Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

In the Matter of	)	
	)	
Amendment of Part 90 of the Commission's Rules	)	WP Docket No. 07-100
	)	
	)	

To: The Commission

COMMENTS OF PHILIPS HEALTHCARE SYSTEMS

Philips Healthcare Systems ("Philips") hereby responds to the Commission's Second Further Notice of Proposed Rule Making ("Second Further Notice") in the above-captioned proceeding.[1] Philips is the world leader in patient monitoring equipment and was one of the first providers of 1.4 GHz WMTS equipment to health care facilities.

As explained below, Philips strongly supports extending spectrum parity in the telemetry band by allowing devices in the Wireless Medical Telemetry Service ("WMTS") secondary access to the non-primary portions on a par with the secondary access accorded fixed and mobile non-medical telemetry in the primary WMTS spectrum. Modern cognitive technologies enable WMTS systems to utilize secondary spectrum effectively and seamlessly without fear of impairing patient safety or interfering with others. Backstopping the cognitive approach and ensuring interference-free operation by non-cognitive devices is the spectrum coordination process already required by the Commission, implemented by industry, and proven effective.

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[1] *See Amendment of Part 90 of the Commission's Rules*, Second Report and Order and Second Further Notice of Proposed Rule Making, 25 FCC Rcd 2479 (2010), Order on Reconsideration, FCC 10-75, __ FCC Rcd ____ (released May 7, 2010).

INTRODUCTION

In its Report and Order in this proceeding, the Commission in effect concludes that permitting non-medical telemetry operations on WMTS primary spectrum is consistent with the safe operation of WMTS devices, but that allowing WMTS devices to share the non-medical telemetry primary spectrum implicates issues of safety and interference. However, from an engineering point of view, the situations are identical. Either medical and non-medical telemetry operations are capable of sharing the spectrum without interference, or they are not. The Commission nowhere explains why sharing the WMTS primary spectrum is fine, but the functionally identical sharing of adjacent non-WMTS spectrum by the exact same entities and systems raises safety and interference concerns. While primary and secondary status determine priority of use, safety and interference are engineering issues that must be decided on a sound scientific basis. Nor does the Commission address why it disagrees with the original recommendation made by the interested parties themselves that such sharing is feasible and should be permitted.[2]

In truth, as Philips submitted in its Reply Comments to the original Notice, the chance of interference is negligible due to the technical characteristics of the WMTS cognitive devices that would access the spectrum. Additionally, the frequency coordination process provides an additional layer of protection for cognitive devices and allows non-cognitive devices also to operate safely on a secondary basis in unused non-medical spectrum.[3]

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[2] *See Joint Statement of Position by the American Medical Hospital Association Task Force on Medical Telemetry and Itron, Inc.* (dated March 8, 2001) ("AHA/Itron Agreement"), attached to Comments of Itron, Inc. in WT Docket 02-08, and discussed in the earlier stage of this proceeding by Philips, *see* Reply Comments of Philips Medical Systems, WP Docket No. 07-100 at 2-3 (filed September 11, 2007).

[3] *See* Reply Comments of Philips Medical Systems, *supra note* 2 at 3-5.

As a technical matter, WMTS access to additional spectrum on a secondary basis where such spectrum lies vacant would *decrease*, not increase, the potential for interference because more spectrum options for WMTS devices would provide more frequency options that could be used to avoid conflicting signals. Allowing secondary access to this spectrum also would foster competition among WMTS devices by increasing the spectrum available to accommodate devices and systems from competitive providers.

PHILIPS HEALTHCARE

Philips is the world leader in patient monitoring equipment and one of the largest suppliers of medical equipment in the United States.[4] For over 25 years, Philips has delivered solutions that acquire, analyze, and present patient data in ways that are meaningful for clinicians in the most challenging clinical areas. Philips provides clinical informatics and patient care solutions that help improve and save lives, lower the overall cost of healthcare, and simplify clinician workflow.

Philips operates in five main healthcare areas: healthcare information, diagnostic imaging systems, clinical solutions, customer services and home healthcare solutions. Its product lines include best-in-class technologies in patient monitoring and remote telehealth monitoring as well as in radiology and cardiology enterprise imaging and information management, eICU, X-ray, ultrasound, magnetic resonance, computed tomography, nuclear medicine, PET, personal emergency response systems, and resuscitation products.

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[4] *See* F&S Market Research Report 2000-2008, based on the countries composing 90% of the world market (United States, Canada, France, Germany, Italy, Spain, United Kingdom, Belgium, Netherlands, Russia, Brazil, Mexico, Japan, China, India, Australia, Turkey and Malaysia).

Philips was one of the first providers of medical monitoring equipment to health care facilities using the 1.4 GHz WMTS frequencies. Its 1.4 GHz IntelliVue Telemetry System utilizes smart-hopping cognitive technology and spectrum sensing capabilities to ensure reliable communications by automatically detecting and avoiding other transmissions and spectrum noise. Its technology provides reliable two-way telemetry communications by seeking clear channels to carry the signals in the most reliable manner. Use of access points distributed throughout covered health care facilities enhances system reliability and flexibility. Philips' IntelliVue systems efficiently support clinical decision support tools and facilitate electronic record keeping. These functions lead directly to better health care at lower cost.

BACKGROUND

Philips' WMTS IntelliVue system improves patient care, creates electronic health records, and reduces healthcare costs, all of which are national goals established by Congress last year in the HITECH Act[5] and amplified upon this year in the Patient Protection and Affordable Care Act.[6] Employing wireless devices using the WMTS spectrum will help achieve these Congressional goals and benefit all Americans. Authorizing WMTS systems to use the 1.4 GHz spectrum as intended would provide increased protection against interference and allow the needed density to be achieved where multiple large hospitals require thousands of devices to be deployed in close proximity.

In 2001, after detailed technical analysis, Itron, representing Part 90 telemetry interests, and the American Hospital Association's Task Force on Medical Telemetry, representing the

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[5] *See Health Information Technology for Economic and Clinical Health Act* ("HITECH Act"), adopted as Title XIII of the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5 (2009) ("ARRA"). *See also* http://healthit.hhs.gov.

[6] Pub. L. No. 111-148 (2010).

WMTS community, agreed to share the 1427-1432 MHz spectrum with each other and submitted that agreement to the Commission.[7] Each service was to have primary status in 2.5 MHz of the spectrum and secondary status in the other 2.5 MHz. Underlying the agreement to share in this manner was the implicit conclusion that the technical attributes of the specific telemetry devices themselves, the controlled locations at which the WMTS telemetry devices would be used,[8] and the transparent coordination procedures proposed would amply protect against any potential for harmful interference.

In its Order in this proceeding, however, the Commission for the first time explicitly rejected the 2001 consensus agreement of the affected parties on its merits when it deleted the secondary allocation for WMTS, notwithstanding that there is no known case of interference and no technical analysis indicating that interference might occur on the non-medical telemetry primary spectrum but not on the medical telemetry primary spectrum. Even more puzzling, the Commission articulated a concern with interference *to* WMTS devices without explaining why, if this were so, it permits non-medical telemetry to share the primary spectrum allocated exclusively to WMTS. It would be irrational to permit fixed and mobile non-medical utility devices to operate co-channel with WMTS devices if the Commission has doubts about the efficacy of spectrum sharing by medical and non-medical telemetry systems. Nowhere in its Report and Order does the Commission substantively address multiple submissions in the record

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[7] *See supra* note 2 and Comments of Philips Medical Systems, WP Docket No. 07-100 (filed August 13, 2007), Reply Comments (filed September 11, 2007) and *Ex Parte* Presentation filed by Letter to Marlene H. Dortch, Secretary (dated June 26, 2008).

[8] WMTS telemetry devices are limited to use by authorized health care providers in health care facilities, *see* 47 C.F.R. § 95.1107.

discussing use of cognitive devices and frequency coordination to avoid the possibility of interference.[9]

Accordingly, secondary access to spectrum as envisaged in the 2001 agreement should be permitted at the earliest opportunity. Doing so will speed deployment of the medical devices essential to improving healthcare at the least cost and in a manner that furthers the public interest in meeting the Congressional goals.

DISCUSSION

A. WMTS Should Have Access to Secondary Spectrum

As the Commission is aware, cognitive devices promote efficient spectrum use by sensing the spectrum and, without human intervention, reconfiguring use as necessary to create clear paths for the signals. Properly implemented, communications using cognitive radios are free from causing or suffering interference. Such devices increasingly are being deployed in various services. The Commission itself repeatedly has recognized the benefits of cognitive radio devices, including the ubiquitous 802.11 series of WiFi wireless broadband devices and held a workshop and conducted proceedings that address in substantive detail the benefits of deploying radios that use cognitive technologies.[10]

A defining characteristic of cognitive radio devices is that efficiency improves with additional available spectrum because the devices then have more options from which to select clear frequencies to avoid occupied channels. Permitting secondary use by WMTS devices

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[9] *Supra* note 7.

[10] *See, e.g., Facilitating Opportunities for Flexible, Efficient, and Reliable Spectrum Use Employing Cognitive Radio Technologies,* ET Docket No. 03-108, 20 FCC Rcd 5486 (2005). Additional Commission activities concerning the capabilities of cognitive radio devices are referenced at: http://www.fcc.gov/oet/cognitiveradio/

would improve the performance of cognitive devices wherever crowded spectrum conditions exist. Cognitive WMTS devices should be authorized to use the subject secondary spectrum without restriction as to the availability of primary frequencies or other regulatory constraint. The clearest unoccupied channel then could be selected using the cognitive technology based upon the spectrum condition found by the device, which can change by the second, rather than being artificially restricted by regulation notwithstanding the availability of suitable spectrum at the location of interest.

Manufacturers and users of non-cognitive WMTS devices may seek to use primary WMTS spectrum before secondary spectrum, but there is no technical reason why such devices also should not have access to secondary spectrum after frequency coordination. Under the Commission's Rules, the spectrum coordinators maintain a complete database of locations and frequencies in use, and both medical and non-medical telemetry devices are professionally planned and installed. Where suitable spectrum lies unused, it would be nonsensical to not permit its use on a secondary basis.

Philips' IntelliVue system employs cognitive designs that allow it to be deployed in hospitals without fear of suffering or causing interference on both primary and secondary spectrum. A brief description is attached to these Comments. Four years ago, Philips successfully began implementing this version of cognitive radio in the WMTS band without incident, as it briefed the Commission at earlier stages of this proceeding.[11] Permitting secondary use of the WMTS spectrum will enable the use of new, innovative devices such as Philips' IntelliVue system that are needed for better medical care. Moreover, access to the

[11] *See supra* note 7.

spectrum on a secondary basis will foster competition and allow superior service for operation of both cognitive and non-cognitive devices.

B. WMTS Need for the Adjacent Secondary Spectrum

The Commission in its Second Further Notice seeks comment on the need for secondary spectrum for WMTS. As discussed above, the performance of cognitive radio systems improves with additional spectrum options. Since such systems automatically avoid occupied and noisy channels, there is no known reason not to authorize their use on a secondary basis.

Furthermore, as WMTS devices are increasingly deployed, there will be increasing numbers of instances where sufficient primary spectrum is lacking to accommodate demand. This is projected to be the case in areas where large health care facilities exist that have increasing demands for monitoring.

Access to secondary spectrum serves an ancillary public interest purpose in promoting competition among device manufacturers by providing a means for non-cognitive devices to be deployed at the same locations as cognitive devices. As the spectrum fills up, the secondary spectrum provides a belts-and-suspenders approach to efficiently accommodate demand in locations where the spectrum is not being used by the primary user. The coordination process fully protects against interference.

We project substantial increases in demand over the next five years as America's health care facilities invest in new systems to improve patient monitoring and deploy electronic medical records as encouraged by the HITECH Act. Large hospitals typically have hundreds of devices deployed and continue to expand. Many hospitals plan to monitor every patient for multiple vital signs. Access to the secondary spectrum for WMTS devices will permit seamless expansion where spectrum crowding in the primary band develops, acting as a safety valve allowing use of

wireless medical monitoring devices to increase and meet the public's demand for improved wireless medical monitoring and integrated electronic record keeping at health care facilities.

Finally, access to the secondary spectrum would increase by 25 percent the spectrum available to WMTS in the 1.4 GHz band. This will facilitate future innovation in devices and development of lower cost solutions.

C. Restrictions on Access to Secondary Spectrum Are Not Needed

The Commission in the Second Further Notice asks whether certain monitoring functions, such as monitoring specific types of patients or for specific medical information, should be conducted only on primary spectrum to ensure patient safety. As explained above, additional spectrum on a secondary basis would *improve* system performance for both cognitive and non-cognitive implementations. Limiting use of such systems to primary spectrum would have a result opposite that intended -- system performance would be degraded in some circumstances compared to that readily achievable through the use of secondary spectrum. Even for non-cognitive devices, access to the secondary spectrum would improve monitoring functions.

With regard specifically to device safety, the Food and Drug Administration ("FDA") closely regulates medical device safety, requiring that all monitoring devices be safe and perform to standards under adverse circumstances. FDA review of WMTS devices includes, but is not limited to, wireless coexistence, performance, data integrity, security and electromagnetic compatibility (EMC).[12] Philips is deploying its state-of-the-art cognitive WMTS monitoring

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[12] The FDA evaluates wireless medical device safety pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 351 *et seq.* *See* 21 C.F.R. §§ 820 *et seq.* *See also,* Draft Guidance for Industry and FDA Staff: Radio Frequency Wireless Technology in Medical Devices, Doc. 1618, at url: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077272.pdf.

system precisely because it provides monitoring functions in a superior and reliable fashion. Whether manufactured by Philips or by one of its competitors, each medical monitoring system is required to be extensively evaluated and tested -- including the spectrum component -- to ensure patient safety.

In addition, Philips notes that the primary WMTS spectrum is shared with secondary non-medical telemetry users as authorized by the Commission. There is no safety or other concern with such sharing as currently implemented through the coordination process. Extending secondary access for WMTS as originally envisaged would present no more a safety or interference issue than those analyzed and resolved with regard to secondary sharing of the WMTS primary spectrum. It is illogical to treat the subbands differently. If medical and non-medical devices can safely share spectrum in one portion of the band, the same devices can share spectrum in the other portion of the band as well.

D. User Notifications of Secondary Status Would Serve no Purpose

In its Second Further Notice, the Commission asks whether WMTS equipment manufacturers or vendors should be required to notify users that installed equipment will operate on a secondary basis. No such requirement exists for other bands where medical devices utilize spectrum on a secondary basis, and there is less reason for such a unique requirement in this band inasmuch as spectrum coordinators have immediate access to device deployment information and to the professionals responsible for installations. Any and all issues therefore can be resolved quickly. Any user can determine the identity and contact information for the person or persons responsible for radio equipment at any specific health care facility.

CONCLUSION

As discussed above, Philips urges the Commission to authorize secondary access to the 2.5 MHz of spectrum adjacent to the WMTS primary spectrum in the 1427-1432 MHz band. This spectrum is needed to achieve the best performance of wireless monitoring equipment under the variety of demand situations encountered by health care facilities and to accommodate projected substantial growth. There is no safety or other reason not to permit secondary operation.

Respectfully submitted,

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Always in touch

IntelliVue Telemetry System with Smart-hopping technology, surveillance of ambulatory cardiac patients

PHILIPS

Real clinical network

strength includes flexibility

When you have mobile cardiac patients who need constant monitoring, that's when clarity matters. Your network should essentially be invisible. The information you rely on should be available when and where it's needed, whether the source is a wireless monitor, a networked bedside monitor, or a laboratory information system.

As wireless medical devices proliferate, our robust clinical network will evolve with you to support your wired and wireless patient data flows.

1.4 GHz IntelliVue Telemetry System

Smart-hopping™ technology for a clear connection

The IntelliVue Telemetry System uses a cellular architecture with Smart-hopping technology to provide reliable two-way communications between transceivers and the IntelliVue Information Center. Smart-hopping technology dodges interference and seeks out the strongest available signal to achieve seamless connections wherever patients roam on the network. Access points give you considerable flexibility in setting up your system.

Wireless bedside monitoring and telemetry on the same infrastructure

Our Common Wireless Infrastructure supports wireless bedside monitoring and telemetry. This gives hospitals the benefit of a shared infrastructure that still protects sensitive patient monitoring transmissions from enterprise network traffic.

Device location

Hospitals typically lose 10 to 20 percent of their telemetry devices each year, and the ripple effects of down beds extend to ICUs, ORs and the emergency department. Device location helps hospitals contain equipment costs and prevent interruptions to care.

System design and installation

Philips technical consultants work closely with your clinical staff along with IT, biomedical, and facilities departments to design and implement a system that will work for you now, and for years to come.

Locate missing transceivers quickly with device location.

Our Common Wireless Infrastructure supports wireless bedsides and telemetry.

IntelliVue Teleme

The IntelliVue Telemetry System uses advanced Smart-hopping technology, an adaptation of a protocol originally developed for voice communications, to maintain seamless connections between the central station and telemetry devices. With Smart-hopping, the transceiver will change frequencies only to dodge interference or when it finds a stronger signal. Smart-hopping technology also manages bandwidth usage so efficiently that many more simultaneous users can share a channel, in comparison with simple frequency-hopping. And that means the IntelliVue Telemetry System is highly scalable, with capacity to support up to 1,000 transceivers or wireless bedside monitors.

IntelliVue Telemetry System overview

- Compact, lightweight transceivers
- Cellular WMTS infrastructure for clear two-way communication between transceivers and the IntelliVue Information Center
- Smart-hopping technology
- Auto-resume of monitoring when a device comes back into network range
- 2 V-leads with 6-wire ECG for improved tachycardia assessment
- Audible feedback from transceiver on SpO_2 spot checks, patient out of range
- Coexists with UHF Philips Telemetry System and standard 802.11 networks in the same space

Markings on the leadsets and ports make it easy to set up EASI* or standard ECG monitoring.

AA batteries are significantly less expensive than 9V batteries and easier to change.

Leadset cables are 85cm (33.5″) to accommodate patient movements. Colored leadsets available.

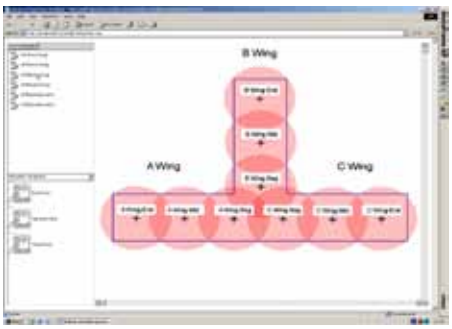
* EASI derived 12-lead ECGs and their measurements are approximations to conventional 12-lead ECGs and should not be used for diagnostic interpretations.

try System
with Smart-hopping technology

Flexible monitoring for flexible care. When your telemetry patients need more monitoring, the portable, wireless IntelliVue MP5 allows you to set up a monitored bed. Wireless TAAP (telemetry as a parameter) allows you to wirelessly connect the transceiver to the IntelliVue MP5 , MP5T, X2, and MP2 to view your patient's data along with other parameters.

A fast switch cable allows ECG monitoring – 3-, 5-, or 6-lead – using the telemetry transceiver or the patient monitor without recabling electrodes.

Locate a missing transceiver from the IntelliVue Information Center. The device will beep at intervals until it is stopped using a button on the front.



IntelliVue Device Location shows which access point a transceiver is associated with so that you can find missing devices more easily. The map application runs on a standard PC, and access point names appear in the associated bed sectors on the IntelliVue Information Center.

The flexible, wired/wireless
It all works

The IntelliVue Clinical Network is the enabling framework for your clinical data flows

The IntelliVue Clinical Network is designed specifically to manage flows of time-critical, round-the-clock patient monitoring data. The network is protected from many of the day-to-day hazards of business networks, including viruses and transmission delays.

At the same time, the IntelliVue Clinical Network can maintain a controlled connection with the hospital LAN so that useful patient information – such as lab results and other clinical applications – can be delivered to the bedside monitor or central station without the risk of disrupting the flow of physiologic data or alarms.

Telemetry as a Parameter (TAAP) allows you to connect your telemetry transceiver to the IntelliVue MP5 patient monitor to display ECG and SpO_2. The sturdy, portable MP5 also provides temperature, pressure, mainstream or sidestream CO_2, and anesthetic gas monitoring capabilities.

IntelliVue Clinical Network: together

The IntelliVue Information Center is the heart of the IntelliVue Clinical Network

Combining advanced patient surveillance capabilities across the network with state-of-the-art clinical decision support tools, the IntelliVue Information Center is so much more than a central station.

The IntelliVue Information Center presents a comprehensive view of patient status past and present, with up to 96 hours of full disclosure. Export 12-lead ECGs to your Holter system or waveform strips to the IntelliVue Clinical Information Portfolio.

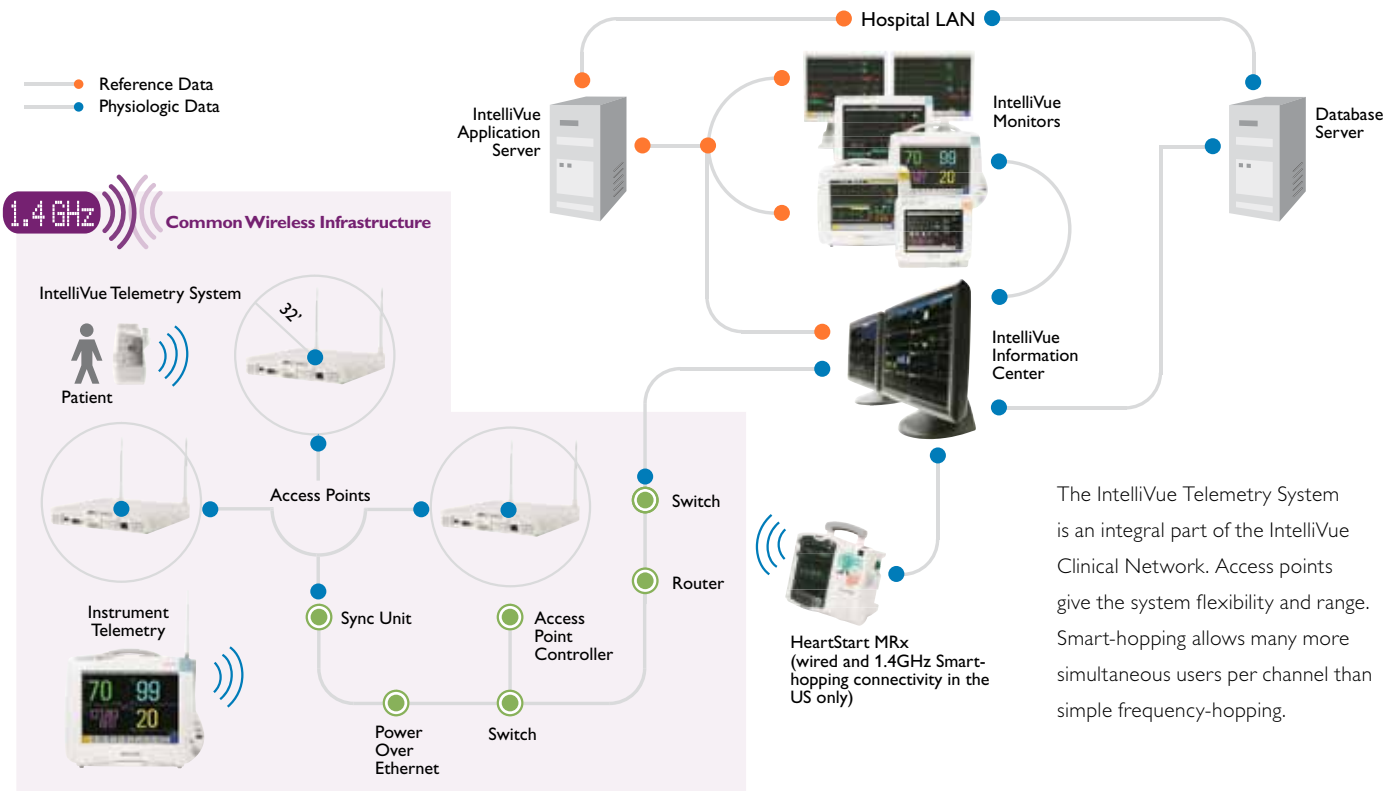
Our suite of clinical review applications includes arrhythmia analysis, alarm review, and event-based surveillance. Web-based access enables everything from better informed consults to the remote ICU care model.

Flexible wireless monitoring applications

Hospitals have discovered that telemetry systems have broad applications, from the emergency department where incoming patients with suspected cardiac abnormalities can be monitored without necessarily tying up a monitored bed, to neuroscience units where ECG telemetry can be useful in caring for stroke patients.

- **Emergency department**: Mobile monitoring for patients with suspected cardiac problems
- **ICU stepdown:** Less intensive monitoring for recovering patients
- **Cardiac unit:** Continuous surveillance for ambulatory cardiac patients
- **Neuroscience unit:** Critical surveillance for arrhythmias in the aftermath of a stroke

IntelliVue Clinical Network with IntelliVue Telemetry System



The IntelliVue Telemetry System is an integral part of the IntelliVue Clinical Network. Access points give the system flexibility and range. Smart-hopping allows many more simultaneous users per channel than simple frequency-hopping.

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