08
Device Model Arctic Sun™ Stat Temperature Management System	Software Revision V1.0.4	Software Release Date 2020-06-12	

Manufacturer or Representative Contact Information	Company Name BD (Becton, Dickinson and Company) Representative Name/Position 1-800-531-4140	Manufacturer Contact Information Becton, Dickinson and Company Attn: Product Security and Privacy 1 Becton Drive, Franklin Lakes, New Jersey 07417-1880

Intended use of device in network-connected environment:
The intended use of the Arctic Sun™ Stat Temperature Management System is a tool to manage patients' temperature. The Arctic Sun™ Stat Temperature Management System helps create, store, or transfer the temperature data for record keeping purposes. It also helps have easy access to information related to health conditions and to communicate information that could be reviewed for determination of potential medical conditions to their healthcare provider.
Intended purpose of integrating the Device into an IT-Network: EMR Charting

MANAGEMENT OF PRIVATE DATA

	Refer to Section 2.3.2 of HIMSS/NEMA HN 1-2013 standard for the proper interpretation of information requested in this form.	Yes, No, N/A, or See Note	Note #
A	Can this **device** display, transmit, or maintain **private data** (including **electronic Protected Health Information** [**ePHI**])?	No	1,2
B	Types of **private data** elements that can be maintained by the **device**:		
	B.1 Demographic (e.g., name, address, location, unique identification number)?	No	
	B.2 Medical record (e.g., medical record #, account #, test or treatment date, **device** identification number)?	No	
	B.3 Diagnostic/therapeutic (e.g., photo/radiograph, test results, or physiologic data with identifying characteristics)?	No	
	B.4 Open, unstructured text entered by **device user/operator**?	No	
	B.5 **Biometric data**?	No	
	B.6 Personal financial information?	No	
C	Maintaining **private data** - Can the **device**:		
	C.1 Maintain **private data** temporarily in volatile memory (i.e., until cleared by power-off or reset)?	No	
	C.2 Store **private data** persistently on local media?	No	
	C.3 Import/export **private data** with other systems?	No	
	C.4 Maintain **private data** during power service interruptions?	No	
D	Mechanisms used for the transmitting, importing/exporting of **private data** – Can the **device**:		
	D.1 Display **private data** (e.g., video display, etc.)?	No	
	D.2 Generate hardcopy reports or images containing private data?	No	
	D.3 Retrieve **private data** from or record **private data** to **removable media** (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick, etc.)?	No	
	D.4 Transmit/receive or import/export **private data** via dedicated cable connection (e.g., IEEE 1073, serial port, USB, FireWire, etc.)?	No	
	D.5 Transmit/receive **private data** via a wired network connection (e.g., LAN, WAN, VPN, intranet, Internet, etc.)?	No	
	D.6 Transmit/receive **private data** via an integrated wireless network connection (e.g., WiFi, Bluetooth, infrared, etc.)?	No	
	D.7 Import **private data** via scanning?	No	
	D.8 Other? N/A	N/A	

Management of **private data** notes:
1. Device does not have the ability to gather, display, or maintain private data.
2. Device does not have the ability to generate hardcopy or retrieve any private data.

Device Category	Manufacturer BD (Becton, Dickinson and Company)	Document ID N/A	Document Release Date 2020-05-08
Device Model Arctic Sun™ Stat Temperature Management System	Software Revision V1.0.4	Software Release Date 2020-06-12	

SECURITY CAPABILITIES

Refer to Section 2.3.2 of HIMSS/NEMA HN 1-2013 standard for the proper interpretation of information requested in this form.	Yes, No, N/A, or See Note	Note #
1 AUTOMATIC LOGOFF (ALOF) The **device**'s ability to prevent access and misuse by unauthorized **users** if **device** is left idle for a period of time.		
1-1 Can the **device** be configured to force reauthorization of logged-in **user**(s) after a predetermined length of inactivity (e.g., auto-logoff, session lock, password protected screen saver)?	No	1
1-1.1 Is the length of inactivity time before auto-logoff/screen lock **user** or administrator configurable? (Indicate time in notes.)	No	
1-1.2 Can auto-logoff/screen lock be manually invoked (e.g., via a shortcut key or proximity sensor, etc.) by the **user**?	No	
ALOF notes: 1. Device does not utilize user log-in function to allow usage of the equipment, identify user, or to provide user lockout function.		
2 AUDIT CONTROLS (AUDT) The ability to reliably audit activity on the **device**.		
2-1 Can the **medical device** create an **audit trail**?	No	
2-2 Indicate which of the following events are recorded in the audit log:		
2-2.1 Login/logout	N/A	
2-2.2 Display/presentation of data	N/A	
2-2.3 Creation/modification/deletion of data	N/A	
2-2.4 Import/export of data from **removable media**	N/A	
2-2.5 Receipt/transmission of data from/to external (e.g., network) connection	N/A	
2-2.5.1 **Remote service** activity	N/A	
2-2.6 Other events? (describe in the notes section)	N/A	
2-3 Indicate what information is used to identify individual events recorded in the audit log:		
2-3.1 **User** ID	N/A	
2-3.2 Date/time	N/A	
AUDT notes: 1. Device, by design, does not track events, or track user events and record in a log file to create an audit trail of activity.		
3 AUTHORIZATION (AUTH) The ability of the **device** to determine the authorization of **users**.		
3-1 Can the **device** prevent access to unauthorized **users** through **user** login requirements or other mechanism?	No	1
3-2 Can **users** be assigned different privilege levels within an application based on 'roles' (e.g., guests, regular **users**, power **users**, administrators, 0etc.)?	No	1
3-3 Can the **device** owner/**operator** obtain unrestricted administrative privileges (e.g., access operating system or application via local root or admin account)?	No	1
AUTH notes: 1. Device does not utilize user log-in function to allow usage of the equipment, or to identify the user, or to assign differing levels of usage privilege or authorization.		

Device Category Mobile app	Manufacturer BD (Becton, Dickinson and Company)	Document ID N/A	Document Release Date 2020-05-08
Device Model Arctic Sun™ Stat Temperature Management System	Software Revision V1.0.4	Software Release Date 2020-06-12	

Refer to Section 2.3. of HIMSS/NEMA HN 1-2013 standard for the proper interpretation of information requested in this form.	Yes, No, N/A, or See Note	Note #
4 CONFIGURATION OF SECURITY FEATURES (CNFS) The ability to configure/re-configure **device security capabilities** to meet **users'** needs.		
4-1 Can the **device** owner/**operator** reconfigure product **security capabilities**?	No	
CNFS notes: N/A		
5 CYBER SECURITY PRODUCT UPGRADES (CSUP) The ability of on-site service staff, **remote service** staff, or authorized customer staff to install/upgrade **device**'s security patches.		
5-1 Can relevant OS and **device** security patches be applied to the **device** as they become available?	Yes	1
5-1.1 Can security patches or other software be installed remotely?	No	2
CSUP notes: 1. BD approved upgrades can be applied to the device. This requires BD personal to do such and is not directly available to customers. 2. System does not provide ability of remote connection into the device for control.		
6 HEALTH DATA DE-IDENTIFICATION (DIDT) The ability of the **device** to directly remove information that allows identification of a person.		
6-1 Does the **device** provide an integral capability to de-identify **private data**?	No	1
DIDT notes: 1. The device does not collect or store any private data.		
7 DATA BACKUP AND DISASTER RECOVERY (DTBK) The ability to recover after damage or destruction of **device** data, hardware, or software.		
7-1 Does the **device** have an integral data backup capability (i.e., backup to remote storage or **removable media** such as tape, disk)?	No	1
DTBK notes: 1. Device is not equipped with or design to provide backup functionality as private data is not collected or stored.		
8 EMERGENCY ACCESS (EMRG) The ability of **device users** to access **private data** in case of an emergency situation that requires immediate access to stored **private data**.		
8-1 Does the **device** incorporate an **emergency access** ("break-glass") feature?	No	1
EMRG notes: 1. The device does not collect or store any private data.		
9 HEALTH DATA INTEGRITY AND AUTHENTICITY (IGAU) How the **device** ensures that data processed by the **device** has not been altered or destroyed in an unauthorized manner and is from the originator.		
9-1 Does the **device** ensure the integrity of stored data with implicit or explicit error detection/correction technology?	No	
IGAU notes: 1. The device does not employ any additional means and measures against data integrity as no private data are gathered, processed, or manipulated		

Device Category Mobile app	Manufacturer BD (Becton, Dickinson and Company)	Document ID N/A	Document Release Date 2020-05-08
Device Model Arctic Sun™ Stat Temperature Management System	Software Revision V1.0.4	Software Release Date 2020-06-12	

Refer to Section 2.3.2 of HIMSS/NEMA HN 1-2013 standard for the proper interpretation of information requested in this form.	Yes, No, N/A, or See Note	Note #
10 MALWARE DETECTION/PROTECTION (MLDP) The ability of the **device** to effectively prevent, detect and remove malicious software (**malware**).		
10-1 Does the **device** support the use of **anti-malware** software (or other **anti-malware** mechanism)?	Yes	1
10-1.1 Can the **user** independently re-configure **anti-malware** settings?	No	
10-1.2 Does notification of **malware** detection occur in the **device user** interface?	No	
10-1.3 Can only manufacturer-authorized persons repair systems when **malware** has been detected?	Yes	
10-2 Can the **device** owner install or update **anti-virus software**?	No	
10-3 Can the **device** owner/**operator** (technically/physically) update **virus** definitions on manufacturer-installed **anti-virus software**?	No	2
MLDP notes: 1. Cylance Protect is the anti-malware application used. 2. Cylance Protect does not use virus definitions, it is an AI and machine learning based system.		
11 NODE AUTHENTICATION (NAUT) The ability of the **device** to authenticate communication partners/nodes.		
11-1 Does the device provide/support any means of node authentication that assures both the sender and the recipient of data are known to each other and are authorized to receive transferred information?	No	
NAUT notes: N/A		
12 PERSON AUTHENTICATION (PAUT) Ability of the **device** to authenticate **user**s		
12-1 Does the **device** support **user**/**operator**-specific username(s) and password(s) for at least one **user**?	No	1
12-1.1 Does the **device** support unique **user**/**operator**-specific IDs and passwords for multiple **users**?	No	1
12-2 Can the **device** be configured to authenticate **users** through an external authentication service (e.g., MS Active Directory, NDS, LDAP, etc.)?	No	1
12-3 Can the **device** be configured to lock out a **user** after a certain number of unsuccessful logon attempts?	No	1
12-4 Can default passwords be changed at/prior to installation?	No	1
12-5 Are any shared **user** IDs used in this system?	No	1
12-6 Can the **device** be configured to enforce creation of **user** account passwords that meet established complexity rules?	No	1
12-7 Can the **device** be configured so that account passwords expire periodically?	No	1
PAUT notes: 1. Device does not utilize user log-in function to allow usage of the equipment, or to identify the user.		
13 PHYSICAL LOCKS (PLOK) Physical locks can prevent unauthorized **users** with physical access to the **device** from compromising the integrity and confidentiality of **private data** stored on the **device** or on **removable media**.		
13-1 Are all **device** components maintaining **private data** (other than **removable media**) physically secure (i.e., cannot remove without tools)?	N/A	1
PLOK notes: 1. Device does not collect or store any private data.		

Device Category Mobile app	Manufacturer BD (Becton, Dickinson and Company)	Document ID N/A	Document Release Date 2020-05-08
Device Model Arctic Sun™ Stat Temperature Management System	Software Revision V1.0.4	Software Release Date 2020-06-12	

Refer to Section 2.3.2 of HIMSS/NEMA HN 1-2013 standard for the proper interpretation of information requested in this form.	Yes, No, N/A, or See Note	Note #
14 ROADMAP FOR THIRD PARTY COMPONENTS IN DEVICE LIFE CYCLE (RDMP) Manufacturer's plans for security support of 3rd party components within **device** life cycle.		
14-1 In the notes section, list the provided or required (separately purchased and/or delivered) operating system(s) - including version number(s).	See Note	
14-2 Is a list of other third party applications provided by the manufacturer available?	Yes	1,2,3
RDMP notes: 1. Windows 10 Enterprise LTSB 2016 64-bit Build 14393 2. Cylance Version 2.0.1510.10 3. VeraCyrpt Version 1.23		
15 SYSTEM AND APPLICATION HARDENING (SAHD) The **device**'s resistance to cyber attacks and **malware**.		
15-1 Does the **device** employ any hardening measures? Please indicate in the notes the level of conformance to any industry-recognized hardening standards.	Yes	1
15-2 Does the **device** employ any mechanism (e.g., release-specific hash key, checksums, etc.) to ensure the installed program/update is the manufacturer-authorized program or software update?	Yes	
15-3 Does the **device** have external communication capability (e.g., network, modem, etc.)?	Yes	
15-4 Does the file system allow the implementation of file-level access controls (e.g., New Technology File System (NTFS) for MS Windows platforms)?	N/A	
15-5 Are all accounts which are not required for the **intended use** of the **device** disabled or deleted, for both users and applications?	Yes	
15-6 Are all shared resources (e.g., file shares) which are not required for the **intended use** of the **device**, disabled?	Yes	
15-7 Are all communication ports which are not required for the **intended use** of the **device** closed/disabled?	Yes	
15-8 Are all services (e.g., telnet, file transfer protocol [FTP], internet information server [IIS], etc.), which are not required for the **intended use** of the **device** deleted/disabled?	Yes	
15-9 Are all applications (COTS applications as well as OS-included applications, e.g., MS Internet Explorer, etc.) which are not required for the **intended use** of the **device** deleted/disabled?	Yes	
15-10 Can the **device** boot from uncontrolled or **removable media** (i.e., a source other than an internal drive or memory component)?	No	
15-11 Can software or hardware not authorized by the **device** manufacturer be installed on the device without the use of tools?	No	
SAHD notes: 1. DISA STIG per BD policy		
16 SECURITY GUIDANCE (SGUD) The availability of security guidance for **operator** and administrator of the system and manufacturer sales and service.		
16-1 Are security-related features documented for the **device user**?	No	1
16-2 Are instructions available for **device**/media sanitization (i.e., instructions for how to achieve the permanent deletion of personal or other sensitive data)?	No	1
SGUD notes: 1. The device does not have any interface for security changes to be made by the device user.		

Device Category Mobile app	Manufacturer BD (Becton, Dickinson and Company)	Document ID N/A	Document Release Date 2020-05-08
Device Model Arctic Sun™ Stat Temperature Management System	Software Revision V1.0.4	Software Release Date 2020-06-12	

Refer to Section 2.3.2 of HIMSS/NEMA HN 1-2013 standard for the proper interpretation of information requested in this form.	Yes, No, N/A, or See Note	Note #
17 HEALTH DATA STORAGE CONFIDENTIALITY (STCF) The ability of the **device** to ensure unauthorized access does not compromise the integrity and confidentiality of **private data** stored on **device** or **removable media**.		
17-1 Can the **device** encrypt data at rest?	Yes	1
STCF notes: 1. While the device does not collect or store any private data, the system does use a TPM and bitlocker.		
18 TRANSMISSION CONFIDENTIALITY (TXCF) The ability of the **device** to ensure the confidentiality of transmitted **private data**.		
18-1 Can **private data** be transmitted only via a point-to-point dedicated cable?	No	1
18-2 Is **private data** encrypted prior to transmission via a network or **removable media**? (If yes, indicate in the notes which encryption standard is implemented.)	No	1
18-3 Is **private data** transmission restricted to a fixed list of network destinations?	No	1
TXCF notes: 1. The device does not collect or store any private data.		
19 TRANSMISSION INTEGRITY (TXIG) The ability of the **device** to ensure the integrity of transmitted **private data**.		
19-1 Does the **device** support any mechanism intended to ensure data is not modified during transmission? (If yes, describe in the notes section how this is achieved.)	No	
TXIG notes: N/A		
20 OTHER SECURITY CONSIDERATIONS (OTHR) Additional security considerations/notes regarding **medical device** security.		
20-1 Can the **device** be serviced remotely?	No	
20-2 Can the **device** restrict remote access to/from specified devices or **users** or network locations (e.g., specific IP addresses)?	No	
20-2.1 Can the **device** be configured to require the local **user** to accept or initiate remote access?	No	
OTHER Notes: N/A		

Disclaimer

The information contained in this Product Security White Paper is for reference purposes only. Nothing contained in this document or relayed verbally to any customer will be deemed to amend, modify or supersede the terms and conditions of any written agreement between such customer and BD, or BD's subsidiaries or affiliates (collectively, "BD"). BD does not make any promises or guarantees to customer that any of the methods or suggestions described in this Product Security White Paper will restore customer's systems, resolve any issues related to any malicious code or achieve any other stated or intended results. Customer exclusively assumes all risk of utilizing or not utilizing any guidance described in this Product Security White Paper, and customer agrees to indemnify and hold BD harmless from the same.