

# 医疗设备即插即用 (Medical Device Plug-and-Play)

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June 21, 2009



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需求



现有的工作



前瞻和计划

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需求



Existing Efforts



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我们为什么需要医疗设备即插即用 (MDPnP)? (特别是无线医疗设备即插即用?)

柔性 (Flexibility)、更多的医疗应用/手段

安全性 (Safety)

舒适性、更高的工作效率 (Convenience and Efficiency)

独立性 (Independence): 不再受制于设备厂家

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当今的医院已经在使用数万、数十万种医疗设备; 而多数设备是被设计成单独使用的, 不开放

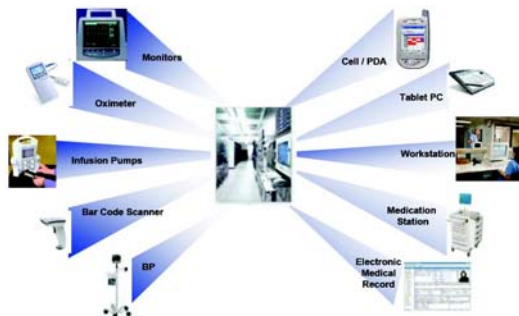


Figure Credit: P. Carleton, RN

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允许医疗设备**柔性**组合将使更多医疗方法称为可能

病人自控的麻醉 (PCA)



护士



病人



疼痛按钮

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允许医疗设备**柔性**组合将使更多医疗方法称为可能

病人自控的麻醉(PCA)

自动注射器

计算机

疼痛按钮

病人

常规生命指标监视设备

特殊生命指标监视设备

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医疗设备间的互联/互锁有助于提高**安全性**

测量血压

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医疗设备间的互联/互锁有助于提高**安全性**

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医疗设备间的互联/互锁有助于提高**安全性**

测量血压

建议：病床和血压计通过MDPnP互联/互锁

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常见事故：心肺体外循环与呼吸机

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常见事故：心肺体外循环与呼吸机

心肺体外循环机      粗心失误      呼吸机

“... In the second case, the anesthesiologist forgot to resume ventilation after separation from cardiopulmonary bypass. The delayed detection of apnea was attributed to the fact that the audible alarms for the pulse oximeter and capnograph had been disabled during bypass and had not been reactivated. Both patients sustained permanent brain damage.”

Anesthesiology. 87(4):741-748, October 1997

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常见事故：心肺体外循环与呼吸机

心肺体外循环机      建议：  
多种医疗设备通过MDPnP互联/互锁      呼吸机

MDPnP 总控单元

二氧化碳计      血氧计

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医疗设备间的互联/互锁有助于提高**安全性**

事故：X-光机与呼吸机



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Picture provided by Mu Sun

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事故：X-光机与呼吸机



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医疗设备间的互联/互锁有助于提高**安全性**

事故：X-光机与呼吸机



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医疗设备间的互联/互锁有助于提高**安全性**

事故：X-光机与呼吸机



"A 32-year-old woman was having a laparoscopic cholecystectomy performed under general anesthesia. ... At some point, the anesthesiologist glanced at the EKG and noticed severe bradycardia. He realized he had never restarted the ventilator ...  
The patient ultimately died."  
APSF Newsletter, Winter, 2005.

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Picture provided by Mu Sun

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医疗设备间的互联/互锁有助于提高**安全性**

事故：X-光机与呼吸机

建议：  
X-光机与呼吸机通过MDPnP互联/互锁



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医疗设备间的互联/互锁有助于提高**安全性**

事故：输氧与激光刀



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医疗设备间的互联/互锁有助于提高**安全性**

事故：输氧与激光刀

建议：  
激光刀与氧浓度监测计通过MDPnP互联/互锁  
含氧量超过30%时，气管激光手术被禁



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医疗设备间的互联/互锁有助于提高**安全性**

传染病人向护士紧急呼救



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医疗设备间的互联/互锁有助于提高**安全性**

传染病人向护士紧急呼救



烈性传染病：必须配戴防毒面具！

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医疗设备间的互联/互锁有助于提高**安全性**

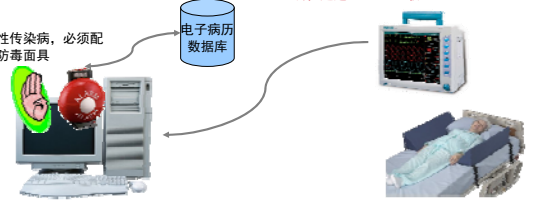
传染病人向护士紧急呼救

建议：  
电子病历、护士工作站、生命体征监测仪通过MDPnP互联

电子病历数据库

护士工作站

烈性传染病，必须配戴防毒面具



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医疗设备即插即用 (MDPnP), 特别是无线MDPnP, 有助于提高**舒适性** (安全性) 和**工作效率**

手术室现状与隐患: 狼藉不堪

High-acuity care today:  
How do we prevent errors?  
How do we keep track of all this?

June 21, 2009  
Picture quoted from www.mdnp.org

医疗设备即插即用 (MDPnP), 特别是无线MDPnP, 有助于提高**舒适性** (安全性) 和**工作效率**

公告板, 有助于医生、护士有条理地合作

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Picture quoted from www.mdnp.org

医疗设备即插即用 (MDPnP), 特别是无线MDPnP, 有助于提高**舒适性** (安全性) 和**工作效率**

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LiveData OR Dashboard

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Picture quoted from www.mdnp.org

医疗设备即插即用 (MDPnP), 特别是无线MDPnP, 有助于提高**舒适性** (安全性) 和**工作效率**

管线缠绕的手术室

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Picture quoted from www.mdnp.org

医疗设备即插即用 (MDPnP), 特别是无线MDPnP, 有助于提高**舒适性** (安全性) 和**工作效率**

医疗设备即插即用所引入的互联/互锁会进一步加重手术室的管线密度

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Picture quoted from www.mdnp.org

医疗设备即插即用 (MDPnP), 特别是无线MDPnP, 有助于提高**舒适性** (安全性) 和**工作效率**

管线缠绕的手术室 和 无线手术室 对比

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**独立性：** 医院使用数以万计的不同种类设备，不想受制于某个供货商

Figure Credit: P. Carleton, RN  
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**我们为什么需要医疗设备即插即用 (MDPnP)? (特别是无线医疗设备即插即用?)**

- 柔性 (Flexibility)、更多的医疗应用/手段
- 安全性 (Safety)
- 舒适性、更高的工作效率 (Convenience and Efficiency)
- 独立性 (Independence)：不再受制于设备厂家

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**MDPnP 对谁有益?**

- 医院：** 独立性、医疗能力、安全性
- 医生：** 医疗能力、安全性、舒适性
- 病人：** 医疗能力、安全性、价格
- 政府：** 责任事故调查能力、医保成本
- 供货商：** 更大的市场
- 科研机构：** 典型的计算机物理系统一体化课题

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**IEEE 1073 工作组**


- IEEE 1073 (5/1996):** 总体架构 overall network/middleware architecture
- ISO/IEEE 11073-10101 (6/2004):** 用词规范 nomenclature
- ISO/IEEE 11073-20601 (9/2008):** 中间件交互管理 middleware group management and communication protocol guideline
- ISO/IEEE 11073-30200 (1/2000):** 电缆通信 cable PHY ~ transportation layer
- ISO/IEEE 11073-10441 (1/2009):** 心血管监测设备具体规范 device spec. - cardiovascular fitness and activity monitor

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**American Society for Testing and Materials (ASTM), International Standardization**

- Draft ASTM TC F29.21 N21 (2008):**
- 医疗设备与系统 - 病人集成医疗环境 (ICE) 中医疗设备的基本安全要求 - 第一部分：总体要求与概念体系结构
- Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General requirements and conceptual architecture


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 美国政府的工作

美国食品药品监督管理局 FDA:

Draft Guidance for Industry and FDA Staff: Radio-Frequency Wireless Technology in Medical Devices, draft released for comment on Jan 3, 2007


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 美国政府的工作

总统科技顾问委员会 President's Council of Advisors on Sci. & Tech. (PCAST):

2007 Report on Federal Networking and Information Technology R&D list Cyber-Physical Systems as the top of the eight priorities for federal research investments.

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 美国政府的工作

美国自然科学基金 NSF:

Call for Proposals: Cyber-Physical Systems (CPS), solicitation 08-611, deadline: Feb., 2010.

"... Research advances in cyber-physical systems promise to ... enhance societal wellbeing (e.g., assistive technologies and ubiquitous healthcare monitoring and delivery) ... NSF ... are spear-heading the Cyber-Physical Systems (CPS) program because of its ... impact ... critical to U.S. Security and competitiveness, including ... healthcare ..."

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 美国政府的工作

国家网络信息技术研发协调中心 National Coordination Office for Networking and Information Technology Research and Development Program (NCO/NIRTD):

高可靠性的医疗设备: 面向21世纪医疗的计算机-物理系统 High-Confidence Medical Devices: Cyber-Physical Systems for 21<sup>st</sup> Century Health Care, Feb., 2009

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 工业界、学术界的工作

MDPnP: <http://www.mdnp.org>, 发起人:



- NIST (National Institute for Standards and Technology)
- NSF (National Science Foundation)
- Society for Technology in Anesthesia
- DocBox
- Philips Healthcare
- Etc.

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 工业界、学术界的工作

MDPnP: <http://www.mdnp.org>, 发起人:

Conference: June 2007



from June conference agenda available on [www.cisit.org/mdnp/june07/start.htm](http://www.cisit.org/mdnp/june07/start.htm)



Proceedings published by IEEE Source: www.mdnp.org 32 48





## 工业界、学术界的工作

**CIMIT:** <http://www.cimit.org>

医疗与创新技术集成中心：一个由12家单位发起的组织。创始成员包括马萨诸塞总医院、哈佛医学院、麻省理工、波士顿退伍军人医疗管理局等。现有四十余家成员。

Center for Integration of Medicine & Innovative Technology, a non-profit consortium initiated by 12 institutes, including Mass. Gen. Hospital, Harvard Medical School, MIT, VA Boston Healthcare System etc.

More than 40 industry partners.



## 工业界、学术界的工作

**IEEE Computer:** Insup Lee, George J. Pappas, Rance Cleaveland, John Hatcliff, Bruce H. Krogh, Peter Lee, Harvey Rubin, Lui Sha: High-Confidence Medical Device Software and Systems. IEEE Computer 39(4): 33-38 (2006)

**CPS Week:** since 2008 (NSF CPS Summit), involving RTAS, IPSN, HSCC

**CPS Track:** since 2007, IEEE RTSS

## 目录



Demand



Existing Efforts



前景和路线图



## 设备生产商的机遇

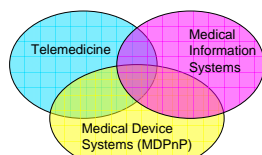
可靠的电缆通信底层：交换机、网卡

可靠的无线通信标准和设备：交换机、网卡

中间件、操作系统、MDPnP总控机、互锁/互锁软件



Healthcare CPS can involve and stimulate the growth of nearly every CS area.



## 谢谢!



Demand



Existing Efforts



Vision and Roadmap