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行政院衛生署 90 年度委託研究計畫

電子病歷資訊之擷取與傳輸應用
Acquisition and Communication of Medical Information in Electronic Medical Record

委託研究成果報告

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目　　錄

壹、計畫摘要

中文摘要

關鍵字：醫療資訊匯流排(Medical Information Bus)、醫療設備系統(Medical Device System，MDS)、病患照護系統(Patient Care System，PCS)、通訊協定(Communication Protocol)

目的：

我國醫療資訊標準工作，在衛生署十多年來不遺餘力的推動與主導之下，已有具體的基礎與成果。然而，由於國內醫療資訊體系龐大而複雜，各院所也各自有其系統架構與運作機制；若要順利推動其全面標準化與整合醫療資訊，建構完整而易於應用之「全國醫療資訊網」，除了針對歐美醫療資訊標準發展作通盤性研究，取其符合未來國際趨勢且適合我國效法之處作為我國制定標準之依據之依據，同時要能發展符合醫療院所在資源整合與成本效益之平台或應用工具，以利於整體計劃之推展。

在醫療影像方面大多數醫療院所皆已遵循 DICOM 標準，醫療資訊之交換也依循著 HL7 標準執行，但在國內利用醫療設備資料之傳輸標準（IEEE 1073）使之有共同使用之介面設計者甚少；本研究應用國際醫療設備傳輸之使用標準及通訊協定（Medical Information Bus, MIB），設計一套系統其符合 IEEE 1073 國際標準，期望能加強國內對醫療資訊標準化之應用。

研究方法：

在此計劃中我們將研究歐美先進國家於醫療設備系統(MDS)與病患照

護系統(PCS)資料傳輸與整合之應用狀況，以了解醫療資訊匯流排(MIB)之標準技術發展狀況，並探討美國國家標準機構(American National Institute)與電機電子工程協會(IEEE)與歐盟在此領域之要求與可運用之資源。研擬出我國醫療設備之通訊協定標準納入我國 CNS(Chinese National Standard)標準之建議。

主要發現：

IEEE 1073 標準，針對於醫療儀器設備的通訊控制端(Device Communications Controller, DCC)與床邊整合設備的通訊控制端 (Bedside Communications Controller, BCC)之連接模式(Connection Mode)、傳輸方式(Transport Profile)與實體階層介面的聯結(Physical Layer Interface-Cable Connected)有詳細的定義與說明。但對於醫療設備(Defibrillator、Blood Pressure、Cardiac Output、ECG、Airway Flow、Pulse Oximeter、Temperature 等)輸出參數的定義部份目前皆在尚未認可(unapproved)的階段。在未來邁入 e 化醫療的時代，醫療設備資訊的交換與傳輸方面，若是標準尚無建立，可能在資訊的接收方會出現臨床數據輸出的不足或過多而無法做準確的判讀或系統的不穩定。

結論：

本計畫之結論在未來在是否採用醫療設備資訊標準的建議上，應考慮以下四點：(1)能否持續性遵循國際標準、(2)能否具備不同醫療儀器製造商間相容的能力、(3)能有不同廠牌互為連接運作功能、(4)若醫療資訊匯流排之標準化技術已建立，則產品應能通過此標準化之符合性測試。

IC 卡明年七月將先在台北市、台中市、高雄市、澎湖縣先試辦，93 年五月將推行至全台，因此醫療相關資訊的標準化乃為時勢所需。參考現有

醫療儀器之軟硬體設計，評估其輸出資料為MIB之標準格式之可行性及研擬後續推廣計劃將是刻不容緩的，後續政府政策的推動、醫療儀器商的支持、標準化產品之推廣、應用與各醫療院所的接受度，將是另一個重要的討論課題。

Abstract

Keyword: Medical Information Bus、Medical Device System(MDS)、Patient Care System(PCS)、Communication Protocol

The standardization of medical information is very important to the integration and information exchange between of different medical systems. The domestic medical information systems are usually huge and complicated, and every medical institute has its own system structure and operation mechanism. In terms of medical image, most medical institutions already follow the DICOM standard for the exchanges of medical information, most of they are trying to follow the HL7. However, in local, there are only few medical institutions that utilize IEEE1073 to constitute the common medium design. The standards for medical device system(MDS) and patient care system(PCS) are not well established. It has been a problem that to exchange and integrate data for MDS and PCS is very difficult.

The purpose of this project is: (1) To study the present Communication standard and protocol for medical devices. An good example is the IEEE 1073 (Medical Information Bus, MIB) which is developed by the IEEE Standards Association and supported by the Medical Device Communications Industry Group (MDCIG) to accelerate the development of the Standards, as well as market and demonstrate the capabilities of standardized medical data communications. (2) To evaluate the possibility for the incorporation of MIB in the local medical device systems.

This research applied Medical Information Bus (MIB) to design a system that fits IEEE1073 international standard to improve the application of domestic medical information standardization. Ventilators have been commonly used in all medical institutions, but different Ventilators have different output information because different medical institution has its own HIS, PCS, and

clinic information management system. This project uses IEEE 1073 standard to design and evaluate a Ventilator integration management system.

Our suggestions on the migration to adopt the medical device information standards are: (1) To conform the international standard continuously, (2) To have the ability of establishing compatibility between different medical devices for different manufactures, (3) To establish a procedure for testing the conformability of the IEEE1073 standard for medical devices.

貳、本文

一、前言

研究問題之背景與現況：

衛生署早自民國 76 年起就開始推動"全國醫療資訊網"相關建設，建構醫療資訊網路(HIN1.0)；建立區域資訊中心、衛生所資訊系統(PHIS)、公用性系統、個別化醫療應用系統，並逐步完成資料格式之標準化及作業制度統一之資訊標準化工作。

近年來，為了配合政府推動國家資訊基礎建設(NII)，衛生署亦積極進行我國醫療資訊基礎建設工作。同時揭示了健康資訊之兩大政策：
一為保障民眾(Patient)的健康資訊權。二為推動醫療衛生服務業(Provider)資訊化及網路化，以提昇醫療品質，增進全民健康。其中更揭示了電子病歷/遠距醫療/網路醫療/轉診連線/醫療軟體管理等項目。

其中在醫療資訊化與網路化部分，計劃之推動與電子資訊之交換環境/交換模式/甚至於法規標準都有極大之關聯性。因此整體計劃之成功與是否能順利推動，亦端賴於有容易操作應用之平台。

針對現行推動之醫療資訊標化，其應用架構較偏向高層次之醫療資訊傳輸交換;如 HIS 對 HIS 之間，或是 HIS 對 HIN 之間，例如 HL7 與 DICOM3.0 之應用。若能將病患照護與醫療儀器之間資訊交換也能納入考量，則將使醫療資訊之整合更為完整，並能促進資料流通、間接提高醫療服務品質。

研究目的：

現有國內計劃引進之醫療資訊標準如 HL7 與 DICOM3.0 之通訊交換其應用定義較偏向於高階部分，如醫療院所院際之間系統資訊之交換或醫學

影像之傳輸。但對於較低階而直接影響病患與病房臨床醫護人員之醫療儀器資訊系統(MDS)與病患照護系統(PCS)之間之資料整合與傳輸則有賴於醫療資訊匯流排之標準化與應用開發方能竟其功。

國內之醫療儀器 80%有賴國外進口，其廠牌級系統形形色色，對於病患照護系統之資訊整合與醫護人員醫療資訊之取得無疑的增加許多困擾。推動醫療資訊匯流排之標準化，將其納入國家標準，間接引導醫療服務機構將醫療資訊匯流排標準列入新儀器與軟硬體設備的採購規格中，將可降低系統整合成本、促進資料流通、間接提高醫療服務品質。

二、材料與方法

(一)何謂 IEEE 1073

IEEE1073 為醫療儀器傳輸標準，用來定義「醫療資訊匯流排(MIB)」第一層通訊之必要條件，其標準的內容大綱如下：

1073. 醫療設備通訊之架構與摘要

1073.1 醫療設備資料語言(Medical Device Data Language, MDDL)之架構與摘要

1073.2 醫療設備應用(Medical Device Application Profile, MDAP)之架構與摘要

1073.3 傳輸層(Transport Profile)

1073.4 實體層(Physical Layer Supplement)

1073.5 線上作業(Internetworking)

直到目前為止，第一章IEEE-STD-P1073.1為醫療設備資料語言(Medical Device Data Language, MDDL)，目前仍在草案階段，主要是定義 MDDL 共通的定義、MDDL 的命名準則、虛擬醫療設備之產生(Virtual Medical Device Generalization, VMD)、VMD 點滴注射器(Specialization Infusors)、VMD 生命跡象監視器(Specialization Vital Sign Monitors)、VMD 呼吸器(Specialization Ventilators)、VMD 光脈血氧計 (Specialization Pulse Oximeters)、VMD 心臟電擊器(Specialization Defibrillators)、核心資料格式(Kernel Data Format, KDF)。第二章 P1073.2 目前仍然是草案階段，內容是醫療設備應用(Medical Device Application Profile, MDAP)，共分為 P1073.2.0 基本核心 MDAP Kernel Base、P1073.2.1 最小核心輪廓 MDAP Minimum Kernel Profile、P1073.2.2 基本核心輪廓 MDAP Basic Kernel Profile、P1073.2.3 延伸核心輪廓 MDAP Extended Kernel Profile。第三章 1073.3 是

傳輸層(Transport Profile)，目前已有正式版。第四章 1073.4 為實體層(Physical Layer)，目前有支援 Cable Connected 及 IRDA，至於無線電則仍然在進行中。第五章 P1073.5 為 Internetworking。

IEEE 1073 針對開放系統連結(OSI 7-Layer)各層分類成三大應用，如圖一所示(P.34)，分別為應用層面(A-Type)、傳輸層面(T-Type)與實體層(Physical Layer)。

應用層面(A-Type)包含：

一、 對話層(Session Layer)：負責收發單位與網路系統的連接及解除。

二、 呈現層(Presentation Layer)：負責將應用層的格式及語法，轉換成網路上的格式及語法。

三、 應用層(Application Layer)：是 OSI 模式的最高層，可幫助使用者使用網路的各項服務。

傳輸層面(T-Type)包含：

一、 傳輸層(Transport Layer)：傳輸層將資料分割成小的單位並且予以編號，以便收訊人可將之重組，同時在這一層也可以做錯誤的偵測。

二、 網路層(Network Layer)：定義網路中封包(Packet)的走法及控制路徑的資料流程。

三、 資料連結層(Data Link Layer)：定義所要傳送之訊息的最基本單位格式，以及控制第一層在網路上運作的程序。

實體層(Physical Layer)為定義各種電子與機械之特性。

(二)醫療資訊匯流排(MIB)架構

1.MIB 之定義

醫療院所之醫療設備功能廣泛，包含了臨床的監視器材、診斷醫療儀器、以及治療用之設備，而醫療保健系統(Healthcare Information System)則整合了臨床資料管理系統、病患照護系統(PCS)與醫院行政資訊系統。
醫療資訊匯流排(MIB)之計劃功能主要在於提供醫療設備(Medical Device)與醫療保健資訊系統(HIS)有互相連接與共同使用之介面。藉由 MIB 之標準化，建立可應用之通訊平台及醫療設備輸出檔案之標準化，可建立標準之病歷資料，同時儀器設備資料可與醫療保健系統相容，達到資源共享之目的。

2.MIB 目標需求

- 安全性需求：病患或使用者對醫療儀器所能提供之安全要求。
- 網路架構適用性需求：MIB 之標準化資料可供網路傳輸。
- 簡易之使用介面：提供使用者很容易把醫療設備與其他醫療網路連線。
- 獨立性要求：可提供單一醫療儀器對應單一病患或病房。
- 電腦科技之廣泛支援：可操作於單一病房監控及多個病房或護理單位之應用。
- 單純化需求：對於使用繁複或功能複雜之醫療設備能降低其複雜性。
- 內部網路的連接：每一個床邊醫療設備一定會有一個點對點

(Point-to-Point)的連接，讓設備的界面能夠容易直接接上區域網路(Local-Area Network, LAN)。

- 可靠性需求：完整的通訊，也就是當其中一個訊號點是中斷的但不影響整個內部網路的運作。
- 同步性：系統必須能夠在同一時間抓取不同醫療設備的資料，尤其是即時的在系統顯示出複雜生理訊號波形。
- 遠端控制：一個標準界面的發展是不管任何的機型的醫療設備，都必須能夠完整的提供遠端控制的運用。
- 與 HL7 間的共通性：不論資料從哪裡發出，在相同的點(Point)資料必須能夠轉變成 HL7 可使用的(例如：經由一個介面(Gateway)的處理，例如：病歷管理系統、藥房(Pharmacy)系統、ADT(Admit-Discharge-Transfer)系統。

3.MIB 通訊架構

IEEE 1073 的範圍是在醫療照顧上提供開放系統通訊架構(open system communications) ，主要是介於床邊醫療設備與醫院病歷資訊系統(patient care information system)之資料交流。其目的是讓所有的醫療設備製造商可以依據標準提供其產品與電腦化的病歷資訊系統間之介面，讓所有合乎 IEEE 1073 標準的醫療設備均可相互連線。連線是透過「醫療資訊匯流排」(Medical Information Bus, MIB)。

通訊系統可概略區分兩大部分：一為資訊部分，二為傳輸資訊之機制；對於傳輸與接收主體雙方必須對資訊之語法與規格有共同之協定，資訊本身方能為通訊雙方主體所接受與了解。其次對於雙方之系統必須架構傳輸之機制以傳送資訊。以下定義出本計劃中 MIB 標準應用之通訊協定與服務之架構與範圍：

3.1 基礎醫療儀器設備：

以基礎醫療儀器設備-自動輸液幫浦(IV Pumps)與床邊電腦系統(Bedside Computer System)資料之傳輸為例，如圖二所示(P.35)，自動輸液幫浦(IV Pumps)其資訊的交換是透過一種 ISO 的通訊網路架構(Network)標準，其分成七層(7-Layer)來管理通訊協定，稱之為 OSI 7-Layer (Open System Interconnect 7-Layer Model)，其利用第一層實體層(Physical Layer)來將醫療儀器設備的通訊控制端(Device Communications Controller, DCC)與床邊整合設備的通訊控制端 (Bedside Communications Controller, BCC)來做聯結；再利用醫療設備語言(Medical Device Language)來溝通、理解。

在 IEEE 1073 實體層(Physical Layer)中，其資料的傳輸速率分成兩大類三小項，低速資料讀取(2400 Bd and 9600 Bd)與高速資料讀取(1Mb/s)，一般醫療設備其輸出資料速度幾乎為 9600Bd，也就是低速度資料讀取(此後之相關資訊皆以此方面來做設定與說明)；資料的傳送格式(Transmission format)是 8 個位元為一組的編碼，如圖三所示(P.35)，代表開始的 bit 是"0"，代表結束的 bit 是"1"，位元(bits)1~8 為資料訊息。相關語法、說明與資料定義請詳閱附錄 IEEE Standard for Device Communications-Physical Layer Interface-Cable Connected(P.49)。

連接頭(connector)其在電氣特性的要求上，如附表一所述(P.45)，直流接觸電阻(DC Contact Resistance)初始值須小於 30mΩ、直流電阻(DC Resistance)須小於 20MΩ、最大電流量(Maximum Current capacity)大於等於 500Ma、最小電流量(Minimum Current capacity)大於等於 100μA……等；在連接頭(connector)其在機械特性的要求上，如附表二所述(P.46)，最小與最大的插入力量為 8 磅與 20 磅、最小與最大的拔除力量為 1.1 磅與 6.5 磅、靜電放電的保護、連接頭的安全性……等；在連接線(Cable)的材質上，如

附表三所述(P.47)，其外被(Jacket)、隔離(Shield)、絕緣(Insulation)……等都有其特別的要求；其他如 EMC(Electromagnetic compatibility)與安全性(safety)上面的規定，對於醫療設備要與臨床上 (人體)的接觸，更是需要去注意與了解的，詳如附錄 IEEE Standard for Device Communications-Physical Layer Interface-Cable Connected (P.49)。

3.2 通訊的模式

醫療設備資訊的傳輸，如圖四-1(P.36)、四-2(P.37)所示。OSI 網路管理係採用共同管理資訊服務元件（Common Management Information Service Element, 簡稱 CMISE）負責管理通訊能力之邏輯部分。

CMISE 可分為二方面：

(1) 共同管理資訊服務（Common Management Information Service,簡稱 CMIS）用來規定 OSI 系統管理提供原始操作服務之使用者介面。
(2) 共同管理資訊通訊協定（Common Management Information Protocol, 簡稱 CMIP）用來規定通訊協定資料單元（Protocol Data Unit,簡稱 PDU） 格式與其結合的程序。

CMISE 使用者為了完成管理操作，首先必須透過結合控制服務元件（Association Control Service Element, 簡稱 ACSE） 建立結合關係，再經由遠程操作服務元件（Remote Operation Service Element, 簡稱 ROSE） 要求遠端去執行相對應的管理操作。

3.3 病房環境：

針對病房環境，MIB 之使用在於蒐集病患監視設備之資料與主機電腦之資料交換，以提供病房臨床護理人員醫護參考，如圖五所示(P.38)，一個床邊整合設備的通訊控制端 (Bedside Communications Controller, BCC)最多

可以跟125個醫療儀器設備的通訊控制端(Device Communications Controller, DCC)來做連接。簡單的來說， Bedside Communication Controller (BCC)為MIB的主控者，Device Communication Controller (DCC)則為介於BCC與醫療設備之間連絡的橋樑；其動作模式(Dynamic model)如圖六-1(P.39)、六-2(P.40)所示。BCC與病房以外的醫院資訊系統市以TCP/IP相互連結。醫護人員可以透過安全認證後存取病患資料或是調整醫療設備上的設定。

在因應上述臨床醫護之需求，如圖七所示(P.41)，其通訊之模式在於病患臨床資訊(來自病房醫療儀器)與病患照護系統(Patient Care System)之資料交換。

病患端之醫療設備可能為生理/生化監視器、人工呼吸器、心電圖機……等，其相關診斷或監視資訊必需透過標準化處理及介面之傳輸，轉換為病患照護系統(PCS)之主機系統可接受之格式，如圖八所示(P.41)；此資訊可提供臨床醫護人員監護病患適時提醫療服務，尤其對於重症加護病房(ICU)的病患與醫護人員而言，更可提高其整體的醫療品質。

（三）IEEE 1073與其他相關標準之關係

1. 資料交換標準：

資料交換標準（HL7），是制定一個應用對應用的一個文件交換標準。而其目的主要是提供一個能夠在各個醫療照護提供者的電腦系統間交換資料並不用太多的程式設計界面，如接收病患ADT(入院/ 掛號/ 出院和轉院）資料、病患排程、檢查結果報告、帳單等，目前已經廣泛的應用在美國、加拿大、澳洲、日本、荷蘭、德國、紐西蘭等國。

2. 醫學影像標準：

DICOM（Digital Imaging and Communications in Medicine）是醫學圖像

及其相關資訊的通訊標準。主要是推動開放式與廠牌無關的醫療數位影像的傳輸與交換，目前如 X 光機(X-RAY)、核磁共振掃描設備(MRI)、電腦斷層掃描設備(CT)、超音波儀器(ECHO)等所產生之影像，利用 DICOM 的標準予以數位化存入電腦。並可透過網路與各醫院連線，進行醫學影像傳輸及處理的功能顯示。近年來由於 ACR 與 NEMA 在醫療數位影像傳輸規範的發展與努力，DICOM 已成為北美、歐洲及日本各國在 Health Care Informatics 影像應用的標準。

結合 MIB、HL7、DICOM 以上三種之所提供之數據與資訊，便是一套相當完整的電子病歷，裡面詳細的記載病患所有資訊，便於醫療工作者能夠及時的做更進一步的治療與診斷。

三、結果

在此計畫中，以一般呼吸機為應用之對象來發展一套呼吸訊號整合管理系統，其方式概略如圖九所示(P.41)，首先使用 RS-232 傳輸線來連接呼吸機與電腦，將所擷取到的資料以 IEEE P1073.1.1.1 之標準來建立資料庫，最終藉由網際網路，讓使用者可在遠端來獲得即時性的臨床資料。此系統之開發概略分成五大步驟，為前端連結部份、呼吸資料整理部份、呼吸資料之整合與顯示部份、呼吸參數之資料儲存部份、系統與網路整合部份。

前端連結部份：

此系統是用 LabView 來作為系統開發軟體，藉由 RS-232 傳輸埠來連結呼吸機與電腦間的溝通與訊息傳輸，如表四、表五所示(P.47)；表四所述為資料傳輸定義，其鮑率(Baud Rate)為呼吸機與電腦間 RS232 介面之通訊速度、位元長度(Data Bits)為資料的長度、同位核定(Parity)為當資料傳送時，用來檢查資料是否正確無誤的被傳送過來的一個核對碼……等，表所列之五項呼吸機與電腦間必需要一致才能進行資料之傳送；表五所述為電腦向呼吸機要求資料的格式，Byte 1 為 STX(Start of Text)為資料封包的起頭碼、Byte 2 為向呼吸機要參數資料的 identifier，例如"ASCII 40"就得到呼吸機的通氣模式(Mode)、Byte 3 為 EXT(End of Text)為資料封包的結束碼、Byte 4 為 CR(Carriage Return)為移到所在該行之最前端，也就是歸位的意思。

在呼吸資料整理部份：

將所接收到的資料利用程式做進一步的處理與分類，如表六所述(P.48)，為呼吸機之輸出資料格式，其為一連串之 ASCII 碼。Byte 1、2、8、9 意義如上所述，Byte3~7 為所指定輸出參數之輸出值。

在呼吸資料之整合與顯示部份：

其顯示於電腦上分為四大部份，為控制參數設定界面(Control settings interface)、警告參數設定界面(Alarm settings interface)、病患端監視參數界面(Monitored Parameters interface)、呼吸參數波形界面(Wave Form interface)。

在控制參數設定界面顯示的有：

Mode、fcmv、fsimv、Tidal Volume、Insp. Time、Pause Time、Flow Pattern、Pressure Trigger、PEEP/CPAP、Pressure Support、Oxygen。如圖十所示(P.42)。舉例來說 PEEP/CPAP(cmH20)為 Positive End Expiratory Pressure / Continuous Positive Airway Pressure，吐氣末氣壓/連續氣道壓力，Range：0 to 99 cmH20；呼氣流量在最高吐氣流量有小部份降低後的平均壓力。在通氣模式(Mode)部分總計有 12 種模式，在此以 SIMV 來做解釋，SIMV(Synchronized Intermittent Mandatory Ventilation)，同步間歇性強制通氣；為一種協助病患脫離呼吸器的呼吸模式，在各強制通氣之間，允許病人經由另一回路自然呼吸，銜接處會與病人同步，不會

產生 fighting，為更理想的一種 weaning mode。

在警告參數設定界面顯示的有：

High Rate、High Pressure、Low Exp Min Vol、Low Oxygen、High Oxygen。如圖十一所示(P.42)，為當機器對病患之警告參數之設定範圍，如高壓(High pressure)、氧氣不足(Low Oxygen)……等。

在病患端監視參數界面顯示的有：

Insp. Volume、Exp. Volume、Vexp/min、f total、f spont、I:E ratio、Pmax、Pmean、PEEP/CPAP、P plateau、t Exp Pat、Oxygen、Rinsp、Rexp、compliance、Insp. Flow。如圖十二所示(P.43)。舉例來說 P plateau (cmH20) 為 Plateau Pressure or End-Inspiratory Pause Pressure Measured During a Plateau，高原期吸氣壓力或者為在高原期吸氣末中斷壓力的量測，Range：0 to 99 cmH20；此為反應吸氣末肺的順從性，應用在流量控制的強制性呼吸上。I:E Ratio 為 Inspiratory : Expiratory Ratio，吸氣、吐氣比例，Range：1:9.9 to 9.9:1；為病患呼氣與吐氣時間的比例，其包含了強迫與自發性的呼吸……等。

在呼吸參數波形界面顯示的有：

Vexp/min、Insp. Flow。如圖十三所示(P.43)，將 Vexp/min、Insp. Flow 以圖形方式顯示，以利專科醫師判讀。

在呼吸參數資料儲存部份：

呼吸參數資料將依 IEEE P1073.1.1.1 之標準來儲存至資料庫，格式訊號的名稱(Name)、物件類別(Object Class)的不同來存取之，以下我們以控制參數與病患端監視參數來說明：

以下所示為部份之參數部份：

舉例來說：在機器輸出名稱(Machine output Name)為 Mode，在 IEEE1073 標準下標準名稱為 Ventilator mode type，其在 IEEE.1.1.1 的 ID 為 NOM_VENT_MODE_TYPE，簡稱(Abbrev)為 N/a(表示尚未定義)，物件類型(Object Class)為列舉(Enumeration)。在機器輸出名稱(Machine output Name)為 Oxygen，在 IEEE1073 標準下標準名稱為 Oxygen Concentration，其在 IEEE.1.1.1 的 ID 為 NOM_VENT_CONC_AWAY_O2，簡稱(Abbrev)為 N/a(表示尚未定義)，物件類型(Object Class)為數值(Numeric)……等。

Name	**Machine output Name**	**IEEE.1.1.1**	**Abbrev**	**Object Class**
Ventilator mode type	Mode	NOM_VENT_MODE_TYPE	N/a	Enumeration
Oxygen Concentration	Oxygen	NOM_VENT_CONC_AWAY_O2	N/a	Numeric
⋮	⋮	⋮	⋮	⋮

以下所示為部份之病患端監視參數：

舉例來說：在機器輸出名稱(Machine output Name)為 Insp. Volume，在 IEEE1073 標準下標準名稱為 Patient Inspiratory Tidal Volume，其在 IEEE.1.1.1ID 為 NOM_VOL_AWAY_TIDAL，簡稱(Abbrev)為 VTi，物件類型(Object Class)為數值(Numeric)。在機器輸出名稱(Machine output Name)為 Exp. Volume，在 IEEE1073 標準下標準名稱為 Patient Expiratory Tidal Volume，其在 IEEE.1.1.1 的 ID 為 NOM_VOL_AWAY_TIDAL，簡稱(Abbrev)為 VTe，物件類型(Object Class)為數值(Numeric) ……等。

Name	**Machine output Name**	**IEEE.1.1.1**	**Abbrev**	**Object Class**
Patient Inspiratory Tidal Volume	Insp. Volume	NOM_VOL_AWAY_TIDAL	VTi	Numeric
Patient Expiratory Tidal Volume	Exp. Volume	NOM_VOL_AWAY_TIDAL	VTe	Numeric
Patient Expiratory Minute Volume	Vexp/min	NOM_VOL_MINUTE_AWAY_EXP	MVe	Numeric
⋮	⋮	⋮	⋮	⋮

其資料傳輸與儲存的概略架構如圖十四所示(P.44)，將自呼吸機所得到之呼吸參數資料經電腦傳送至資料庫(Data Base)將資料重新定義成為符合 IEEE1073 之格式後，醫院資訊系統 HIS(Hospital Information System)或遠端使用者之系統只需符合 IEEE 1073 標準下來做讀取，由於其名稱、ID 為一

致，便可輕鬆讀取資料庫資料，減少因名稱之不同所發生之錯誤判讀的可能性。

本實驗先期將以 Microsoft Access 做為資料庫的應用，之後將視其的穩定性與需求再做進一步的改善。其中資料庫以 IEEE P1073.1.1.1 標準之要求來建構。

系統與網路整合部份：

將此使用者介面與網路結合，可讓醫護人員自遠端來監視病患的呼吸狀態，進而做進一步的醫療處置，減少病患的不適。監視部份是經由 Client 端來完成，系統執行部份則是在 Server 端進行。此系統目前設計為單純的遠端監視，Client 端為無法執行反應、回傳及對 Server 端的系統執行提供任何的輸入，故對於醫療行為的執行，仍需呼吸治療師至 bedside 來調整呼吸機的相關控制參數。

根據實地調查與採訪，大部份醫院之臨床醫護人員在照護病房病患時；不僅需要作醫療處理(臨床處置)，同時對病房醫療儀器，必需抄寫其狀況記錄；提供臨床醫師作處置參考，回到醫護站後，若因應電子化系統，將要將其抄寫資料輸入病患照護系統。如此一來以往，不僅費時耗力，更增加醫護人員之工作負荷，令其無法全心全力投入其專業之工作上。

醫護人員雖然有此迫切之需求，但在醫療器材廠商眾多，且缺乏標準化之醫療資訊排匯流排，目前資料應用與系統之整合尚未能竟其功；雖然國內針對加護病房環境下已經有了全中文化介面的即時病患連線監視系統，可以與生理監視器等設備連接並做資料的收集且與醫院資訊系統連線(如 Laboratory)，但是需要投入相當大的資金才得以實現(包含了設備的升

級、資料轉換器、連結器等相關應用設備，一個ICU約需上千萬的資金)。目前僅HP發展之HOST系統僅可整合HP公司(現已改成Philips公司)部份之醫療儀器資訊與其他簽訂合作合約之公司所產機器，雖然如此，對醫護人員而言，卻已節省了約50%之工作量，其影響可謂不小，另一方面也增加對病患直接照護(Direct Care)的時間，減少病患留置ICU時間。若能普遍的應用標準化之醫療資訊來做存取，不僅可以減少費用的支出，當更能吸引院方及醫護人員之使用。

在市場上現有絕大部份的醫療儀器無法與醫院臨床資訊系統CIS (Clinical Information System)系統相容，終究其問題所在，在於機器本身的廠牌、出廠年份、機型的新舊、傳輸功能的提供及資料之傳輸、溝通格式……等的不同原因，讓院方無法為不同廠牌、型式的醫療機器一一來與院內資訊系統做連接，因為此舉所花費的人力與經費將是無法想像。甚至還有一個有趣的發現就是醫院在進行採購業務時，購買了相當先進的機型其擁有資料傳輸的功能，但機器本身卻未附有(或未購買)傳輸卡(Serial Port)???

國內之醫療儀器市場80%以上仰賴國外進口，且每年進口額高達數百億以上，但是各種醫療儀器其臨床診斷之輸出資料亦未經過標準化，其為廠商自訂之格式，因此加護病房使用之重症儀器，其臨床資料的收集與儲存皆必須由院方與合作廠商自行創造(Create)、設計一套監視系統，將診斷或監視儀器之結果輸入；檢驗科所作之生理/生化分析資訊則必需藉助人工重新輸入以建立檢驗之子系統；……，種種資料需透過醫院本身之資訊系統(MIS)重新輸入、處理，方成為完整之醫院保健資訊系統(HIS)。又或者某些診斷資訊則依賴紙張病歷或文件歸檔之方式，根本無法整合併入資訊系統，更不用說診斷資訊之後續處理與應用。

醫療儀器設備，在每一間醫院是相當的多且複雜的，如果各為每一廠

牌、機種做出不同的 MIB 界面，在時間與金錢的花費下是相當的不值得。若能建立醫療儀器介面-通訊之協定，規範醫療儀器輸出資訊之交換標準，定義出統一之資料格式，則對於醫院本身之資訊整合與人力/紙張之節省無異往前跨一大步，同時對於推動國內醫療資訊化與網路化，也有正面之助益。在標準推行的同時，製造廠商的支持，將是成功與否的最大關鍵。但是由於醫療產業界普遍認為 MIB 標準相當複雜，要實際建置出來並不容易，因此執行意願並不高；為此 ALARIS 公司公佈有關注射幫浦(infusion pump)的實驗軟體，此軟體只能提供些許不同廠牌注射幫浦的連結，且只有部份符合 IEEE1073 標準，其將病患端的注射幫浦連接到監測系統或醫院的資訊系統，並使得之間的資料傳輸格式能夠相通，其已在麻州總醫院實際證明其可行性。此舉是為了讓醫療產業界瞭解其可行性並期望能夠早日將其所發展、生產之機器介面完全符合 IEEE1073 標準，未來國內在於醫療儀器其資訊交換的界面應用上，便可早日達到一個即插即用"Plug and Play"的境界，並與各醫院的醫院資訊系統（HIS）做個完美的整合。

因應各國福利政策與健保之推動，各國衛生機關與大行醫療院所莫不積極施行數位化以促進作業之便利性與精簡不必要之作業及人力；但在數位化同時，現場醫護人員之困擾與需求也是考量的重點，如此就更能收到事半功倍之效。

四、討論

一個完整的 MIB 醫療資訊匯流排，必須具備有設備傳輸通信協定（Device Communication Protocols）、系統管理功能（System Management Functions） 及被管理物件（Managed Objects） 三方面。設備傳輸協定負責管理系統與或設備間訊息的傳遞，而系統管理功能則描述了系統管理的行為方式（behavior），並提供系統開發者標準的服務（service），至於被管理物件則儲存了管理資訊的內容。此外，需另就下列數項做進一步的探討與分析，如規範共識程度、產品可獲得性、規範穩定性、規格完整性、技術成熟性、業界使用狀況、符合性驗證等，都是相當重要的。

近年來，為了配合政府推動國家資訊基礎建設(NII)，衛生署亦積極進行我國醫療資訊基礎建設工作。同時揭示了健康資訊之兩大政策：

一為保障民眾(Patient)的健康資訊權。二為推動醫療衛生服務業(Provider)資訊化及網路化，以提昇醫療品質，增進全民健康。其中更包含了電子病歷/遠距醫療/網路醫療/轉診連線/醫療軟體管理等項目。

其中在醫療資訊化與網路化部分，計劃之推動與電子資訊之交換環境/交換模式/甚至於法規標準都有極大之關聯性。因此整體計劃之成功與是否能順利推動，亦端賴於有容易操作應用之平台。

針對現行推動之醫療資訊標準化，其應用架構較偏向高層次之醫療資訊傳輸交換；如 HIS 對 HIS 之間，或是 HIS 對 HIN 之間，例如 HL7 與 DICOM3.0 之應用。若能將病患照護與醫療儀器之間資訊交換也能納入考量，則將使醫療資訊之整合更為完整，並能促進資料流通、間接提高醫療服務品質。

五、結論與建議

在邁入科技化醫療的時代，醫院的資訊化、行動化，已成為熱門的話題；如何將醫療資訊以低成本、高效率來整合管理，成為醫療院所 e 化能否成功的關鍵。行政院衛生署將在明年 7 月發出第一張健保 1C 卡，後年 5 月 IC 卡全面上路，將可防範不必要的醫療資源浪費，這也宣告醫療 e 世代即將來臨。

推動醫療資訊標準化之工程非一蹴可幾，首要的工作為標準的制訂。在凡事講求全球化的現在，遵循國際標準，將可避免日後資訊在傳輸與解讀上的困擾與不便。IEEE1073 目前已制訂了一些標準可供遵循，雖然整體而言所提供的訊息針對醫療儀器上輸出參數(Parameter)的定義與要求並不完整，但已有其大方向，且許多的相關法案、條文持續在批准、與規劃進行中；後續政府政策的推動、醫療儀器商的支持、標準化產品之推廣、應用與各醫療院所的接受度，將是另一個重要的討論課題。

未來在是否採用 IEEE 1073 的建議上，應考慮以下四點：

1. 能否持續性遵循國際標準（包括管理協定部份、系統管理功能部份及被管理物件部份）。
2. 能否具備不同醫療儀器製造商間相容的能力。
3. 能有不同廠牌互為連接運作功能。
4. 若醫療資訊匯流排之標準化技術已建立，則產品應能通過標準之符合性測試。

我們也預期在未來的醫療儀器資訊傳輸標準化後，將可

1. 減少醫療資源浪費：建立標準之 MIB，可使醫院之週邊診斷設備(如病房生理監視器、病患 24 小時心電圖計、生化分析儀等)之診斷資訊可以與醫院資訊系統整合，減少不必要之文書作業或其他資料重輸入之資源浪費。同時標準之資料傳輸，可使醫療服務業者減少多種資訊系統之購置與後續之維修成本。
2. 醫療資訊之正確快速取得：由於標準介面與資料規格之制訂，各種診斷醫療資訊可以直接傳輸，不僅減少人工作業、避免人為疏失；同時在醫院單位及主管審查機關都可正確而快速的取得原始資訊。
3. 遠距醫療(Telemedicine)的應用：國內由於城鄉的差距、人口分佈不均、村里部落的分散與醫療院所設備及專科醫師的不足，導致某些特殊或重症病患無法在第一時間得到最佳的醫療照護與諮詢。隨著網際網路(Internet)的發達與普遍性，近年來政府持續的針對偏遠山區推廣遠距醫療的應用，未來如果將此標準落實應用，區域醫院、醫學中心等將可直接藉由網際網路傳送病人臨床生理訊號，不用擔心因編碼與解讀的系統不同而有錯誤的訊息出現。
4. 國內醫療電子產業之整體提昇：醫療器材產品技術係根據西醫及中醫的醫學理論及方法，再應用整合物理、化學、醫學、電子、光電、電腦、資訊、機械、材料和生物等尖端工程科技所產生之結晶；由於醫療器材產業具有產業關聯性大、技術層次高及附加價值高等特性，其產品品質攸關國民健康福祉，所以其產業早在民國 80 年即為政府列入時大新興工業之一。但由於我國醫療器材產業規模尚小，國內醫院使用的器材高達 8 成以上來自於進口。1998 年進口值高達 225 億，其中各式醫療電子產品動輒超過 2 億元以上(如超音波掃描器、血壓計、臨床生化儀、X 光射

線器具)，其中層析與電泳儀器與超音波掃描器在 1999 年分別高達新台幣 7 億元及 8 億元以上。

近年來經濟部科技專案對於「醫療技術發展計劃」也結合產、學、研界積極的推動及扶植產業升級。但在產品設計開發、製程、產品驗證部分均有待迎頭趕上。

若能制訂切合國際趨勢之醫療資訊規格標準，製造符合國際應用環境之醫療器材，其效益不只在建立產業界對醫療電子產品之系統評估與規劃能力，同時可開發新的模組產品，無異增加了國產醫療器材在國際上的競爭力。亦能減少醫療服務業對進口產品之依賴度。

另外，雖然 IEEE-STD-1073 為美國所制定的，但是歐盟 (European Union)藉著 CEN 於 1997 年十月在比利時 Brussels 所召開的 European Workshop for Open Systems(EWOS)會議中採納了 IEEE-STD-1073 作為床邊醫療設備的通訊標準，編號為 CEN TC251。這樣一來使其成為歐洲標準跨出了第一步。於 1998 年中時澳大利亞與加拿大的醫療資訊研究院 (Institute of Healthcare Informatics)相繼地採納了 IEEE-STD-1073 作為其國家標準。由於美、加、澳、歐盟均有強烈的意願更進一步地制定其為國際標準，國際標準組織 ISO 底下的技術委員會(Technical Committee)著手制定了 ISO/TC215，目前尚在草案階段，但是其 Draft Standards 已經日益成熟，值得去瞭解消化，依循國際標準開發的床邊醫療設備才具產品競爭能力，為國內相關廠商開闢一條新路。

未來的醫療資訊系統將醫師診療、護理作業、病患照料、長期看護、病患臨床生理資訊、配藥批價等前端作業系統，透過 wireless LAN 或 Intranet 的方式，與後段 HIS 系統整合，成為一份完整的電子病歷，充分發揮醫療 M 化及 e 化整合成效。未來在逐步整合中央健保 IC 卡、HL7 資訊規格將

可使全民得到最佳的醫療品質，對於醫療資源的節約，或查處醫師的浮報虛報，均有很大之幫助。

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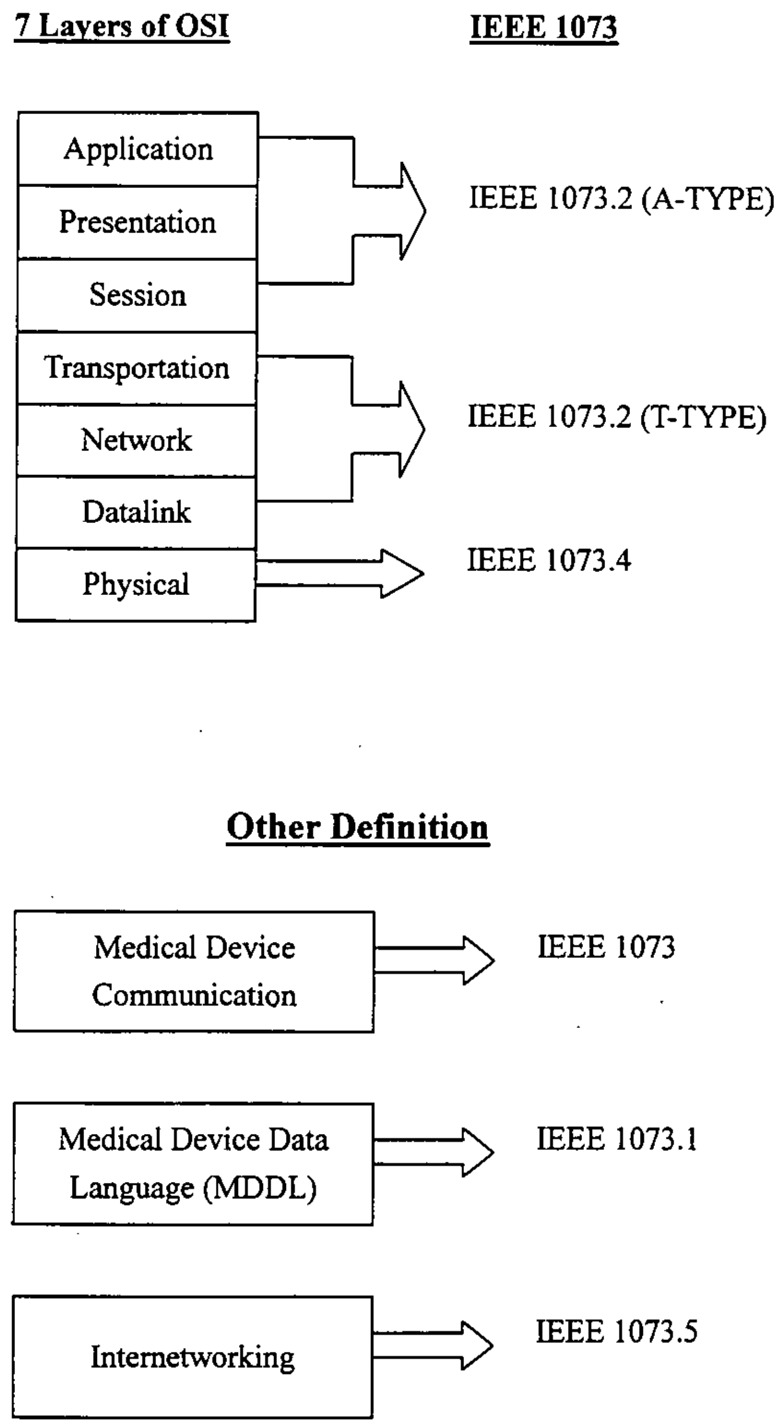
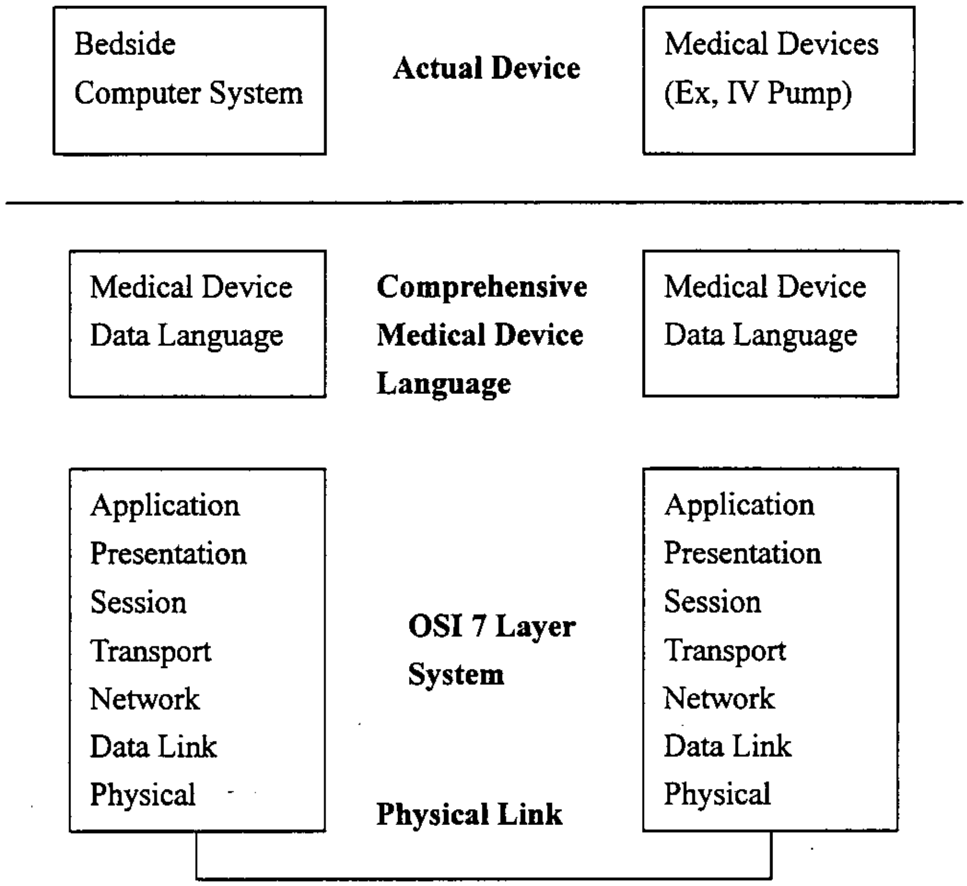
七、圖



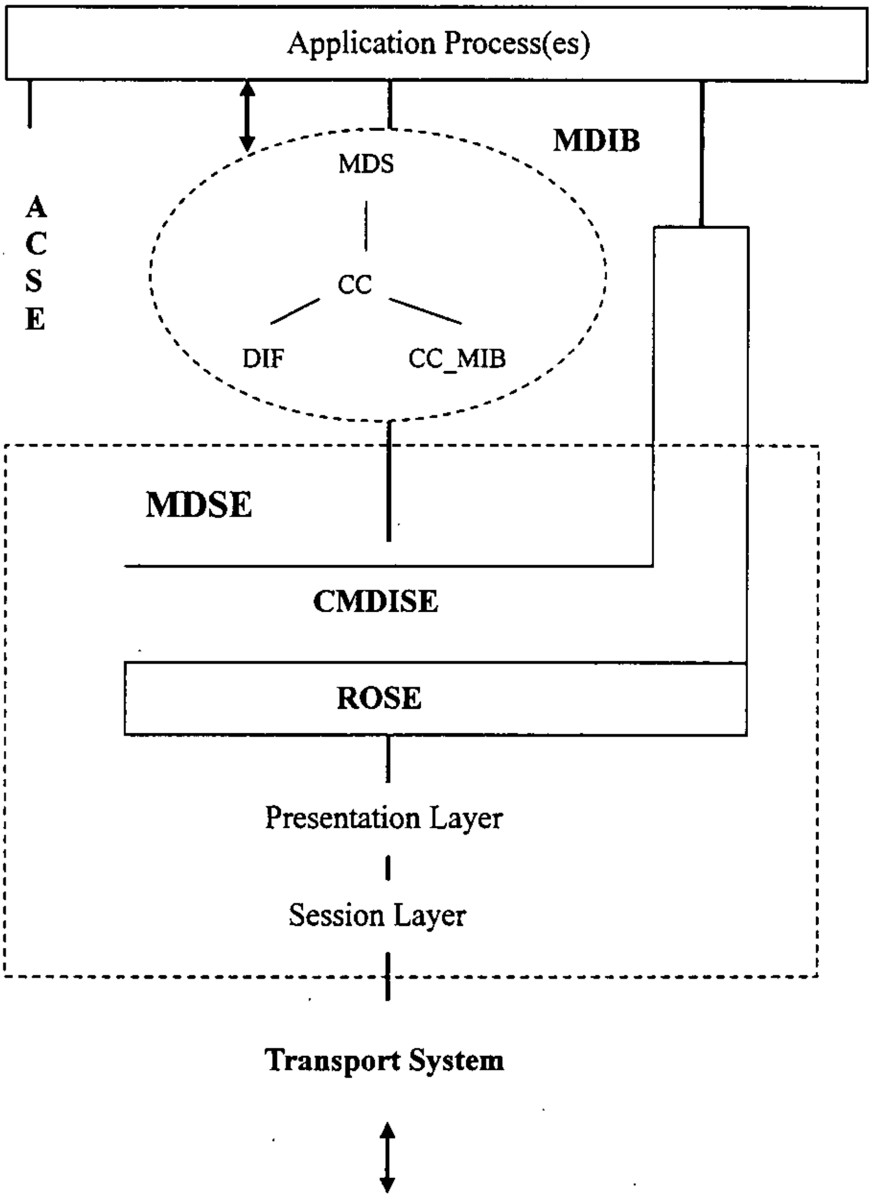
圖一、ISO VS. 1073



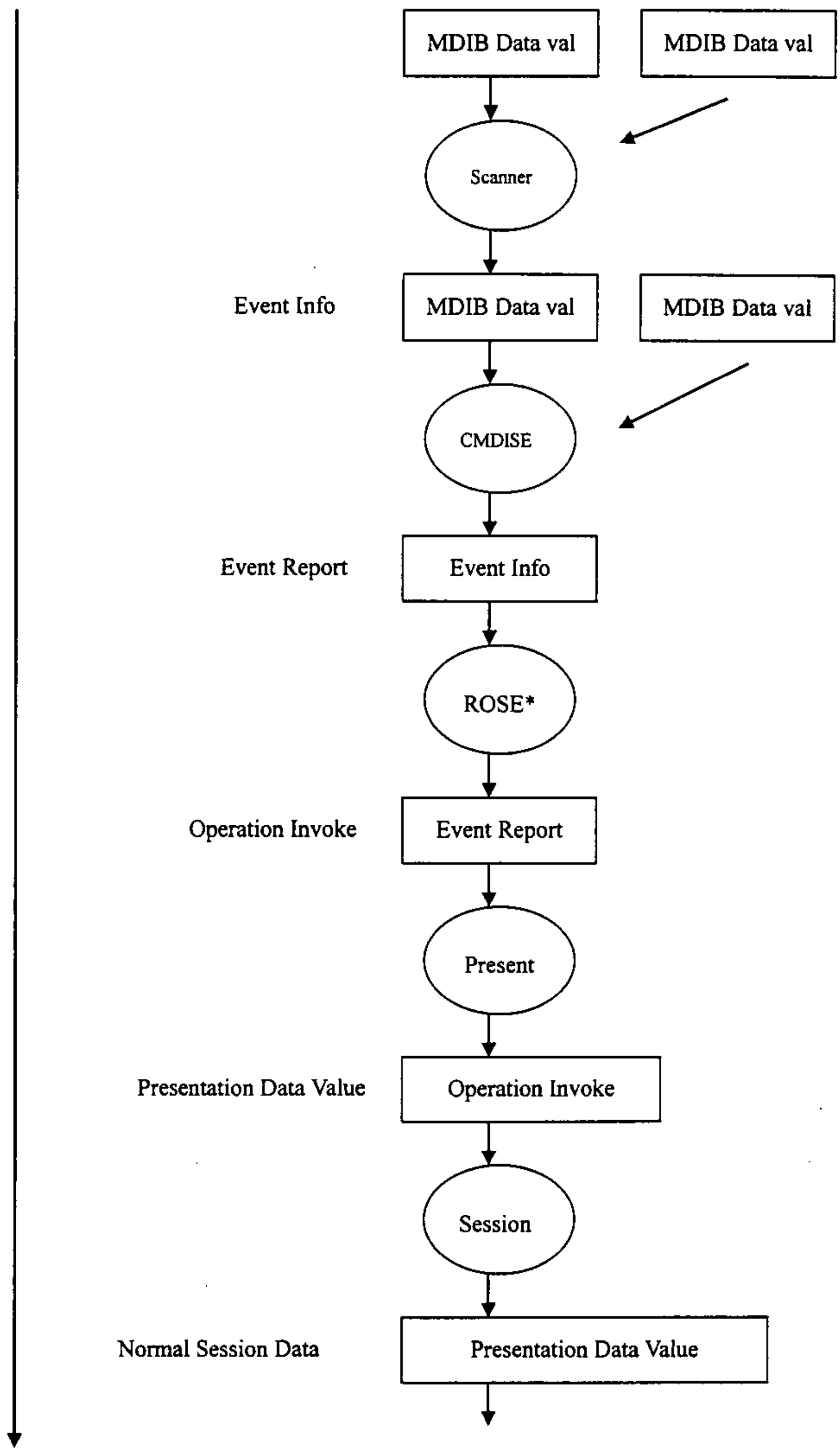
圖二、資料傳輸之網路系統架構

START BIT (LOGIC "0")	DATA (BIT#1)	DATA (BIT#2)	●●●●	DATA (BIT#8)	STOP (LOGIC "1")

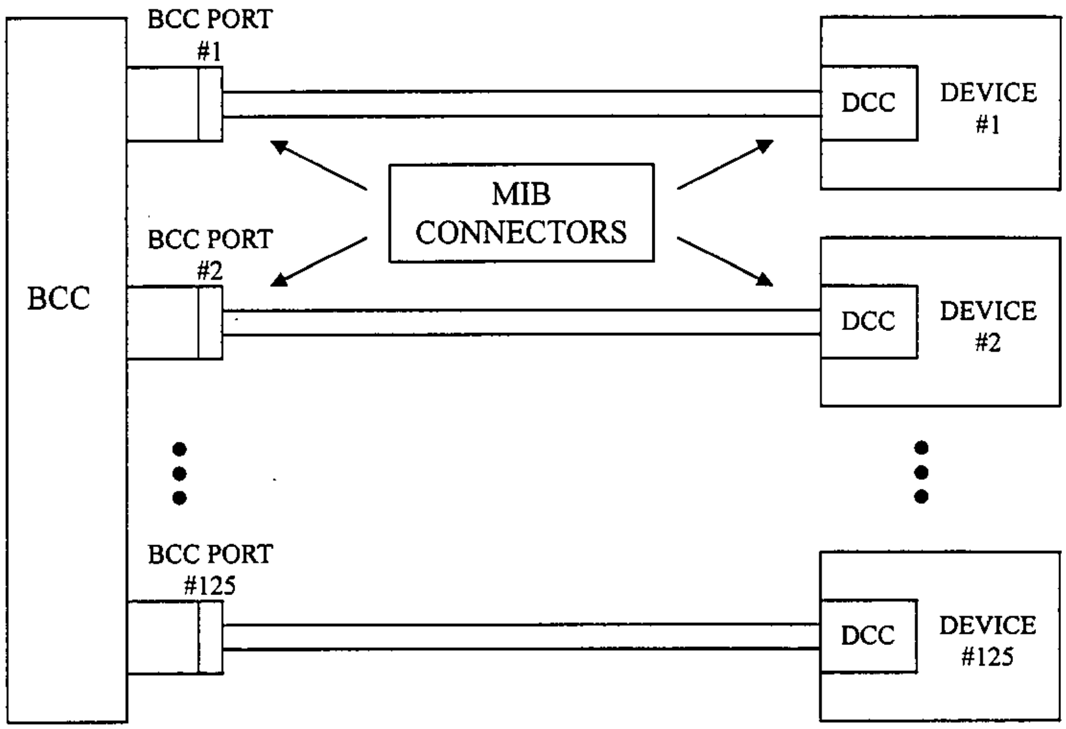
圖三、Low- Speed Octet Encoding



圖四-1、Medical Device Communication Stack

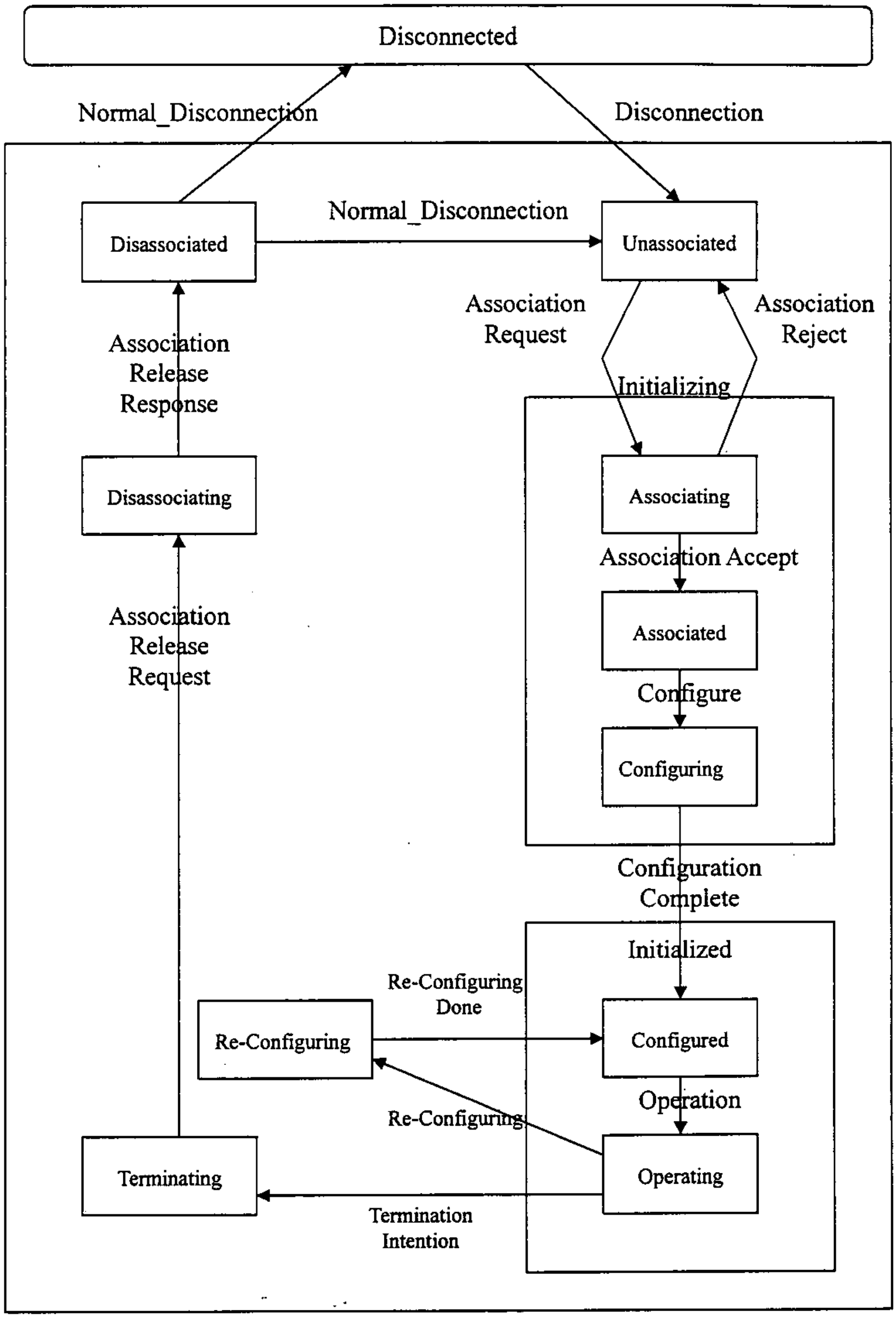


圖四-2、Data Flow through the communication Stack

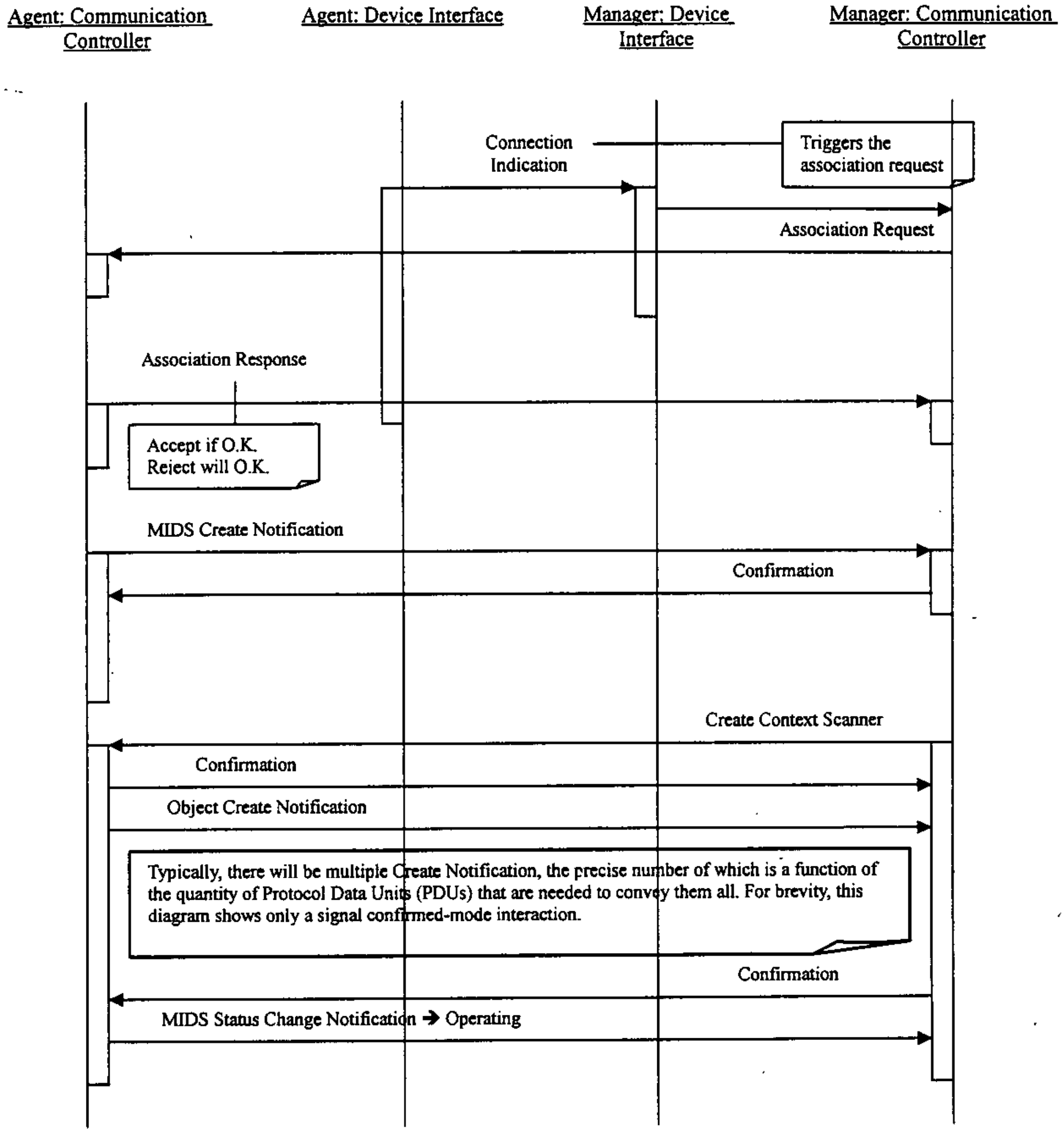


圖五、一個 BCC 經由 MIB 的介面，一次最多可容納 125 個 DCC

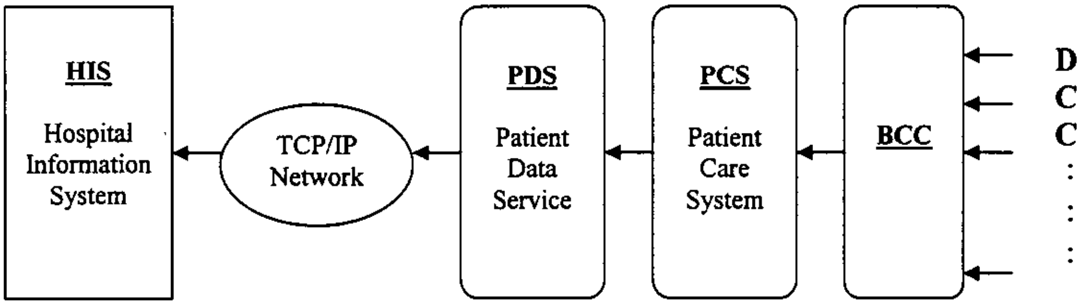
Device Finite-State-Machine (FSM)



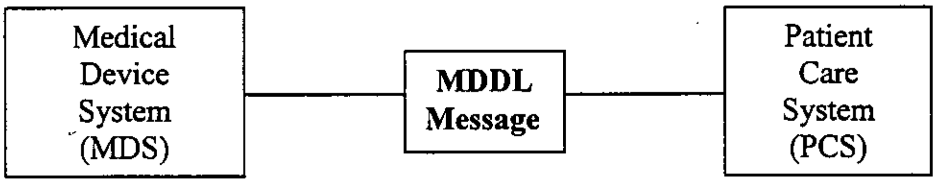
圖六-1 Device State Machine



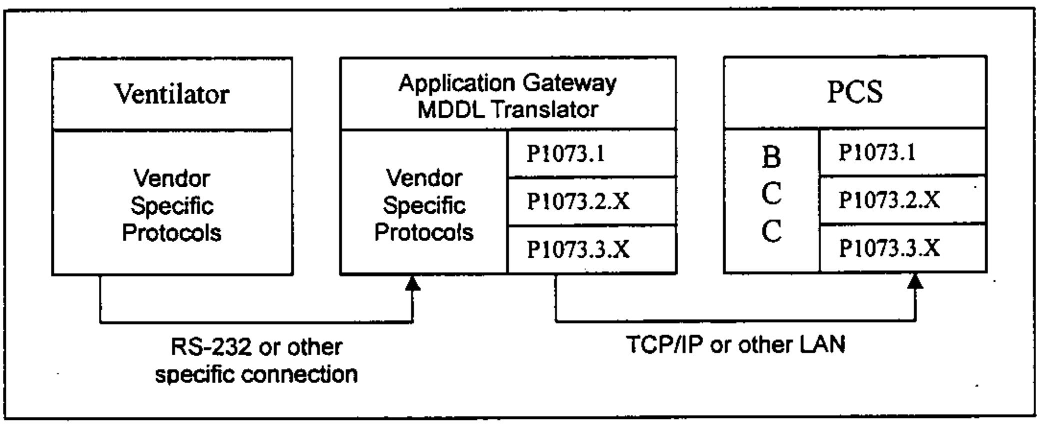
圖六-2　Start-up after Connection



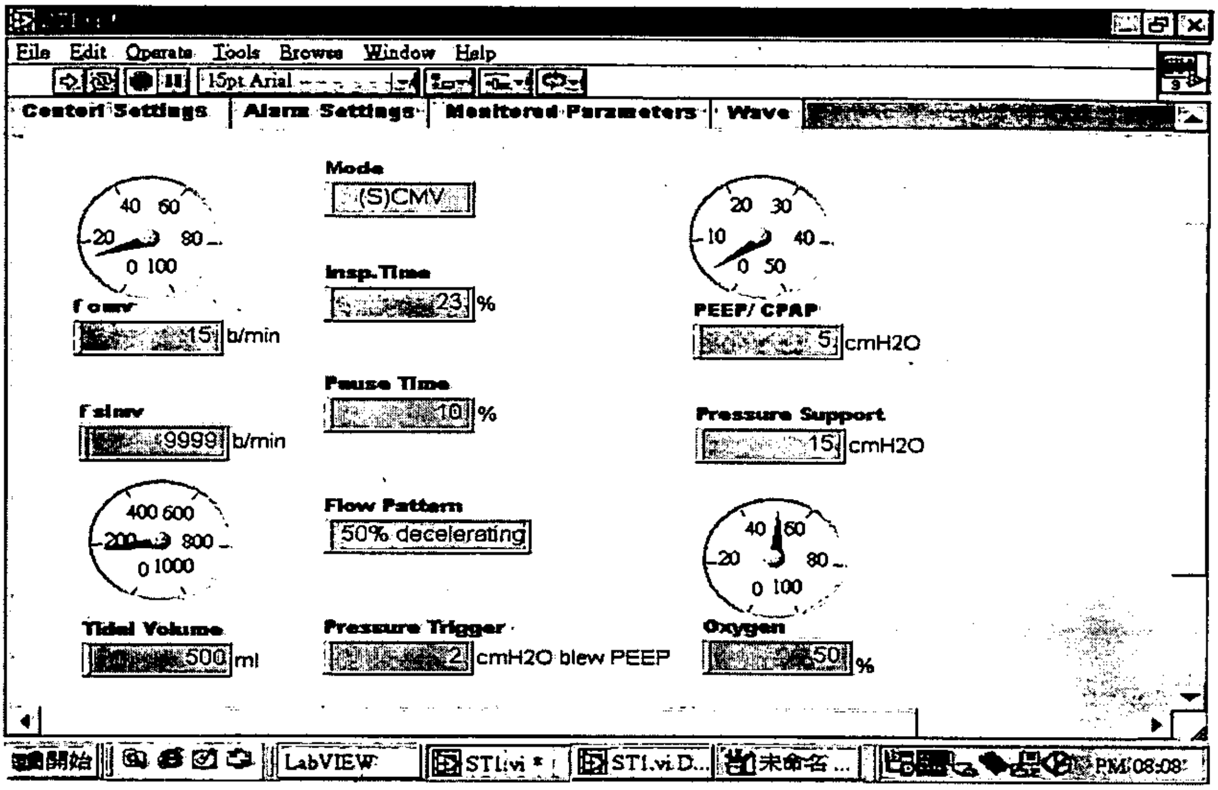
圖七、DCC 的資料經由 BCC 做整合後傳送到病換照護系統(PCS)，以利醫護人員隨時得知病患的生理資訊，做進一步的治療或記錄，經由 TCP/IP 傳送到醫院資訊系統(HIS)



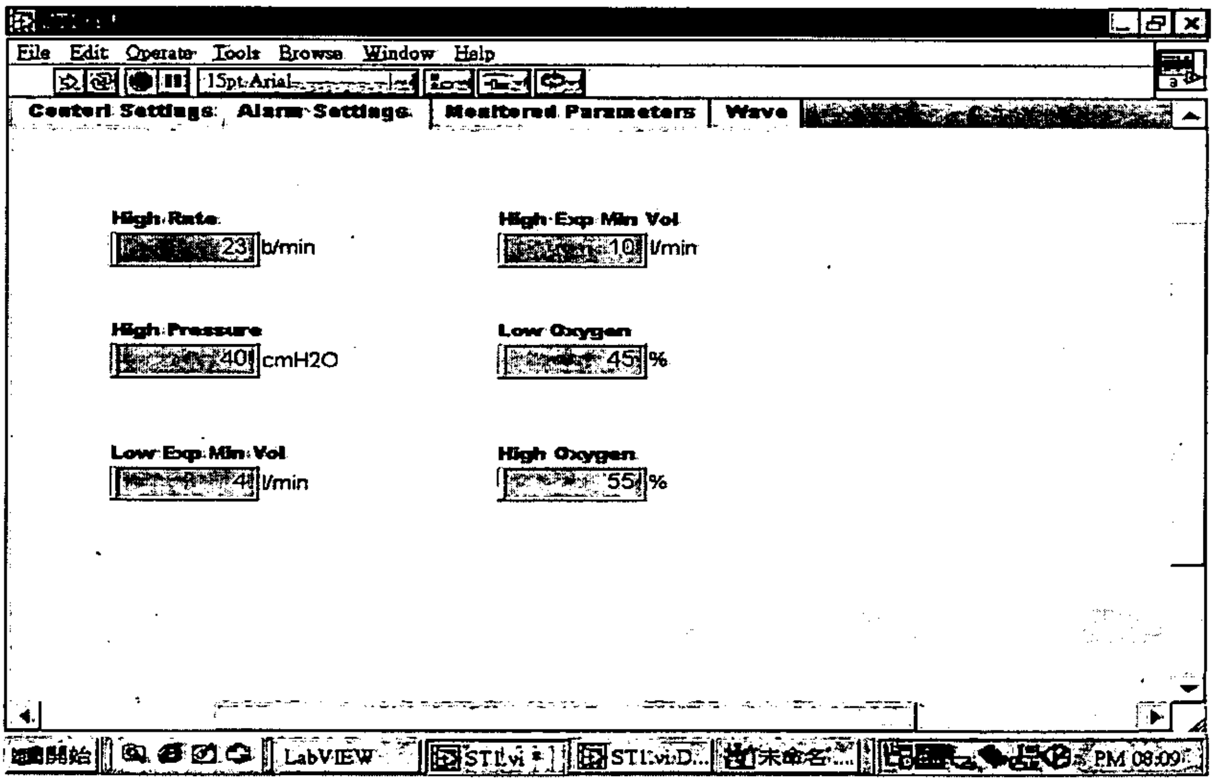
圖八、資訊的交換是藉由醫療設備資料語言(Medical Device Data Language)來做溝通



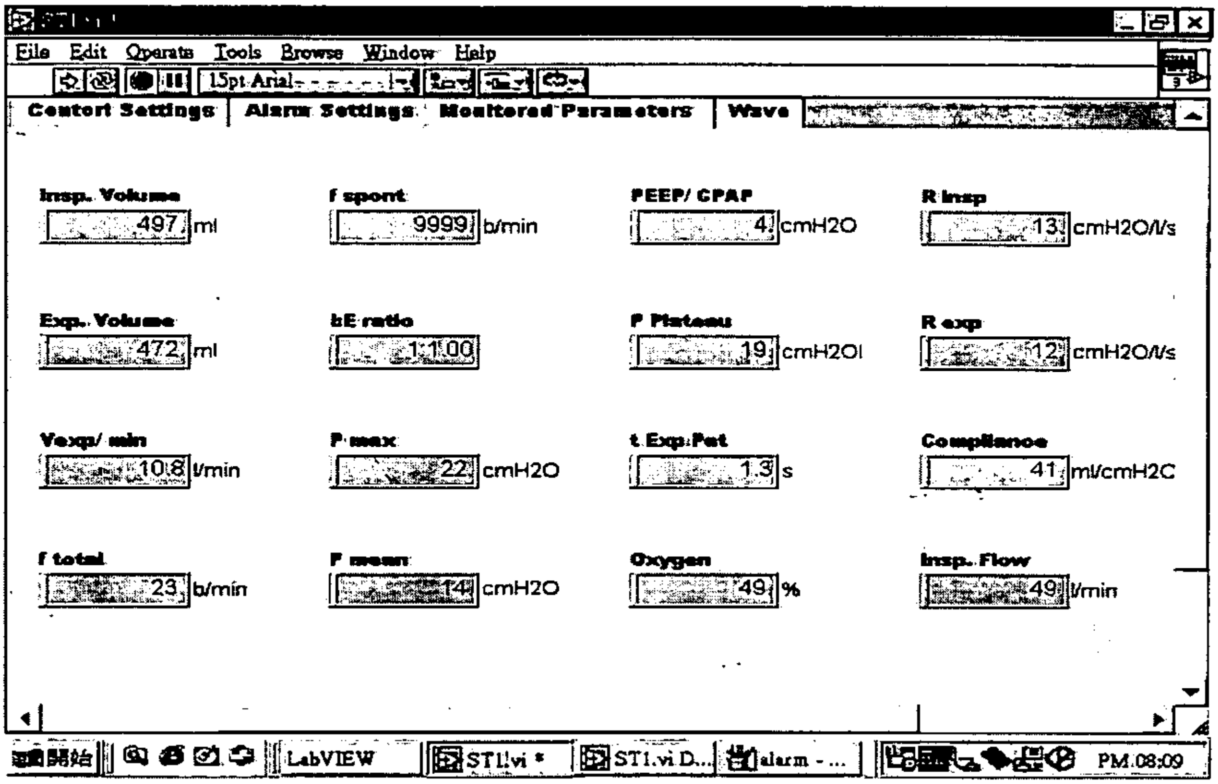
圖九、系統開發概括圖



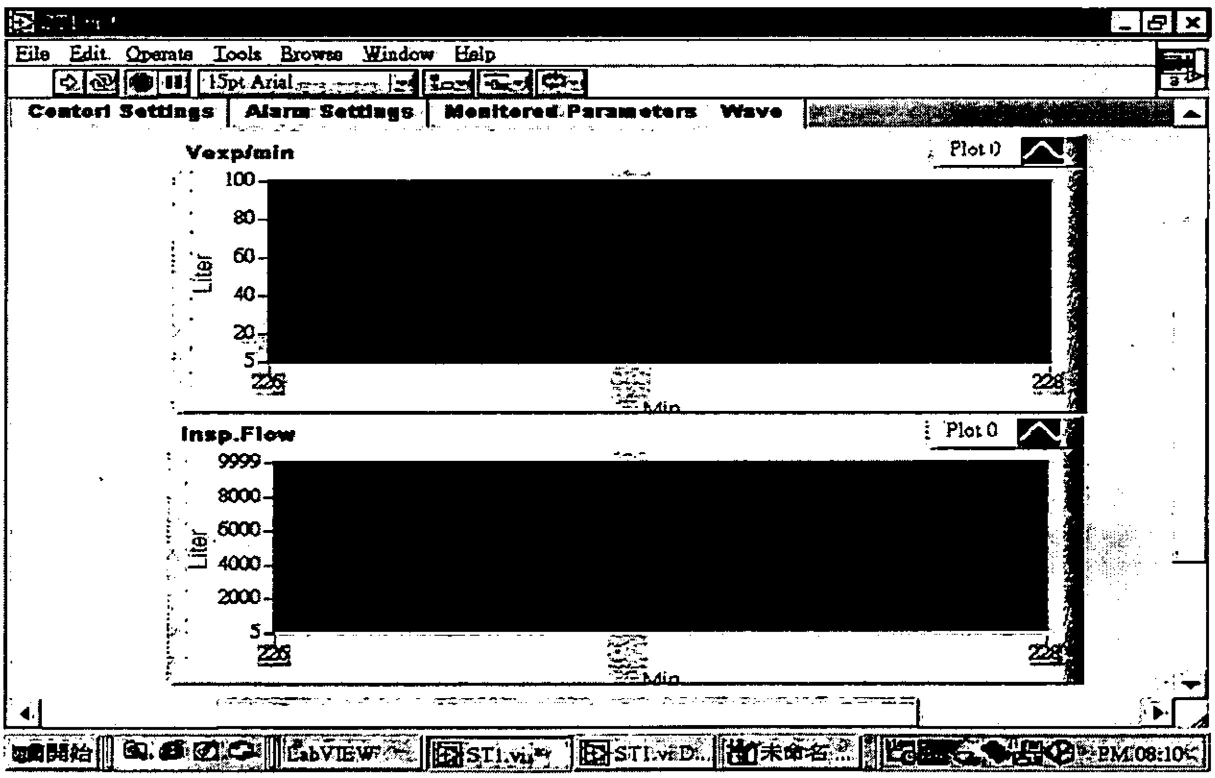
圖十、呼吸機控制參數設定介面(Control settings Interface)



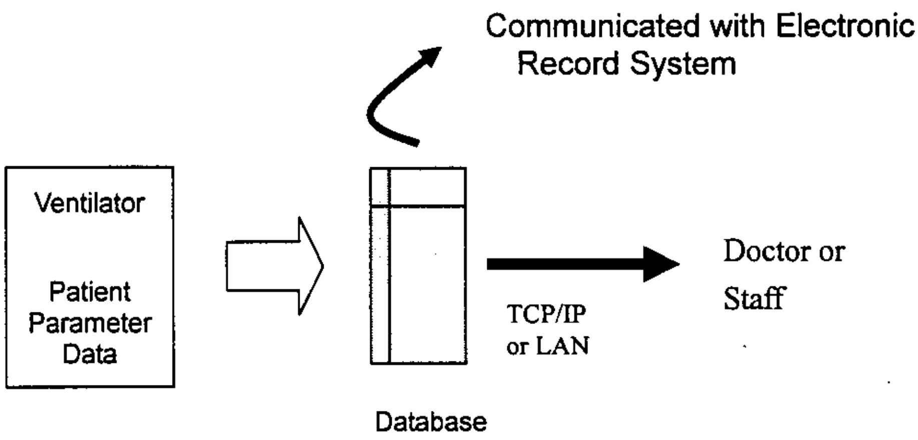
圖十一、呼吸機警告參數設定介面(Alarm settings Interface)



圖十二、呼吸機病患端監視參數介面(Monitored Parameters Interface)



圖十三、呼吸機呼吸參數波形介面(Wave Form Interface)



圖十四、臨床生理參數之儲存模式與電子病例系統之整合

八、表

Parameter	Value
DC contract resistance (pin of meted pair)	30mΩ maximum, initial value
Number of insertions	>5000, with 50mΩ maximum mated pair contact resistance
DC resistance (shield)	20mΩ maximum
Maximum current capacity	≧500mA
Minimum current capacity	DC contact resistance shall remain within the above resistance specification with circuit current ≧100μA
Voltage/ current	30V ac at 1.5A maximum
Breakdown voltage contact-to-contact	≧300V dc
Breakdown voltage contact-to-shield	≧500V dc
Shielding effectiveness	20dB minimum reduction from 70MHZ to 500MHZ; 10dB minimum reduction from 500MHZ to 1GHZ

表一、Connector electrical characteristics

Parameter	Value
Receptacle contact material	Phosphor bronze, selective gold over nickel in contact area and tin-lead over nickel on printed circuit board tails
Plug contact material	Phosphor bronze, gold over nickel, selective in contact area
Receptacle housing material	ISO 1210:1992 and ANSI/ UL flame rating 94 V-0, 120℃ ISO 1210:1992 and ANSI/ UL flame rating 94 V-0, 160℃
Plug housing material	ISO 1210:1992 and ANSI/ UL flame rating 94 V-2, 125℃
Minimum mating force	908g (20 lb)
Maximum mating force	3.63kg (8.0 lb)
Minimum extraction force	1.1 lb
Maximum extraction force	500g (6.5lb)
Number of insertions	>5000
Body of connector: Safety	ISO 1210:1992 and ANSI/ UL flame rating 94 V-0. Design of connector precludes bodily contact with signal and power pins, using test probe defined in UL 2601-1:1994, CSA C22.2 NO. 301.1-M90, and IEC 601-1:1998
Electrostatic discharge (ESD) protection	Upon insertion, the shield shell of the connector shall be designed to engage before any of the circuit contacts and to maintain contact upon withdrawal until all circuit contacts have separated.
Drip immunity and splash immunity	The design, fabrication, or inclusion of an MIB receptacle connector shall not interfere with the equipment's ability to comply with applicable fluid ingress standards such as IEC 529 or others.

表二、Connector mechanical characteristics

Parameter	Value
Jacket	UL-1581: 1991. paragraph 1080,VM-1(Vertical Specimen) Flame Test
Shield	Aluminum polyester with AWG(1559 circular miles) solid drain wire in continuous contact with shield
Insulation	UL-1581: 1991. paragraph 1080,VM-1(Vertical Specimen) Flame Test
Conductors for DATA(+), DATA(-), SENSE/INT/SYNC-IN, and SENSE/INT/SYNC-IN	Minimum 7-atandard, 28 AWG through 24 AWG (159 circular miles through 404 circular miles)
Conductor for +12V and +12V RETURN	Minimum 7-atandard, 24 AWG (404 circular miles)

表三、Cable material

Parameter	**Value**
Baudrate	9600
Databits	7
Stopbits	2
Parity	EVEN
Handshake	XON/XOFF

表四、資料傳輸定義

Byte	**Format**
1	ASCII STX
2	Parameter identifier
3	ASCII EXT
4	ASCII CR

表五、電腦向呼吸機要求資料之格式

Byte	Format
1	ASCII STX
2	Parameter identifier
3	ASCII parameter value
4	ASCII parameter value
5	ASCII parameter value
6	ASCII parameter value
7	ASCII parameter value
8	ASCII EXT
9	ASCII CR

表六、呼吸機回覆電腦之格式

附錄 IEEESTANDARD FOR MEDICAL DEVICE COMMUNICATION

IEEE Std 1073.4.1 1,2000 Edition

from the DCC and provides an input to the BCC. The two special function signals allow a BCC to determine whether a DCC has been connected to a port and allow a DCC to determine whether it has been connected to a BCC port. The special function signals also allow a DCC to issue interrupt requests to the BCC and enable sync pulses to be transmitted by either the BCC or the DCC. Sync pulses may be used for synchronizing a BCC's real-time clock to one or more DCCs, and/or they may be used for event synchronization.

9.2 BCC and DCC special function state tables

Table 2 through Table 8 provide the functional state tables describing the operation of the special function input and output signals for BCCs and DCCs. Table 6 and Table 8 define optional functionality for low-speed DCCs. These two tables are not applicable to low-speed DCCs that do not implement connection sensing, interrupt, or sync capability.

Throughout these tables, "true" refers to a nominal level for the special function input signal of 0 V, and "false" refers to a nominal level for the special function input signal of 12 V. For a BCC, the special function input signal is $\overline{\text{SENSE/INT/SYNC-OUT}}$. For a DCC, the special function input signal is $\overline{\text{SENSE/INT/SYNC-IN}}$.

For Table 2, Initialization: Speed:= high. For the high-speed nominal pulse widths of 3.0 μs, 5.0 μs, and 7.0 μs, a received pulse width within ±500 ns of the nominal width shall be decoded as valid, and a received pulse width outside of ±750 ns from the nominal width shall be decoded as a physical pulse error. For the low-speed nominal pulse widths of 50 μs, 100 μs, and 150 μs, a received pulse width within ±20 μs of the nominal width shall be decoded as valid, and a received pulse width outside of ±22.5 μs from the nominal width shall be decoded as a physical pulse error.

Table 2—BCC special function signals input states

State	Event	Action	Next state
DISCONNECTED	$\overline{\text{SENSE/INT/SYNC-OUT}}$ (input) = true		DISCONNECTED
	$\overline{\text{SENSE/INT/SYNC-OUT}}$ (input) = false		CONNECT TIMER
CONNECT TIMER	$\overline{\text{SENSE/INT/SYNC-OUT}}$ (input) = false and timer (0.1 s) not timed out		CONNECT TIMER
	$\overline{\text{SENSE/INT/SYNC-OUT}}$ (input) = true		DISCONNECTED
	Timer timed out	PH_CONNECT.indication	HIGH-SPEED IDLE
HIGH-SPEED IDLE	PH_DATA_RATE. request, with "speed" parameter = "low"	Speed := low	LOW-SPEED IDLE
	$\overline{\text{SENSE/INT/SYNC-OUT}}$ (input) = false		HIGH-SPEED IDLE
	$\overline{\text{SENSE/INT/SYNC-OUT}}$ (input) = true		0–2.5 μs
0–2.5 μs	$\overline{\text{SENSE/INT/SYNC-OUT}}$ (input) = true and timer (2.5 μs) not timed out		0–2.5 μs
	$\overline{\text{SENSE/INT/SYNC-OUT}}$ (input) = false	PH_PULSE.ERROR. indication	HIGH-SPEED IDLE
	Timer timed out		2.5–3.5 μs

Table 2—BCC special function signals input states (Continued)

State	Event	Action	Next state
2.5–3.5 µs	SENSE/INT/SYNC-OUT (input) = true and timer (1.0 µs) not timed out		2.5–3.5 µs
	SENSE/INT/SYNC-OUT (input) = false	PH_SYNC.indication	HIGH-SPEED IDLE
	Timer timed out		3.5–4.5 µs
3.5–4.5 µs	SENSE/INT/SYNC-OUT (input) = true and timer (1.0 µs) not timed out		3.5–4.5 µs
	SENSE/INT/SYNC-OUT (input) = false	PH_PULSE.ERROR. indication	HIGH-SPEED IDLE
	Timer timed out		4.5–5.5 µs
4.5–5.5 µs	SENSE/INT/SYNC-OUT (input) = true and timer (1.0 µs) not timed out		4.5–5.5 µs
	SENSE/INT/SYNC-OUT (input) = false	PH_INTERRUPT_ ACTIVATE. indication	HIGH-SPEED IDLE
	Timer timed out		5.5–6.5 µs
5.5–6.5 µs	SENSE/INT/SYNC-OUT (input) = true and timer (1.0 µs) not timed out		5.5–6.5 µs
	SENSE/INT/SYNC-OUT (input) = false	PH_PULSE.ERROR. indication	HIGH-SPEED IDLE
	Timer timed out		6.5–7.5 µs
6.5–7.5 µs	SENSE/INT/SYNC-OUT (input) = true and timer (1.0 µs) not timed out		6.5–7.5 µs
	SENSE/INT/SYNC-OUT (input) = false	PH_INTERRUPT_ DEACTIVATE. indication	HIGH-SPEED IDLE
	Timer timed out		DISCONNECT TIMER
DISCONNECT TIMER	SENSE/INT/SYNC-OUT (input) = true and timer (0.1 s) not timed out		DISCONNECT TIMER
	SENSE/INT/SYNC-OUT (input) = false	PH_PULSE.ERROR. indication	HIGH-SPEED IDLE
	Timer timed out	PH_DISCONNECT. indication	DISCONNECTED
LOW-SPEED IDLE	SENSE/INT/SYNC-OUT (input) = false		LOW-SPEED IDLE
	SENSE/INT/SYNC-OUT (input) = true		0–30 µs
0–30 µs	SENSE/INT/SYNC-OUT (input) = true and timer (30 µs) not timed out		0–30 µs
	SENSE/INT/SYNC-OUT (input) = false	PH_PULSE.ERROR. indication	LOW-SPEED IDLE
	Timer timed out		30–70 µs

Table 2—BCC special function signals input states (Continued)

State	Event	Action	Next state
30–70 μs	SENSE/INT/SYNC-OUT (input) = true and timer (40 μs) not timed out		30–70 μs
	SENSE/INT/SYNC-OUT (input) = false	PH_SYNC.indication	LOW-SPEED IDLE
	Timer timed out		70–80 μs
70–80 μs	SENSE/INT/SYNC-OUT (input) = true and timer (10 μs) not timed out		70–80 μs
	SENSE/INT/SYNC-OUT (input) = false	PH_PULSE.ERROR. indication	LOW-SPEED IDLE
	Timer timed out		80–120 μs
80–120 μs	SENSE/INT/SYNC-OUT (input) = true and timer (40 μs) not timed out		80–120 μs
	SENSE/INT/SYNC-OUT (input) = false	PH_INTERRUPT_ ACTIVATE. indication	LOW-SPEED IDLE
	Timer timed out		120–130 μs
120–130 μs	SENSE/INT/SYNC-OUT (input) = true and timer (10 μs) not timed out		120–130 μs
	SENSE/INT/SYNC-OUT (input) = false	PH_PULSE.ERROR. indication	LOW-SPEED IDLE
	Timer timed out		130–170 μs
130–170 μs	SENSE/INT/SYNC-OUT (input) = true and timer (40 μs) not timed out		130–170 μs
	SENSE/INT/SYNC-OUT (input) = false	PH_INTERRUPT_ DEACTIVATE. indication	LOW-SPEED IDLE
	Timer timed out		LOW-SPEED DISCONNECT TIMER
LOW-SPEED DISCONNECT TIMER	SENSE/INT/SYNC-OUT (input) = true and timer (0.1 s) not timed out		LOW-SPEED DISCONNECT TIMER
	SENSE/INT/SYNC-OUT (input) = false	PH_PULSE.ERROR. indication	LOW-SPEED IDLE
	Timer timed out	PH_DISCONNECT. indication	DISCONNECTED

Table 3—High-speed BCC special function signal output states

State	Event	Action	Next state
IDLE	PH_SYNC.request	Delay 1μs SYNC_FLAG := INT_DEACT_ FLAG := false Timer := 3 μs $\overline{\text{SENSE/INT/SYNC-IN}}$ (output) := true	OUTPUT PULSE
	PH_INTERRUPT_ DEACTIVATE.request	Delay 1 μs SYNC_FLAG := INT_DEACT_ FLAG := false Timer := 7 μs $\overline{\text{SENSE/INT/SYNC-IN}}$ (output) := true	OUTPUT PULSE
OUTPUT PULSE	PH_SYNC.request	SYNC_FLAG := true	OUTPUT PULSE
	PH_INTERRUPT_ DEACTIVATE.request	INT_DEACT_FLAG := true	OUTPUT PULSE
	Timer timed out and SYNC_FLAG = true	$\overline{\text{SENSE/INT/SYNC-IN}}$ (output) := false Delay 5 μs SYNC_FLAG := false Timer := 3 μs $\overline{\text{SENSE/INT/SYNC-IN}}$ (output) := true	OUTPUT PULSE
	Timer timed out and INT_DEACT_FLAG = true	$\overline{\text{SENSE/INT/SYNC-IN}}$ (output) := false Delay 5 μs INT_DEACT_FLAG := false Timer := 7 μs $\overline{\text{SENSE/INT/SYNC-IN}}$ (output) := true	OUTPUT PULSE
	Timer timed out and SYNC_FLAG = INT_ DEACT_FLAG = false	$\overline{\text{SENSE/INT/SYNC-IN}}$ (output) := false	IDLE

Table 4—Low-speed BCC special function signal output states

State	Event	Action	Next state
IDLE	PH_SYNC.request	Delay 10 µs SYNC_FLAG := INT_ DEACT_FLAG := false Timer := 50 µs $\overline{\text{SENSE/INT/SYNC-IN}}$ (output) := true	OUTPUT PULSE
	PH_INTERRUPT_ DEACTIVATE.request	Delay 10 µs SYNC_FLAG := INT_ DEACT_FLAG := false Timer := 150 µs $\overline{\text{SENSE/INT/SYNC-IN}}$ (output) := true	OUTPUT PULSE
OUTPUT PULSE	PH_SYNC.request	SYNC_FLAG := true	OUTPUT PULSE
	PH_INTERRUPT_ DEACTIVATE.request	INT_DEACT_FLAG := true	OUTPUT PULSE
	Timer timed out and SYNC_ FLAG = true	$\overline{\text{SENSE/INT/SYNC-IN}}$ (output) := false Delay 50 µs SYNC_FLAG := false Timer := 50 µs $\overline{\text{SENSE/INT/SYNC-IN}}$ (output) := true	OUTPUT PULSE
	Timer timed out and INT_DEACT_FLAG = true	$\overline{\text{SENSE/INT/SYNC-IN}}$ (output) := false Delay 50 µs INT_DEACT_FLAG := false Timer := 150 µs $\overline{\text{SENSE/INT/SYNC-IN}}$ (output) := true	OUTPUT PULSE
	Timer timed out and SYNC_ FLAG = INT_DEACT_FLAG = false.	$\overline{\text{SENSE/INT/SYNC-IN}}$ (output) := false	IDLE

Regarding Table 5, for the high-speed nominal pulse widths of 3.0 µs, 5.0 µs, and 7.0 µs, a received pulse width within ±500 ns of the nominal width shall be decoded as valid, and a received pulse width outside of ±750 ns from the nominal width shall be decoded as a physical pulse error.

Table 5—High-speed DCC special function signal input states

State	Event	Action	Next state
DISCONNECTED	SENSE/INT/SYNC-IN (input) = true		DISCONNECTED
	SENSE/INT/SYNC-IN (input) = false		CONNECT TIMER
CONNECT TIMER	SENSE/INT/SYNC-IN (input) = false and timer (0.1 s) not timed out		CONNECT TIMER
	SENSE/INT/SYNC-IN (input) = true		DISCONNECTED
	Timer timed out	PH_CONNECT.indication	IDLE
IDLE	SENSE/INT/SYNC-IN (input) = false		IDLE
	SENSE/INT/SYNC-IN (input) = true		0–2.5 µs
0–2.5 µs	SENSE/INT/SYNC-IN (input) = true and timer (2.5 µs) not timed out		0–2.5 µs
	SENSE/INT/SYNC-IN (input) = false	PH_PULSE.ERROR.indication	IDLE
	Timer timed out		2.5–3.5 µs
2.5–3.5 µs	SENSE/INT/SYNC-IN (input) = true and timer (1.0 µs) not timed out		2.5–3.5 µs
	SENSE/INT/SYNC-IN (input) = false	PH_SYNC.indication	IDLE
	Timer timed out		3.5–4.5 µs
3.5–6.5 µs	SENSE/INT/SYNC-IN (input) = true and timer (3.0 µs) not timed out		3.5–4.5 µs
	SENSE/INT/SYNC-IN (input) = false	PH_PULSE.ERROR.indication	IDLE
	Timer timed out		4.5–5.5 µs
6.5–7.5 µs	SENSE/INT/SYNC-IN (input) = true and timer (1.0 µs) not timed out		6.5–7.5 µs
	SENSE/INT/SYNC-IN (input) = false	PH_INTERRUPT_ DEACTIVATE.indication	IDLE
	Timer timed out		DISCONNECT TIMER
DISCONNECT TIMER	SENSE/INT/SYNC-IN (input) = true and timer (0.1 s) not timed out		DISCONNECT TIMER
	SENSE/INT/SYNC-IN (input) = false	PH_PULSE.ERROR.indication	IDLE
	Timer timed out	PH_DISCONNECT.indication	DISCONNECTED

Regarding Table 6, for the low-speed nominal pulse widths of 50 µs, 100 µs, and 150 µs, a received pulse width within ±20 µs of the nominal width shall be decoded as valid, and a received pulse width outside of ±22.5 µs from the nominal width shall be decoded as a physical pulse error.

Table 6—Low-speed DCC special function signal input states

State	Event	Action	Next state
DISCONNECTED	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = true		DISCONNECTED
	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = false		CONNECT TIMER
CONNECT TIMER	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = false and timer (0.1 s) not timed out		CONNECT TIMER
	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = true		DISCONNECTED
	Timer timed out	PH_CONNECT.indication	IDLE
IDLE	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = false		IDLE
	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = true		0–30 µs
0–30 µs	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = true and timer (30 µs) not timed out		0–30 µs
	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = false	PH_PULSE.ERROR.indication	IDLE
	Timer timed out		30–70 µs
30–70 µs	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = true and timer (40 µs) not timed out		30–70 µs
	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = false	PH_SYNC.indication	IDLE
	Timer timed out		70–130 µs
70–130 µs	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = true and timer (60 µs) not timed out		70–130 µs
	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = false	PH_PULSE.ERROR.indication	IDLE
	Timer timed out		130–170 µs
130–170 µs	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = true and timer (40 µs) not timed out		130–170 µs
	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = false	PH_INTERRUPT_ DEACTIVATE.indication	IDLE
	Timer timed out		DISCONNECT TIMER
DISCONNECT TIMER	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = true and timer (0.1 s) not timed out		DISCONNECT TIMER
	$\overline{\text{SENSE/INT/SYNC-IN}}$ (input) = false	PH_PULSE.ERROR.indication	IDLE
	Timer timed out	PH_DISCONNECT.indication	DISCONNECTED

Table 7—Special function signal output states for high-speed DCCs

State	Event	Action	Next state
IDLE	PH_SYNC.request	Delay 1 µs Timer := 3 µs SYNC_FLAG := INT_ACT_FLAG := INT_DEACT_FLAG := false SENSE/INT/SYNC-OUT := true	OUTPUT PULSE
	PH_INTERRUPT_ACTIVATE.r equest	Delay 1 µs Timer := 5 µs SYNC_FLAG := INT_ACT_FLAG := INT_DEACT_FLAG := false SENSE/INT/SYNC-OUT := true	OUTPUT PULSE
	PH_INTERRUPT_ DEACTIVATE.request	Delay 1 µs Timer := 7 µs SYNC_FLAG := INT_ACT_FLAG := INT_DEACT_FLAG := false SENSE/INT/SYNC-OUT := true	OUTPUT PULSE
OUTPUT PULSE	PH_SYNC.request	SYNC_FLAG := true	OUTPUT PULSE
	PH_INTERRUPT_ACTIVATE.r equest	INT_ACT_FLAG := true	OUTPUT PULSE
	PH_INTERRUPT_ DEACTIVATE.request	INT_DEACT_FLAG := true	OUTPUT PULSE
	Timer timed out and SYNC_ FLAG := true	SENSE/INT/SYNC-OUT := false Delay 5 µs SYNC_FLAG := false Timer := 3 µs SENSE/INT/SYNC-OUT := true	OUTPUT PULSE
	Timer timed out and INT_ACT_FLAG := true	SENSE/INT/SYNC-OUT := false Delay 5 µs INT_ACT_FLAG := false Timer := 5 µs SENSE/INT/SYNC-OUT := true	OUTPUT PULSE
	Timer timed out and INT_DEACT_FLAG = true	SENSE/INT/SYNC-OUT := false Delay 5 µs INT_DEACT_FLAG := false Timer := 7 µs SENSE/INT/SYNC-OUT := true	OUTPUT PULSE
	Timer timed out and SYNC_ FLAG = INT_ACT_FLAG = INT_DEACT_FLAG = false	SENSE/INT/SYNC-OUT := false	IDLE

Table 8—Special function signal output states for low-speed DCCs with sync and/or interrupt capability

State	Event	Action	Next state
IDLE	PH_SYNC.request	Delay 10 µs Timer := 50 µs SYNC_FLAG := INT_ACT_FLAG := INT_DEACT_FLAG := false $\overline{\text{SENSE/INT/SYNC-OUT}}$:= true	OUTPUT PULSE
	PH_INTERRUPT_ ACTIVATE.request	Delay 10 µs Timer := 100 µs SYNC_FLAG := INT_ACT_FLAG := INT_DEACT_FLAG := false $\overline{\text{SENSE/INT/SYNC-OUT}}$:= true	OUTPUT PULSE
	PH_INTERRUPT_ DEACTIVATE.request	Delay 10 µs Timer := 150 µs SYNC_FLAG := INT_ACT_FLAG := INT_DEACT_FLAG := false $\overline{\text{SENSE/INT/SYNC-OUT}}$:= true	OUTPUT PULSE
OUTPUT PULSE	PH_SYNC.request	SYNC_FLAG := true	OUTPUT PULSE
	PH_INTERRUPT_ ACTIVATE.request	INT_ACT_FLAG := true	OUTPUT PULSE
	PH_INTERRUPT_ DEACTIVATE.request	INT_DEACT_FLAG := true	OUTPUT PULSE
	Timer timed out and SYNC_FLAG := true	$\overline{\text{SENSE/INT/SYNC-OUT}}$:= false Delay 50 µs SYNC_FLAG := false Timer := 50 µs $\overline{\text{SENSE/INT/SYNC-OUT}}$:= true	OUTPUT PULSE
	Timer timed out and INT_ACT_FLAG := true	$\overline{\text{SENSE/INT/SYNC-OUT}}$:= false Delay 50 µs INT_ACT_FLAG := false Timer := 100 µs $\overline{\text{SENSE/INT/SYNC-OUT}}$:= true	OUTPUT PULSE
	Timer timed out and INT_DEACT_FLAG = true	$\overline{\text{SENSE/INT/SYNC-OUT}}$:= false Delay 50 µs INT_DEACT_FLAG := false Timer := 150 µs $\overline{\text{SENSE/INT/SYNC-OUT}}$:= true	OUTPUT PULSE
	Timer timed out and SYNC_FLAG = INT_ACT_FLAG = INT_DEACT_FLAG = false	$\overline{\text{SENSE/INT/SYNC-OUT}}$:= false	IDLE

10. Common electrical interconnection specifications

This standard provides for three different rates of communication between a BCC and DCC:

a) Low-speed rates of 2400 Bd and 9600 Bd
b) High-speed rate of 1 Mb/s

This clause defines the areas of commonality between the two implementations. A DCC is required to operate at one of the three data rates, while all ports of a BCC shall be able to communicate with attached DCCs at all three data rates. A DCC may not change its data rate between the time of logical connection establishment and the time of physical disconnect.

10.1 Overview

The domain of the IEEE 1073.4.1 electrical interconnection equipment is to provide a point-to-point data transmission medium between the BCC and the DCC.

The remainder of this clause defines the electrical and mechanical characteristics for the equipment that are applicable to both data rates. This ensures provision of a reliable, point-to-point data transmission medium that interconnects a BCC with one or more DCCs.

This clause includes discussions of

a) Topology and configuration rules
b) Power requirements
c) Mechanical, cable, and connector requirements
d) Electromagnetic compatibility (EMC) and safety
e) Electrical and functional operation of the special function signals, $\overline{\text{SENSE/INT/SYNC-IN}}$ and $\overline{\text{SENSE/INT/SYNC-OUT}}$
f) BCC-to-DCC interconnection drawing

As shown in Figure 13, the electrical interconnection occupies the lowest level of the Open Systems Interconnection (OSI) reference model.

Additionally, the BCC supplies to the DCC +12 V power, which may be used to power isolate communications hardware or may be used for other purposes by the DCC. In the same cable connection, provisions are included to allow the BCC to determine whether a DCC is connected to a particular port without having to poll that particular port. For the low-speed version of the Physical layer, a mechanism is provided to allow a transmitting Physical layer entity to delineate the beginning and end of individual frames to the receiving Physical layer entity.

In addition, a pair of special function wires allows a DCC to issue interrupt requests to a BCC and for a BCC or a DCC to provide a synchronization output pulse. This pulse may be used to synchronize the values of the real-time clocks for a BCC and one or more DCCs.

The specified cable provides six conductors consisting of a twisted pair for serial data transmission, a twisted pair for power (+12 V and +12 V RETURN), and individual conductors for the two special function signals, $\overline{\text{SENSE/INT/SYNC-IN}}$ and $\overline{\text{SENSE/INT/SYNC-OUT}}$. See Figure 18 and Figure 19. The naming of the two special function signals is with respect to the DCC, not the BCC.

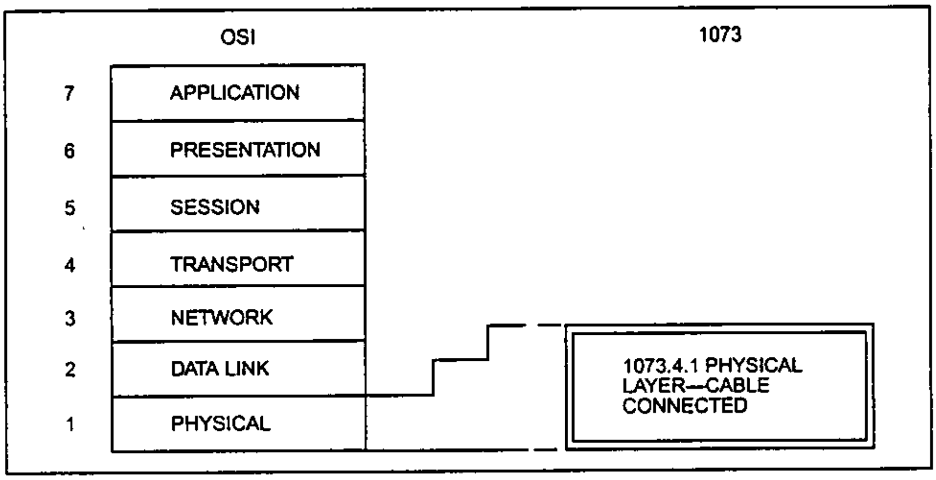


Figure 13—IEEE 1073.4.1 Physical layer relationship to OSI reference model

The cable includes an overall shield, enclosing all six conductors. The shielding conductor is radio frequency (RF) bonded to the backshells of the cable plug connectors. The shield is provided to minimize susceptibility of the data to outside interference and prevent undesirable interference emissions.

Data generators and receivers for IEEE Std 1073.4.1, 2000 Edition are specified to conform to the requirements of ISO/IEC 8482:1993. For this standard, if any differences exist between this standard and ISO/IEC 8482:1993, this standard shall have precedence.

The IEEE 1073.4.1 connector provides for ease of connection and disconnection, with a long service life. While based upon a proven connector technology, it has a unique design specifically for this standard. Features include protected contacts, good shield bonding, ease of use, electrical safety, and resistance to common hospital cleaning agents.

10.2 Topology and configuration rules

The general topology for connecting one or more DCCs/devices to a BCC is illustrated in Figure 14. There is a separate MIB cable for each DCC/device connection. A maximum of 125 different DCCs/devices can be connected to a single BCC. The Data Link layer provides support for up to 125 port addresses on a BCC. A BCC shall not be associated with more than one patient. There is no limitation on the number of BCCs that may be used to connect to DCCs/devices for the same patient.

10.3 BCC power distribution to DCCs

Every BCC port shall provide +12 V power for the data communication hardware of a DCC connected to it. Use of the supplied +12 V power is optional for DCCs.

10.3.1 BCC requirements

10.3.1.1 Voltage

Each BCC port shall supply +12 V ± 0.6 V dc. The +12 V positive terminal will carry +12 V dc relative to the +12 V RETURN terminal. This voltage tolerance will be applicable over the range of current from 0 mA to 325 mA.

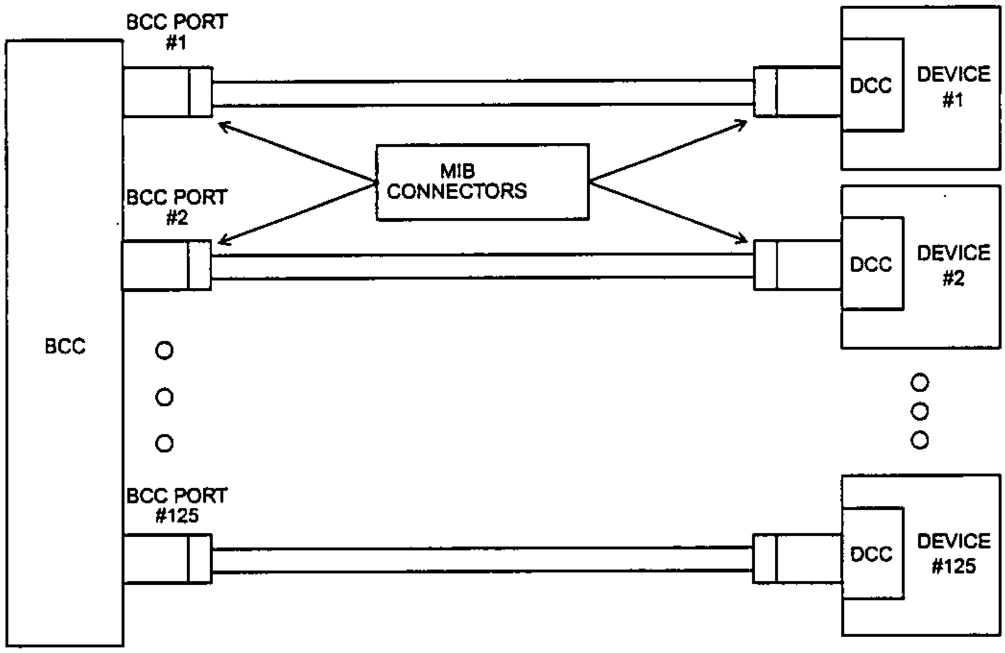


Figure 14—BCC-to-DCCs connection topology

10.3.1.2 Ripple voltage

The maximum ripple voltage shall be 250 mv peak to peak.

10.3.1.3 Current limit

For each BCC port, there shall be a current limit, with a limiting value (short-circuit current) of < 600 mA.

10.3.2 Requirements for MIB-powered DCCs

10.3.2.1 Voltage range

For an MIB-powered DCC, the DCC shall operate over the range of voltages from 9.8 V to 12.6 V.

10.3.2.2 Current drain

The maximum DCC current from the BCC port's +12 V output shall not exceed 300 mA.

10.4 Connector requirements

The IEEE 1073.4.1 plug and associated receptacle are unique and purposely incompatible with any existing connector system.

10.4.1 Mechanical dimensions

Mechanical dimensions for the shielded receptacle are detailed in Figure 15. Mechanical dimensions for the shielded cable plug are detailed in Figure 16. The connector latches are illustrated for reference only. Mechanical dimensions for the cable plug boot are detailed in Figure 17.

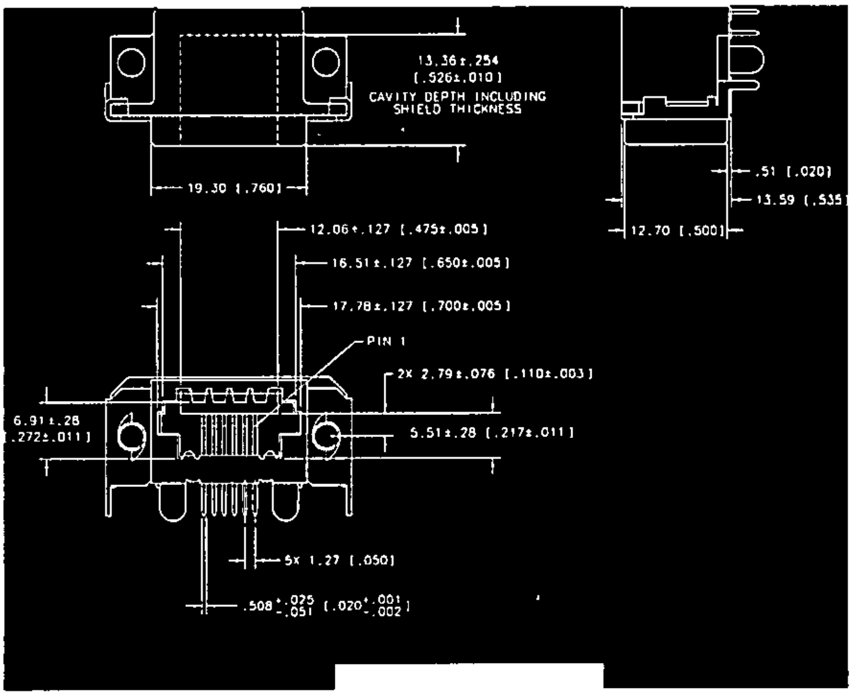
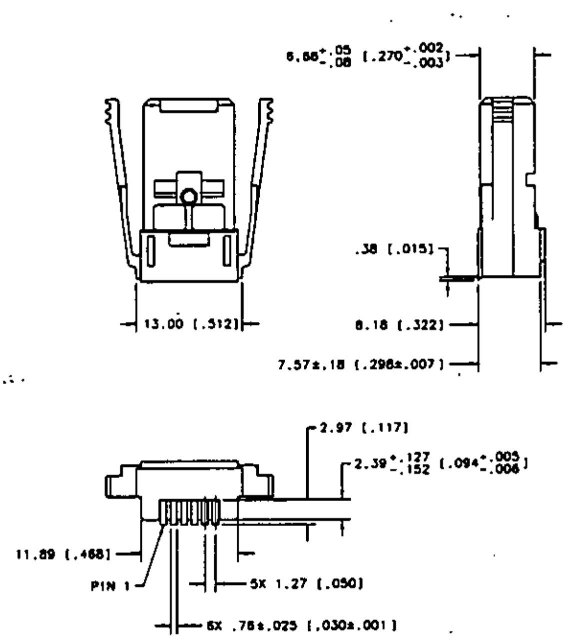


Figure 15—IEEE 1073.4.1 connector-shielded receptacle mechanical specifications



NOTE—DIMENSIONS ARE IN MILLIMETERS [INCHES].

Figure 16—IEEE 1073.4.1 connector-shielded plug mechanical specifications

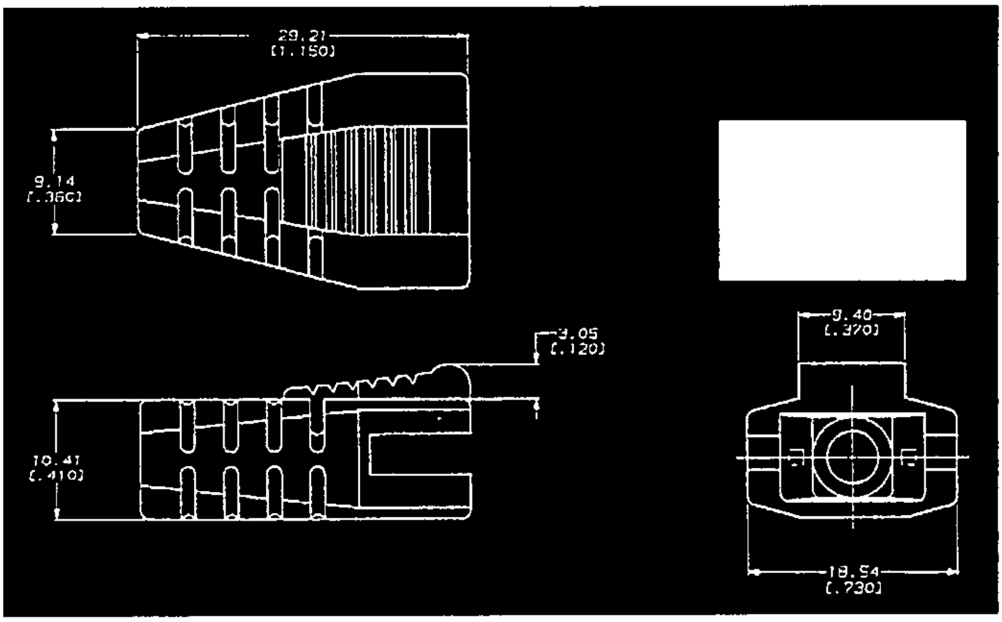


Figure 17—IEEE 1073.4.1 connector-shielded plug boot specifications

10.4.2 Electrical characteristics

Table 9 summarizes the electrical requirements for the connectors.

10.4.3 Mechanical characteristics

Table 10 summarizes the mechanical requirements for the connectors.

10.5 Cable requirements

10.5.1 Number of conductors

The cable shall have six conductors: two data signal conductors, two power conductors, and two special function signal conductors. The two data signal conductors shall be a twisted pair. The two power conductors shall also be a twisted pair. The two special signal conductors shall be individual wires, not a twisted pair. There is also a single shield with a drain wire. Figure 18 provides a schematic representation of the cable configuration. Figure 19 provides a cross-sectional drawing of the cable.

10.5.2 Wire gauge

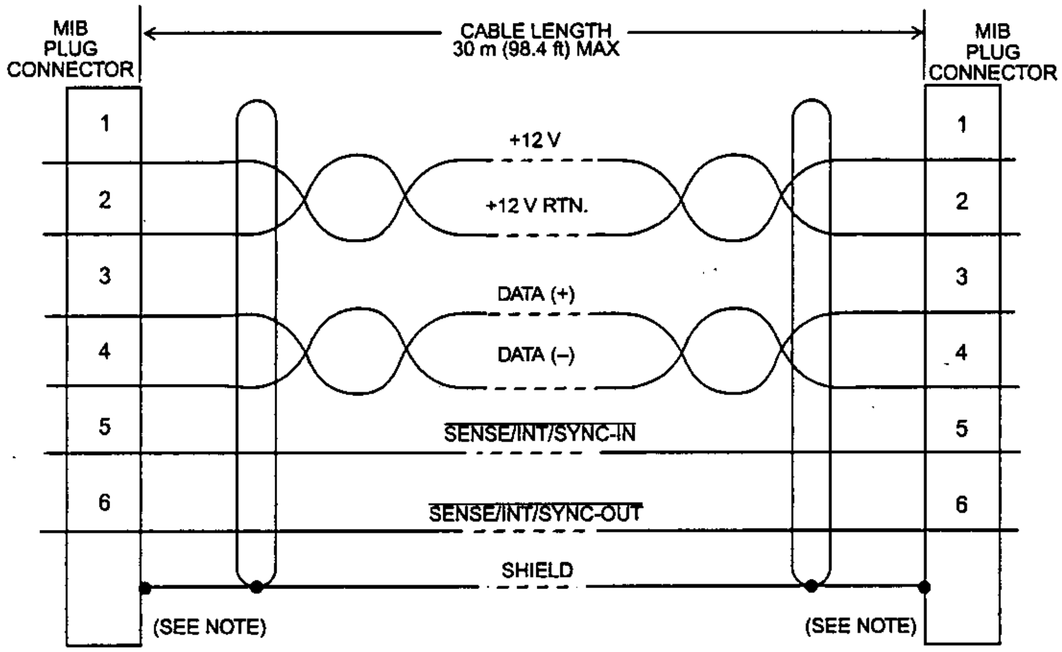
The wire gauge for the power pair shall be 24 AWG (404 circular mils). The wire size for the other four signals shall be between 28 AWG and 24 AWG (159 circular mils and 404 circular mils).

Table 9—Connector electrical characteristics

Parameter	Value
DC contact resistance (pins of mated pair)	30 mΩ maximum, initial value
Number of insertions	> 5000, with 50 mΩ maximum mated pair contact resistance
DC resistance (shield)	20 mΩ maximum
Maximum current capacity	≥ 500 mA
Minimum current capacity	DC contact resistance shall remain within the above resistance specification with circuit current ≥ 100 μA
Voltage/current	30 V ac at 1.5 A maximum
Breakdown voltage contact-to-contact	≥ 300 V dc
Breakdown voltage contact-to-shield	≥ 500 V dc
Shielding effectiveness	20 dB minimum reduction from 70 MHz to 500 MHz; 10 dB minimum reduction from 500 MHz to 1 GHz

Table 10—Connector mechanical characteristics

Parameter	Value
Receptacle contact material	Phosphor bronze, selective gold over nickel in contact area and tin-lead over nickel on printed circuit board tails
Plug contact material	Phosphor bronze, gold over nickel, selective in contact area
Receptacle housing material	ISO 1210:1992 and ANSI/UL flame rating 94 V-0, 120 °C; ISO 1210:1992 and ANSI/UL flame rating 94 V-0, 160 °C
Plug housing material	ISO 1210:1992 and ANSI/UL flame rating 94 V-2, 125 °C
Minimum mating force	908 g (2.0 lb)
Maximum mating force	3.63 kg (8.0 lb)
Minimum extraction force	1.1 lb
Maximum extraction force	500 g (6.5 lb)
Number of insertions	> 5000
Body of connector: Safety	ISO 1210:1992 and ANSI/UL flame rating 94 V-0. Design of connector precludes bodily contact with signal and power pins, using test probes defined in UL 2601-1:1994, CSA C22.2 No. 601.1-M90, and IEC 601-1:1988.
Electrostatic discharge (ESD) protection	Upon insertion, the shield shell of the connector shall be designed to engage before any of the circuit contacts and to maintain contact upon withdrawal until all circuit contacts have separated.
Drip immunity and splash immunity	The design, fabrication, or inclusion of an MIB receptacle connector shall not interfere with the equipment's ability to comply with applicable fluid ingress standards such as IEC 529 or others.



NOTE—THE SHIELDING CONDUCTOR SHALL BE RF BONDED TO THE CONNECTOR BACKSHELLS.

Figure 18—IEEE 1073.4.1 BCC-to-DCC cable schematic

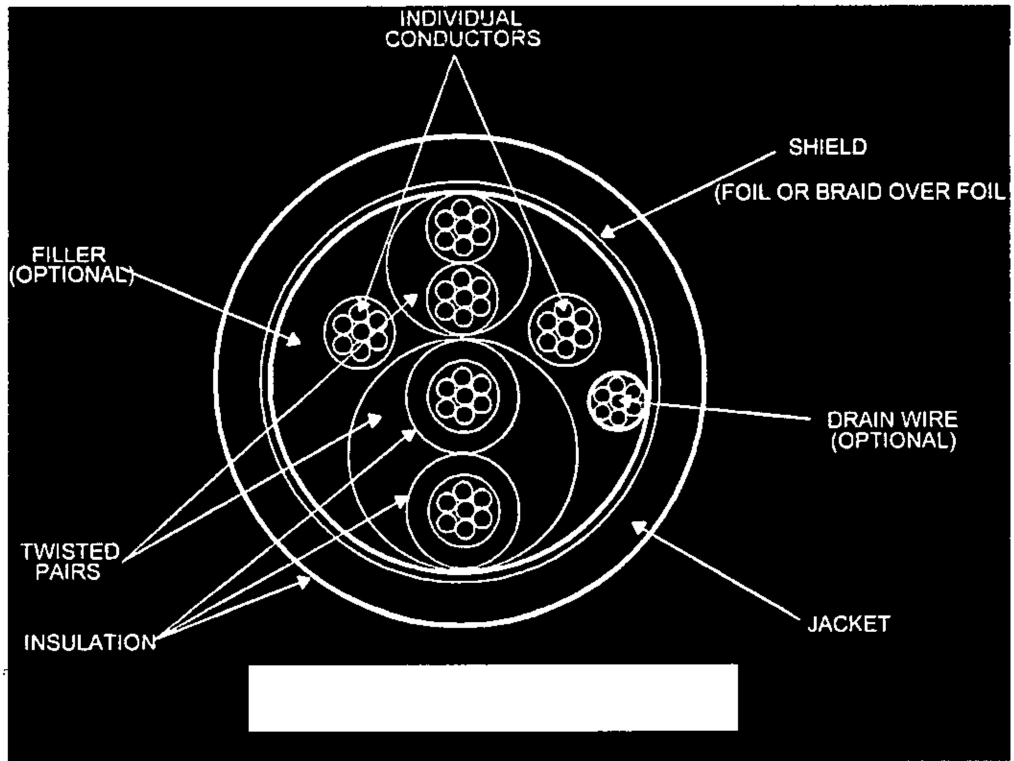


Figure 19—Cable cross-sectional drawing

10.5.3 Shielding

The cable shall contain a single, overall shield around all wires. The shield shall consist of an aluminum polyester foil. In addition, there shall be either a 28 AWG (159 circular mils) drain wire in continuous contact with the shield and/or a minimum of 65% braid coverage of conductive contact over the foil. The drain wire and/or braid shall be RF bonded to the connector backshells. If a braid outer shield is used, there shall be 360° contact with the backshells.

10.5.4 Data signal pair

The signal pair DATA (+) and DATA (–) shall be suitable for data transmission with drivers and receivers conforming to ISO/IEC 8482:1993.

10.5.4.1 Characteristic impedance

The characteristic impedance of the data signal twisted pair shall be 120 Ω ± 10%.

10.5.4.2 Capacitance

Capacitance shall be ≤ 15 pF/ft (49.2 pF/m).

10.5.4.3 Rise and fall time

Rise time for a 30 m (98.4 ft) length of cable (10–90%) shall be < 200 ns, allowing for signal distortion of < 10%, as defined in ISO/IEC 8482:1993, section A.2.2.

10.5.5 Power pair

The power pair of conductors, +12 V and +12 V RETURN, shall be a twisted pair.

10.5.5.1 Current capacity

The power pair shall be capable of carrying ≥ 325 mA.

10.5.5.2 Power conductor loop resistance

The power conductor pair shall have a loop resistance ≤ 5 Ω, for a length of 30 m (98.4 ft). Loop resistance shall be defined as the summed resistance of both power and return wire.

NOTE—The above requirement implies a maximum cable resistance of 82 mΩ/m (25 mΩ/ft).

10.5.6 Special function signal pair

The conductors for the two special function signals, $\overline{\text{SENSE/INT/SYNC-IN}}$ and $\overline{\text{SENSE/INT/SYNC-OUT}}$, shall consist of a pair of individual (nontwisted) wires. The characteristic impedance of each of the conductors for the two special function signals shall be 50 Ω ± 25%.

10.5.7 Crosstalk

The crosstalk between either DATA (+) or DATA (–) and either of the two special function signals shall be < –45 dB for the near end and the far end at a frequency of < 5 MHz.

10.5.8 Cable length

The maximum length of the cable shall be 30 m (98.4 ft).

10.5.9 Cable diameter

The maximum outside diameter of the cable shall be 6.5 mm (0.25 in).

10.5.10 Cable material

Table 11 depicts the material specifications for the cable.

Table 11—Cable material

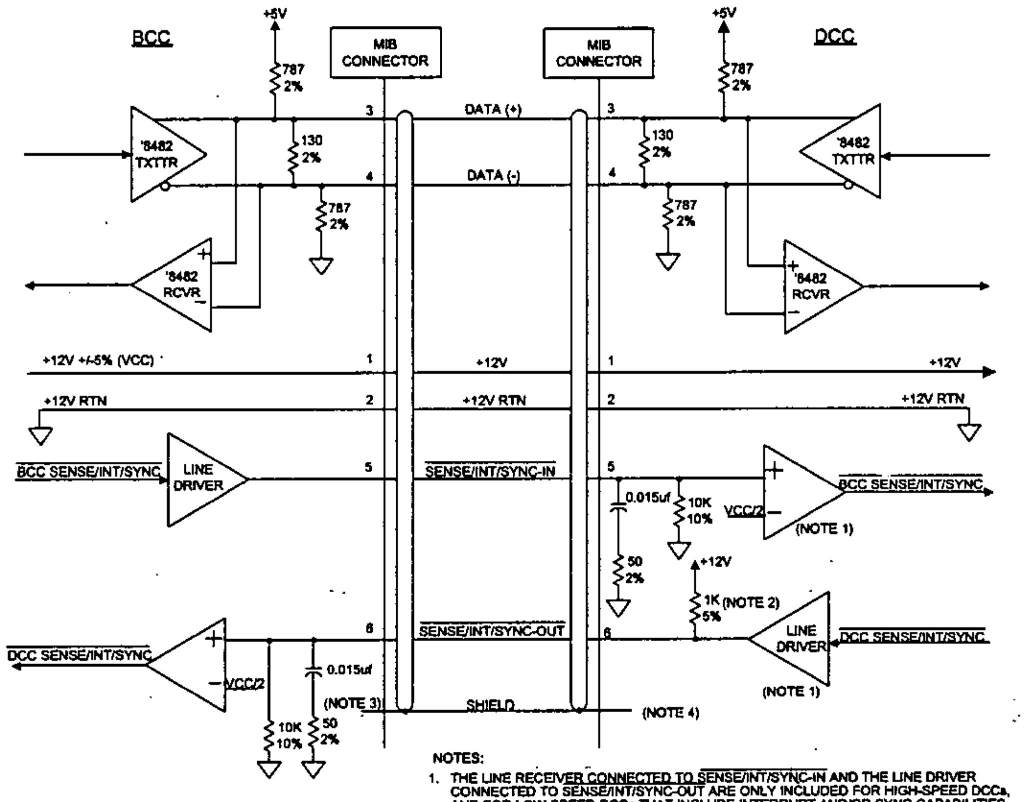
Parameter	Value
Jacket	UL-1581:1991, paragraph 1080, VW-1 (Vertical Specimen) Flame Test
Shielding	Aluminum polyester with 28 AWG (159 circular mils) solid drain wire in continuous contact with shield
Insulation	UL-1581:1991, paragraph 1080, VW-1 (Vertical Specimen) Flame Test
Conductors for DATA (+), DATA (–), $\overline{\text{SENSE/INT/SYNC-IN}}$, and $\overline{\text{SENSE/INT/SYNC-OUT}}$	Minimum 7-strand, 28 AWG through 24 AWG (159 circular mils through 404 circular mils)
Conductor for +12 V and +12 V RETURN	Minimum 7-strand, 24 AWG (404 circular mils)

10.6 Connector pin assignments

The following pin assignments shall be considered as standard for IEEE 1073.4.1 applications:

Pin	Function
1	+12 V
2	+12 V RETURN
3	DATA (+)
4	DATA (–)
5	$\overline{\text{SENSE/INT/SYNC-IN}}$
6	$\overline{\text{SENSE/INT/SYNC-OUT}}$
Shell	Shield

A schematic of the BCC-to-DCC interconnection is shown in Figure 20.



NOTES:

1. THE LINE RECEIVER CONNECTED TO SENSE/INT/SYNC-IN AND THE LINE DRIVER CONNECTED TO SENSE/INT/SYNC-OUT ARE ONLY INCLUDED FOR HIGH-SPEED DCCs, AND FOR LOW-SPEED DCCs THAT INCLUDE INTERRUPT AND/OR SYNC CAPABILITIES.
2. THE 1K OHM RESISTOR BETWEEN +12V AND SENSE/INT/SYNC-OUT IS ONLY INCLUDED FOR LOW-SPEED DCCs THAT DO NOT INCLUDE INTERRUPT AND/OR SYNC CAPABILITIES.
3. THERE SHALL BE AN RF BOND TO CHASSIS FOR THE CABLE SHIELD (CONNECTOR BACKSHELL) AT THE BCC.
4. THERE SHALL BE NO DIRECT CONNECTION BETWEEN CABLE SHIELD (CONNECTOR BACKSHELL) AND EARTH GROUND AT THE DCC.

Figure 20—DCC-to-BCC interconnection schematic

10.6.1 BCC-to-DCC serial data bus interface

The interface of the BCC and DCC ISO/IEC 8482:1993 transmitters and receivers shall be configured as indicated in Figure 20. This includes the pull-up and pull-down resistors, as indicated.

10.6.2 Termination resistors

As illustrated in Figure 20, a termination resistor shall be connected between DATA (+) and DATA (–) in the BCC and the DCC. The value of the termination resistor shall be 130 Ω ± 2%.

10.6.3 Pull-up and pull-down resistors

As illustrated in Figure 20, a pull-up resistor shall be connected between a voltage of +5 V ± 10% and DATA (+) for both the BCC and the DCC. In addition, pull-down resistors shall be connected between DATA (–) and signal +12 V RETURN at the BCC and the DCC. The value of the pull-up and pull-down resistors will be 787 Ω ± 2%. The purpose of the pull-up and pull-down resistors is to provide an offset voltage at times when a station (BCC port or DCC) is not connected to another station.

NOTE—The parallel combination of 130 Ω and 1574 Ω (the two 787 Ω resistors in series) provides an effective termination impedance of approximately 120 Ω, matching the nominal value of the characteristic impedance of the EIA-485 twisted pair wires. The voltage divider network provides a nominal "dead bus" (idle) voltage of 0.381 V, exceeding the maximum receiver threshold of 0.2 V specified by ISO/IEC 8482:1993. This serves to eliminate noise-induced errors that could occur prior to or following the reception of a valid frame.

10.7 EMC and safety

10.7.1 Short circuits and transients

Consistent with the requirements of ISO/IEC 8482:1993, section 3.4, no damage shall be incurred by the BCC or the DCC as a result of shorting any connector pin to any other pin or to chassis or shield.

In addition, transients from a 25 V source of either polarity, having an internal resistance of 100 Ω, shall cause no damage when applied to any pin of the connector, when referenced to chassis, shield, or the power return pin. The transient duration shall be 15 μs, with a duty cycle of 1%.

10.7.2 EMC

The implementation of an MIB interface shall not interfere with the equipment's ability to comply with applicable EMC standards such as IEC 60601-1-2:1993, ANSI Std C63.14-1992 [B1][10], ANSI/IEEE Std 268-1992 [B2], ASTM E 380-91a [B4], IEC 801-1:1984 [B8], EN 60601-1-2:1993, IEC 801-2:1991 [B9], IEC 801-3:1984 [B10], IEC 801-4:1988 [B11], FDA MDS-201-0004:1980 [B6], MIL-STD-461D:1993 [B19], VDE 0871:1987 [B23], FCC Part 15:1994 [B5], MIL-E-6051D:1988 [B17], or others.

NOTE—Compliance to IEC 60601-1-2:1993 has been mandatory in Europe since January 1, 1996.

10.7.3 Safety compatibility and ground isolation

The implementation of an MIB interface shall not interfere with the equipment's ability to comply with applicable safety standards such as IEC 60601-1:1988, IEC 60601-1 Amendment 1:1992, IEC 60601-1 Amendment 2:1995, IEC 60601-1-1:1992, IEC 60601-1-1 Amendment 1:1995, UL 2601-1:1994, EN 60601-1:1995, EN 60601-1-1:1993, or others.

10.7.3.1 DCC earth ground isolation

At the DCC, all MIB power and signal conductors shall be isolated from earth ground to at least 1500 V ac at 50 Hz to 60 Hz with a maximum enclosure leakage current of 100 μA for normal operation, 300 μA for single fault condition at a mains voltage of 120/240 V ac, and 500 μA for single fault condition at a mains voltage of 264 V ac.

NOTE—For worldwide operation, the typical "highest rated mains voltage" is 240 V ac.

10.7.3.2 Additional system-level safety requirements

For a given locality, if additional system-level safety requirements need to be satisfied, the means of meeting those requirements shall be implemented at the DCC.

NOTES

1—This allows the BCC to be constructed in compliance with nonmedical safety standards, such as IEC 950 for office equipment or IEC 1010 for laboratory equipment.

[10]The numbers in brackets correspond to those of the bibliography in Annex A.

2—Examples of such additional requirements include dielectric strengths, leakage currents, creepage distances, air clearances, safety labeling, and documentation needed to comply with IEC 60601-1:1988, IEC 60601-1-1:1992, EN 60601-1:1995, and EN 60601-1-1:1993. Annex C illustrates an example of a means for complying with these standards.

10.7.4 BCC shield connection

There shall be an RF bond to chassis for the cable braid shield and/or drain wire at the BCC.

10.7.5 DCC shield isolation

The cable shield shall be isolated from earth ground and signal +12 V RETURN at the DCC by a minimum impedance of 250 kΩ at 50 Hz to 60 Hz.

NOTE—EMC considerations may require the use of an RF coupling network between the shield and chassis ground at the DCC. A possible network is 1000 pF to 10 000 pF in parallel with 300 kΩ to 1 MΩ.

10.7.6 ESD immunity

The implementation of an MIB interface shall not interfere with the equipment's ability to comply with applicable ESD standards such as EN 50082-1, IEC 801-2:1991 [B9], ANSI C63.14-1992 [B1], ANSI/IEEE Std 268-1992 [B2], ASTM E 380-91a [B4], MIL-STD-883D:1991 [B20], MIL-HDBK-263A:1991 [B18], MIL-STD-1686B:1992 [B22], or others.

10.8 Operation of special function signals

The BCC-to-DCC interconnection provides two wires for the special function signals, SENSE/INT/SYNC-IN and SENSE/INT/SYNC-OUT. These signals are referenced with respect to the signal directions for the DCC. See Figure 20 and Figure 21. The output voltages, pulse widths, and comparator input threshold voltages specified in 10.8.1 through 10.8.8 assume a test condition of a ±1% tolerance on the +12 V power supply voltage of the BCC or DCC.

10.8.1 BCC required functions

All BCC ports shall be capable of sensing whether a DCC has been connected. All BCC ports shall be capable of outputting sync pulses to a DCC, accepting sync pulses from a DCC, and acknowledging interrupt requests from a DCC.

10.8.2 DCC required features

On its SENSE/INT/SYNC-OUT output signal, a high-speed or low-speed DCC is required to provide an indication to a BCC port that it has been physically connected to a BCC port. This signal line shall be driven to a nominal voltage of +12 V following turn-on and connection to a BCC port.

A high-speed DCC is required to be able to determine whether it has been connected to a BCC port, to implement interrupts, and to receive and generate SYNC pulses. Interrupt activate and deactivate pulses, and sync pulses are sent via the SENSE/INT/SYNC-OUT signal. A high-speed DCC is required to receive and decode SYNC and interrupt deactivate pulses on its SENSE/INT/SYNC-IN input.

10.8.3 DCC optional functions

The capabilities to determine connection to a BCC port, to receive sync and interrupt deactivate pulses on SENSE/INT/SYNC-IN, and to generate sync pulses and interrupt activate and deactivate pulses on SENSE/INT/SYNC-OUT are optional for low-speed DCCs.