[Feb DD, 2023]

緊急現場安全通知

醫療器材矯正

URGENT FIELD SAFETY NOTICE

MEDICAL DEVICE CORRECTION

“德塔斯”主動脈氣球導管幫浦(衛部醫器輸字第 025453 號)

Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP)

產品描述 Product Description:	產品代號 Product Code/Part Number:	單一識別碼 UDI Code:
Cardiosave Hybrid	0998-00-0800-53 0998-UC-0800-53	10607567108391 N/A

受影響批號 Distributed Affected Lot Number:	全部 All
製造日期 Manufacturing Dates:	自 2011 12 月 Since December 2011
分銷日期 Distribution Dates:	自 2012 06 月 Since March 06, 2012

Getinge
45 Barbour Pond Drive
Wayne, NJ 07470 USA
www.getinge.com

親愛的客戶您好

Dear Customer

由於四個可能影響 IABP 性能的問題，Getinge 的子公司 Datascope Corp. 正在為 “德塔斯” 主動脈氣球導管幫浦(衛部醫器輸字第 025453 號)啟動自願醫療器材矯正：

Datascope Corp., a subsidiary of Getinge is initiating a voluntary Medical Device Correction for the Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) due to four issues that could affect IABP performance:

議題 1：

由於捲線電纜（部件號 0012-00-1801）和電纜組件背板（部件號 0012-00-1796）與提供顯示頭和主機之間的通訊。 請參考議題 1 下面的圖片以供參考。

注意：此問題僅限於 2012 年 3 月 6 日至 2017 年 7 月 24 日分銷的產品

Issue 1:

An unexpected shutdown of the IABP may occur due to a failure of the connection between the Coiled Cord cable (part number 0012-00-1801) and the Cable Assembly backplane (part number 0012-00-1796) to the Coiled Cord cable which provides the communication between the display head and base unit. Please refer to images below UNDER Issue 1 for reference.

NOTE: This issue is limited to units distributed March 6, 2012 through July 24, 2017

議題 2：

由於執行處理器 PCBA 和影片產生器 PCBA 之間失去通訊，可能會發生 IABP 意外關閉。

Issue 2:

An unexpected shutdown of the IABP may occur due to the loss of communication between the Executive Processor PCBA and the Video Generator PCBA.

議題 3：

據報告，高壓氦氣調節器出現故障可能會導致 Cardiosave 醫院推車發生氦氣洩漏。 高壓氦氣調節器位於 Cardiosave 醫院推車中，用於調節外部氦氣供應的氦氣壓力。 如果氦氣調節

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器出現故障，幫浦控制台的內部氦氣儲存器在停靠到受影響的醫院推車時不會得到補充。 這可能會導致內部儲存器內的氦氣量不足。 請參閱下面議題 3 圖片以供參考。

Issue 3:

There have been reported failures of the high pressure helium regulator which may cause a helium leak in the Cardiosave Hospital Cart. The high pressure helium regulator is located in the Cardiosave Hospital Cart and regulates the helium pressure of the external helium supply. In instance of helium regulator failure, a Pump Console' s internal reservoir of helium will not be replenished when docked into an impacted Hospital Cart. This may result in an insufficient amount of helium within the internal reservoir. Please refer to images below under Issue 3 for reference.

議題 4：

有報告稱 Cardiosave 幫浦控制台快速接頭上的 O 形環損壞、磨損或撕裂導致氦氣罐洩漏。 快速接頭是連接點，當幫浦控制台停靠在醫院推車中時，允許重新填充幫浦控制台的內部氦氣儲罐。 請參閱下面議題 4 的圖片以供參考。

Issue 4:

There have been reports of damaged, worn, or torn O-rings on the Cardiosave Pump Console quick disconnect fitting resulting in helium tank leaks. The quick disconnect fitting is the point of connection that permits the refilling of the Pump Console' s internal helium reservoir when the Pump Console is docked in the Hospital Cart. Please refer to images below under Issue 4 for reference.

議題 1：因捲線電纜和電纜組件背板到捲線電纜的故障而意外關閉

Issue 1: Unexpected shutdown due to failure of the Coiled Cord cable and Cable Assembly backplane to Coiled Cord cable

問題識別：

Datascope/Getinge 已收到有關 Cardiosave IABPs 意外關閉的投訴。

Identification of the issue:

Datascope/Getinge has received complaints reporting Cardiosave IABPs unexpectedly shutting down.

對投訴的內部調查確定意外關閉可能是由於損壞的盤繞電纜線 [部件號 0012-00-1801 和 0012-00-1796] 造成的，這些電纜在顯示頭和主機之間提供雙向通訊。 請參考下面的圖片。
An internal investigation of the complaints determined an unexpected shutdown may be due to damaged Coiled Cable Cords [part numbers 0012-00-1801 and 0012-00-1796] that provide bidirectional communication between the display head and base unit. Please refer to images below for reference.

Datascope/Getinge 2 年內已收到 25 起關於捲線損壞導致意外停機的投訴報告。
Datascope/Getinge has received 25 reported complaints of damaged Coil cords resulting in unexpected shutdown over a 2 year period.

已報告 0 起不良事件
There have been 0 adverse events reported.

健康風險：

意外關閉和由此導致的治療中斷可能會影響到患者的血液動力學穩定性。

Risk to Health:

An unexpected shutdown and resulting interruption to therapy may threaten the hemodynamic stability of the supported patient.

用戶現在採取的操作：

User Actions to be taken now:

1. 使用 Cardiosave IABP 之前，檢查盤繞的電纜線以確保沒有可見的損壞。
   Prior to use of the Cardiosave IABP, inspect the coiled cable cord to ensure that there is no visible damage.

舊幫浦控制台捲線連接:
Old Pump Console Coiled Cord Connection:

新幫浦控制台捲線連接:
New Pump Console Coiled Cord Connection:

圖 1：新舊纏繞電纜線設計的代表圖片

Figure 1: Representative picture of both the old and new Coiled Cable cord design.

2. 如您在治療期間遇到 Cardiosave IABP 意外關閉，請使用另一個 IABP 繼續治療。 在找到替代 IABP 之前，您可以嘗試重新啟動 IABP。 如果 IABP 仍然無法運行，請立即從患者照護環境中移除，以進行進一步的產品評估。
   Should you experience an unexpected shutdown of the Cardiosave IABP during therapy, utilize another IABP to continue therapy. Until an alternative IABP is located you may attempt to restart the IABP. If the IABP remains non-operational, immediately remove from the patient care environment for further product evaluation.
3. 如您的設備仍然無法操作，請聯繫台灣悅廷和有限公司以確定原因並採取所需的必要措施。
   If your device remains inoperable, please contact your service representative to identify the cause and take the necessary actions required.

公司所採取的行動類型：

Datascope/Getinge 開發了硬體改正來解決這個問題。 請務必注意，此問題僅限於 2017 年 7 月 24 日之前分銷的設備。如您的設備在矯正套件可用時受到影響，Datascope/Getinge 服務代表將與您聯繫以安排安裝矯正。 這項工作將在您的機構免費完成。

Type of Action by the Company:

Datascope/Getinge has developed a hardware correction to address this issue. It is important to note that this issue is limited to units distributed prior to July 24, 2017. A Datascope/Getinge service representative will contact you to schedule the installation of the correction if your unit is affected as the correction kit becomes available. This work will be done at no cost to your facility.

議題 2：因執行處理器 PCBA 和影片產生器 PCBA 間失去通訊而意外關機

Issue 2: Unexpected Shutdown due to loss of communication between the Executive Processor PCBA and the Video Generator PCBA.

問題識別：

作為對 Cardiosave IABP 意外關閉持續調查的一部分，Datascope/Getinge 調查團隊確定意外關閉投訴與執行處理器 PCBA 和視頻發生器 PCBA 之間的通訊中斷間存在相關性。 通訊中斷導致 IABP 顯示錯誤代碼 111 和錯誤代碼 112。

代碼 111：本地 Virtual Address Space (VAS) Watch Dog Timer (WDT) 故障
代碼 112：主應用程序 Watch Dog Timer (WDT) 故障

Datascope/Getinge 2 年期間已收到 28 起 Code 111 和/或 Code 112 事件導致意外關閉的投訴。

已報告 0 起不良事件。

Identification of the issue:

As part of an ongoing investigation into unexpected shutdown of the Cardiosave IABP, the Datascope/Getinge Investigation team determined there is a correlation between unexpected shutdown complaints and the loss of communication between the Executive Processor PCBA and the Video Generator PCBA. The loss of communication results in the IABP displaying error code 111 and error code 112.

Code 111: A local Virtual Address Space (VAS) Watch Dog Timer (WDT) Failure
Code 112: A main application Watch Dog Timer (WDT) Failure

Datascope/Getinge has received 28 reported complaints of Code 111 and/or Code 112 occurrences resulting in unexpected shutdown over a 2 year period.

There have been 0 adverse events reported.

健康風險：

意外關閉和由此導致的治療中斷可能會影響到受支持患者的血液動力學穩定性，因為用戶不知道 Cardiosave IABP 的狀態。

Risk to Health:

An unexpected shutdown and resulting interruption to therapy may threaten the hemodynamic stability of the supported patient as the user is left unaware to the status of the Cardiosave IABP.

用戶端現在採取的行動：

1. 如您在治療期間遇到 Cardiosave IABP 意外關閉，或出現凍結或黑色螢幕，請使用另一個 IABP 繼續治療。 在找到替代 IABP 之前，您可以嘗試重新啟動 IABP。 如IABP 仍然無法運行，請立即從患者照護環境中移除以進行進一步的產品評估。

User Actions to be taken now:

1. Should you experience an unexpected shutdown of Cardiosave IABP during therapy, or a present frozen or black screen, utilize another IABP to continue therapy. Until an alternative IABP is located you may attempt to restart the IABP. If the IABP remains non-operational, immediately remove from the patient care environment for further product evaluation.
2. If your device remains inoperable, please contact your service representative to identify the cause and take the necessary actions required.

公司採取的行動類型：

Datascope/Getinge 正在開發一個軟體修正來解決這個問題。 一旦可用，台灣悅廷和有限公司將與您聯繫以安排軟體更新。 這項工作將在您的機構免費完成。

Type of Action by the Company:

Datascope/Getinge is developing a software correction to address this issue. Once available, a Datascope/Getinge service representative will contact you to schedule the installation of the updated software. This work will be done at no cost to your facility.

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議題 3：高壓氦氣調節器洩漏

Issue 3: Leak in the High Pressure Helium Regulator

問題識別：

據報告，高壓氦氣調節器出現故障可能會導致 Cardiosave 醫院推車發生氦氣洩漏。 高壓氦氣調節器位於 Cardiosave 醫院推車中，用於調節外部氦氣供應的氦氣壓力。 如果氦氣調節器出現故障，幫浦控制台的內部氦氣儲存器在停靠到受影響的醫院推車時不會得到補充。 這可能會導致內部儲存器內的氦氣量不足。 請參考下面的圖片以供參考。

Datascope/Getinge 在過去 2 年內收到了 51 起因高壓氦氣調節器故障導致氦氣洩漏的投訴。

已報告 0 起不良事件。

Identification of the issue:

There have been reported failures of the high pressure helium regulator which may cause a helium leak in the Cardiosave Hospital Cart. The high pressure helium regulator is located in the Cardiosave Hospital Cart and regulates the helium pressure of the external helium supply. In instance of helium regulator failure, a Pump Console' s internal reservoir of helium will not be replenished when docked into an impacted Hospital Cart. This may result in an insufficient amount of helium within the internal reservoir. Please refer to images below for reference.

Datascope/Getinge has received 51 reported complaints of helium leak as a result of high pressure helium regulator failure over a 2 year period.

There have been 0 adverse events reported.

健康風險：

如 Cardiosave 的氦氣供應因氦氣壓力調節器受損而耗盡，治療可能會中斷。 與任何治療中斷一樣，隨後的血流動力學穩定程度與患者的整體臨床狀況有關，危重患者更容易出現臨床狀況低下。 向用戶提供提前通知（至少約 24 小時）可降低因氦氣耗盡而導致治療中斷的風

險。 Pump Console 的內部氦氣儲存器可以通過使用另一輛醫院手推車或氦氣加注站來恢復。 如氦氣替代不可行或無法使用其他 IABP 控制台，則醫療保健提供者可能會啟動提供血液動力學支持的替代方法（血管加壓藥、強心劑或替代療法）作為臨時措施。

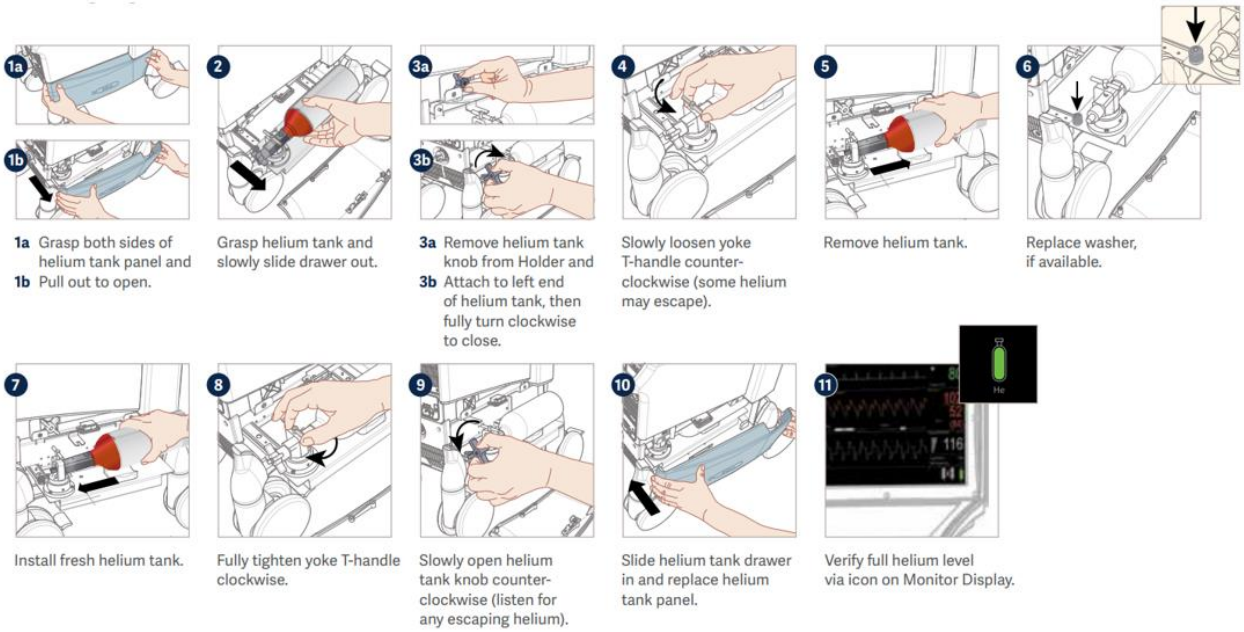
Risk to Health:

Should a Cardiosave' s helium supply be depleted due to an impaired helium pressure regulator, therapy may be interrupted. As with any therapy interruption, the degree of subsequent hemodynamic stability is related to the patient' s overall clinical condition, those critically ill are more vulnerable to clinical decline. The risk of therapy interruption from a depleted helium supply is mitigated by the advanced notice provided to the User (a minimum of approximately 24 hours). The Pump Console' s internal helium reservoir may be restored by utilizing another hospital cart or a helium refilling station. Should helium replacement not be feasible or another IABP console not available for use, alternative means of providing hemodynamic support (vasopressors, inotropes or alternate therapies) may be initiated by a healthcare provider as a temporizing measure.

用戶端現在採取的行動：

User Actions to be taken now:

1. 在按照 Cardiosave 操作說明安裝和更換氦氣罐期間，請確保在插入和/或移除氦氣罐時注意不要損壞氦氣罐或氦氣罐支架。
   During Installation and Replacement of Helium Tank per the Cardiosave Operating Instructions, please ensure care is taken not to damage the helium tank or the helium tank yoke while inserting and/or removing the helium tank.
2. 更換氦氣罐時請按使用說明操作。
   Please follow the instructions for use when changing the helium tank.



議題 2：如 Cardiosave Hybrid 和/或 Rescue 操作說明中所示

Figure 2: As pictured in **Cardiosave Hybrid and/or Rescue Operating Instructions**

3. 如用戶發現高壓調節器有任何可見損壞，請聯繫台灣悅廷和有限公司。
   If user observes any visual damage on High Pressure Regulator, please contact your Datascope/Getinge service representative.

公司採取的行動類別：

Type of Action by the Company:

Datascope/Getinge 目前正在調查此問題以確定根本原因，並將在需要採取其他措施來矯正此問題時通知客戶。

Datascope/Getinge is currently investigating this issue to determine root cause and will notify customers if additional action is to be taken to correct the issue.

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議題 4：幫浦控制台快速接頭處的氦氣洩漏

Issue 4: Helium Leak at the Pump Console Quick Disconnect Fitting

問題識別：

有報告稱 Cardiosave 幫浦控制台快速接頭上的 O 形環損壞、磨損或撕裂導致氦氣罐洩漏。快速斷開接頭是連接點，當泵控制台停靠在醫院推車中時，允許重新填充幫浦控制台的內部氦氣儲罐。 請參考下面的圖片以供參考。

Datascope/Getinge 過去2 年已收到 51 起因 O 形圈損壞、磨損或撕裂而導致氦氣洩漏的投訴。

Identification of the issue:

There have been reports of damaged, worn, or torn O-rings on the Cardiosave Pump Console quick disconnect fitting resulting in helium tank leaks. The quick disconnect fitting is the point of connection that permits the refilling of the Pump Console' s internal helium reservoir when the Pump Console is docked in the Hospital Cart. Please refer to images below for reference.

Datascope/Getinge has received 51 reported complaints of helium leak as a result of damaged, worn, or torn O-rings over a 2 year period.

There have been 0 adverse events reported.

健康風險：

如 Cardiosave 的氦氣供應因快速斷開受損而耗盡，治療可能會中斷。 與任何治療中斷一樣，隨後的血流動力學穩定程度與患者的整體臨床狀況有關，危重患者更容易出現臨床狀況下降。 向用戶提供提前通知（至少約 24 小時）可降低因氦氣耗盡而導致治療中斷的風險。 Pump Console 的內部氦氣儲存器可以通過使用另一輛醫院手推車或氦氣加註站來恢復。 如果氦氣替代不可行或無法使用其他 IABP 控制台，則醫療保健提供者可能會啟動提供血液動力學支持的替代方法（血管加壓藥、強心劑或替代療法）作為臨時措施。

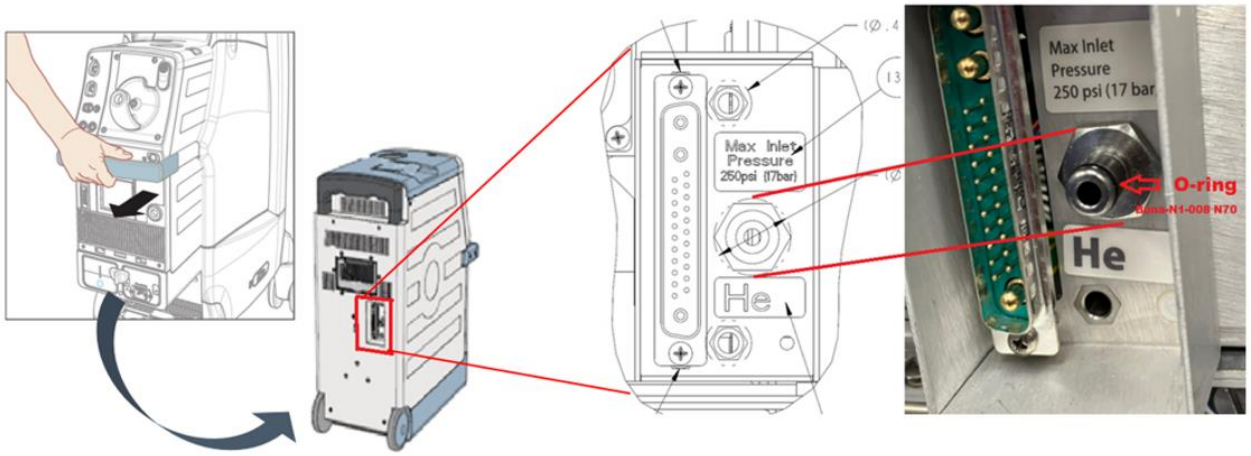
Risk to Health:

Should a Cardiosave' s helium supply be depleted due to an impaired quick disconnect, therapy may be interrupted. As with any therapy interruption, the degree of subsequent hemodynamic stability is related to the patient' s overall clinical condition, those critically ill are more vulnerable to clinical decline. The risk of therapy interruption from a depleted helium supply is mitigated by the advanced notice provided to the User (a minimum of approximately 24 hours). The Pump Console' s internal helium reservoir may be restored by utilizing another hospital cart or a helium refilling station. Should helium replacement not be feasible or another IABP console not available for use, alternative means of providing hemodynamic support (vasopressors, inotropes or alternate therapies) may be initiated by a healthcare provider as a temporizing measure.

用戶現在採取的行動：

User Actions to be taken now:

1. 如用戶發現作為快速接頭的一部分安裝的 O 形環目視有任何損壞，請聯繫台灣悅廷和有限公司。 如果可能，停止患者使用 IABP，直到可以進行適當的維修。
   If user observes any visual damage to the O-ring installed as part of the quick disconnect fitting, please contact your Datascope/Getinge service representative. If possible, remove the IABP from patient use until appropriate repairs can be made.



議題 3：Cardiosave Hybrid 和/或 Rescue 操作說明中的圖紙，以及設備上出現的 O 形圈的最終圖片。

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Figure 3: Drawings as pictured in **Cardiosave Hybrid and/or Rescue Operating Instructions**, along with a final picture of the O-ring as it appears on the unit.

公司採取的行動類型：

Datascope/Getinge 正在更新年度預防保養操作去納入快速接頭 O 形圈的更換

Type of Action by the Company:

Datascope/Getinge is currently updating the annual Preventive Maintenance instruction to include replacement of the quick disconnect fitting O-ring.

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用戶針對本通知中提供的所有問題應採取的行動：
Actions to be taken by the User related to all issues provided in this notification:

回顧我們的紀錄指出，您的機構中可能有 Cardiosave Hybrid 和/或 Cardiosave Rescue 主動脈氣球導管幫浦(IABP)。 請立即檢查您的庫存以確定您是否有任何 Cardiosave Hybrid 和/或 Rescue IABP。
A review of our records indicates that you may have a Cardiosave Hybrid and/or Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) in your facility. Please examine your inventory immediately to determine if you have any Cardiosave Hybrid and/or Rescue IABPs.

請填寫並簽署隨附的緊急現場安全通知醫療器材矯正 – 回函，勾選每個問題複選框 (1-4)，以確認您已收到並理解此通知。 通過電子郵件發送掃描件或將表格傳真至您當地的 Datascope/Getinge 代表或辦公室，將填妥的表格回傳給 Datascope/Getinge。
Please complete and sign the attached URGENT FIELD SAFETY NOTICE MEDICAL DEVICE CORRECTION - RESPONSE FORM (Page 11) checking off each issue checkbox (1-4) to acknowledge that you have received and understand this notification. Return the completed form to Datascope/Getinge by e-mailing a scanned copy or by faxing the form to your local Datascope/Getinge Representative or office.

請將此訊息轉發給您所在醫院/機構內所有當前和潛在的 Cardiosave Hybrid 和/或 Cardiosave Rescue 主動脈內氣球導管幫浦 (IABP) 用戶。
Please forward this information to all current and potential Cardiosave Hybrid and/or Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) users within your hospital/facility.

如您是向客戶銷售過任何受影響產品的經銷商，請將此信轉發給他們，以便他們採取適當的措施
If you are a distributor who has shipped any affected products to customers, please forward this letter to their attention for appropriate action

本次自願矯正通知僅影響第 1 頁所列產品； 沒有其他產品受到此自願矯正的影響。
This voluntary correction notification only affects the products listed on page 1; no other products are affected by this voluntary correction.

對於此醫療器材矯正可能造成的任何不便，我們深表歉意。 如果您有任何疑問，請聯繫台灣悅廷和有限公司。
We apologize for any inconvenience this Medical Device Correction may cause. If you have any questions, please contact your local Datascope/Getinge Representative or office.

誠摯地
Sincerely,

台灣悅廷和有限公司

Getinge
45 Barbour Pond Drive
Wayne, NJ 07470 USA
www.getinge.com

[Month DD, YYYY]

緊急現場安全通知

醫療器材矯正

URGENT FIELD SAFETY NOTICE

MEDICAL DEVICE CORRECTION – RESPONSE FORM

“德塔斯”主動脈氣球導管幫浦(衛部醫器輸字第 025453 號)

Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP)

機構名稱：

機構地址：

聯絡人：

我承認，我已經閱讀並理解了此緊急醫療器材矯正信函，適用於該機構中受影響的 Cardiosave Hybrid 和 Rescue 主動脈內氣球幫浦 (IABP)。
I acknowledge that I have reviewed and understand this Urgent Medical Device Correction Letter for the affected Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s) (IABP(s) at this facility.

我確認已通知相應機構的所有 Cardiosave Hybrid 和 Rescue 主動脈內氣球幫浦 (IABP) 用戶。
I confirm that all users of the Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s) (IABP(s) at this facility have been notified accordingly.

請勾選第 1-4 期每個問題旁邊的框，以確認您已經閱讀、理解並已相應地將這封信分發給您的機構。
Please check the box next to each Issue 1-4 in order to acknowledge that you have reviewed, understand and have distributed this Letter to your facility accordingly.

☐ 議題 1：因捲線電纜和電纜組件背板到捲線電纜的故障而意外關閉
Issue 1: Unexpected shutdown due to failure of the Coiled Cord cable and Cable Assembly backplane to Coiled Cord cable

☐ 議題 2：因執行處理器 PCBA 和影片產生器 PCBA 間失去通訊而意外關機

Issue 2: Unexpected Shutdown due to loss of communication between the Executive Processor PCBA and the Video Generator PCBA.

☐ 議題 3：高壓氦氣調節器洩漏

Issue 3: Leak in the High Pressure Helium Regulator

☐ 議題 4：幫浦控制台快速接頭處的氦氣洩漏

Issue 4: Helium Leak at the Pump Console Quick Disconnect Fitting

請在下面提供所需的資訊和簽名。

Please provide the required information and signature below.

機構代表資訊

Facility Representative Information:

簽名 **日期**

Signature:_____ **Date:**_____

姓名 **電話**

Name:_____ **Phone:**_____

電子郵件

E-Mail Address:_____

職稱 **部門**

Title:_____ **Department:**_____

醫院名稱

Hospital Name:_____

醫院地址

Address, City and State: _____

我們已經銷毀了我們的 Cardiosave Hybrid 和 Rescue 主動脈內氣球幫浦：

We have scrapped our Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s):

圈選一

Circle one 是 **YES** **否 NO**

如是，請填序號

If yes, list Serial Numbers: _____

Getinge
45 Barbour Pond Drive
Wayne, NJ 07470 USA
www.getinge.com

我們已將我們的 Cardiosave Hybrid 和 Rescue 主動脈內氣球幫浦出售/轉移到另一個機構：
We have sold/moved our Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s) to another facility:

圈選一

Circle one 是 **YES** **否 NO**

如是，請填序號

If yes, list Serial Numbers: _____

如果您在上面回答“是”：請在下方提供新機構資訊。

If you answered YES above: please provide new facility information below.

新機構名稱

New Facility Name: _____

新機構地址

New Facility Address: _____

新機構聯絡人姓名 **新機構聯絡人電話**

New Facility Contact Name: _____ **New Facility Phone #:** _____

請將您的回覆交給台灣悅廷和有限公司或其代表

Getinge
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