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September 26, 2003

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VIA ECFS

Marlene H. Dortch, Esq.
Secretary
Federal Communications Commission
Washington, DC 20554

Re: ET Docket 03-92
Ex Parte Notification

Dear Ms. Dortch:

On September 25, 2003, Philip Inglis of TRP, Inc., and I met with Julius Knapp and Bruce Romano of the Office of Engineering and technology to discuss Medtronic's views in this matter, including a discussion of interference-related issues. A copy of the materials provided during the meeting is attached.

Respectfully,

/s/ David E. Hilliard

David E. Hilliard
Counsel for Medtronic

Attachment

cc (via email): Messrs. Knapp and Romano

Biotronik's Waiver Request Fails To Satisfy The FCC's High Hurdle

Biotronik's Request for Waiver of the Medical Implant Communications Service ("MICS") requirements that implant devices "listen before transmitting" ("LBT") fails to present a showing of "undue hardship" for complying with the rules. As petitioner for waiver, Biotronik must demonstrate to the Commission a "compelling need" to waive its rules. *WAIT Radio v. FCC*, 459 F.2d 1203, 1207 (D.C. Cir. 1972); 47 C.F.R. § 1.3 (2002). Biotronik fails to show that: (i) "The underlying purpose of the rule(s) would not be served ... by application to the instant case, and that a grant of the requested waiver would be in the public interest; or (ii) application of the rule(s) would be inequitable, unduly burdensome or contrary to the public interest, or the applicant has no reasonable alternative." 47 C.F.R. § 1.925 (2002).

The public interest is best served by upholding the MICS rules. To operate in the MICS band, Biotronik should develop a MICS-compliant implant, as others have. Otherwise, Biotronik should move the frequency for its transmit-only device outside of the MICS band. It can operate under Part 15 as do other RF medical diagnostic tools. Just months ago, the FCC held that: "To interpret the [rules] as urged by Biotronik, to permit regular and potentially frequent transmissions with no specific instigation, would effectively eviscerate the protective provisions of the rules, and we cannot interpret our rules such that they have no effect." *See Biotronik, Inc. Equipment Authorization for the Medical Implant Communications Service, FCC Identifier PG6BAOT, Memorandum Opinion and Order*, 18 FCC Rcd 3027, rel. Feb. 25, 2003 ("2003 MICS Order") at ¶¶ 15. As shown in the matrix that follows, the support that Biotronik puts forth in its waiver request is without foundation, utterly deficient, and untrue.

Biotronik's Request for Waiver says …	When in reality …
LBT technology for implants is not within the state-of-the-art. "Such a modification to add bi-directionality [to its medical implants] would be an unnecessary and costly imposition upon the healthcare community and cardiac patients. [I]t is doubtful that such a modification is even possible in the current state of the art." Request for Waiver ("RfW") at 8-9.[1] *See also* Comments of Biotronik at 4, June 11, 2003, ET Docket 03-92 ("Biotronik Comments"). "Medtronic has been unable to design an implantable bi-directional circuit" and "does not claim that it has sought equipment authorization for a compliant *implantable* device." Reply Comments of Biotronik at 6 n.21, June 18, 2003, ET Docket 03-92 ("Biotronik Reply Comments").	Medtronic has filed a request for FCC equipment authorization for its fully compliant implant, and on September 4, 2003, Medtronic demonstrated to FCC representatives its MICS-compliant implant device, including Listen Before Transmit ("LBT") functionality. Therefore, MICS-compliant solutions for implants *are* within the state-of-the-art. Several companies offer MICS-compliant transceivers for use in implantable devices. *See* Medtronic *ex parte* filing in ET Docket 03-92, Sept. 4, 2003.

[1] Biotronik goes on to assert that: "Continuous monitoring of the band would deplete the implant's battery in a matter of weeks, rendering the implant device useless." RfW at 10. This is also not true. A properly designed MICS system is more efficient than Biotronik's transmit-only implant. A MICS-compliant device does not need to repeat transmissions of the same message to increase the likelihood of receipt; it also draws no power until requested.

Biotronik's Request for Waiver says …	**When in reality …**
Biotronik's implant is not susceptible to interference from METAIDS. "There is no realistic risk of interference caused to Biotronik's devices from other MICS users or from primary users of the 402-405 MHz band, including users of Metaids." RfW at 6. Remarkably, after receiving NTIA's letter warning of the "very real" risk of interference to Biotronik's implants and (as one of several conditions) asking the FCC to order Biotronik to inform physicians that its devices are not suitable for life-critical transmissions, Biotronik stated that it "has demonstrated that NTIA's concern is unfounded." *See* Biotronik Comments at 2 (emphasis added). Biotronik also stated that NTIA "express[ed] no objection to the grant of Biotronik's waiver request." *Id.* at 3.	NTIA's May 22, 2003, letter says: "We continue to believe that given the right circumstances, the potential interference from the radiosondes to Biotronik devices is very real. … The radiosondes may transmit for a long period of time, possibly exceeding a few hours. Considering the deployment and operational characteristics of radiosondes [], it is very probable that Biotronik devices operating within fairly large geographic area around these launch sites will receive interference." Letter from F. Wentland, NTIA, to E. Thomas, OET, at 2, May 22, 2003. NTIA went on to stipulate five (5) conditions that should form part of the conditions that the FCC places on any waiver grant. Significantly, NTIA's support is conditioned upon Biotronik's representation that it was not sending "critical medical data" and that a patient's health will not be harmed if Biotronik's transmissions are not received. To address the interference risk from METAIDS, Biotronik increased the number of repeat transmissions to raise the likelihood that (at least) one will be received and transmitted to the remote monitoring center; Biotronik also increased its transmit power level. Biotronik fails to mention that these modifications increase the likelihood of interference to MICS-compliant transmissions and other transmit-only operations.

Biotronik's Request for Waiver says ...	**When in reality ...**
Biotronik's devices are immune to interference as they have "gone through rigorous, FDA-approved testing" and are FDA-certified. "All of Biotronik's implantable products are verified to be immune to all sources of electronic noise through exhaustive testing to regulatory standards [including] IEC 60601-1-2 International standard for electromagnetic compatibility for medical electronic equipment, CENELEC standards EN 45502-2-1 for electromagnetic susceptibility, AAMI standard PC69 EMC test protocol for Active implantable medical devices, as well as electronic article surveillance (EAS) systems testing." RfW at 6-7 n.18.	The standards cited by Biotronik bear no relation to the susceptibility of Biotronik's transmissions to other interfering signals within the 402-405 MHz MICS band. No tests are conducted with interfering signals in the MICS band. In fact, the standards *explicitly exempt* the receipt of data by Biotronik's RF receiver system while in the presence of ambient signals at 402-405 MHz. *See* Opposition of Medtronic at 22 n.59, filed June 11, 2003, ET Docket 03-92.
Biotronik's implant will not cause interference to MICS-compliant implants or other transmit-only implants. "The scheduled periodic transmissions emitted by Biotronik's medical implant devices will not cause harmful interference to other MICS users." RfW at 5.	Medtronic's calculations show that Biotronik's device will cause interference to MICS-compliant implants and to other transmit-only implants at distances greater than 10 meters. This is close enough to cause interference in nursing homes, assisted-living dwellings, hospitals, and clinics. *See* Medtronic *ex parte* filing, Sept 4, 2003. If Biotronik is permitted to use higher power, the range of interference could include individual residential housing, such as developments, apartments, condominiums, etc.

Biotronik's Request for Waiver says …	**When in reality …**
There is no other way for physicians to remotely receive the type of data that Biotronik's home monitoring system provides. "[Without Biotronik's approach] this type of data could be collected only through regular office visits by the implant patient or his or her physician once every six months or annually." RfW at 2.	A number of non-MICS systems offer the capability of providing data from patients' implants to physicians located in remote locations. In fact, Biotronik provided the FCC with a videotape of one such system that offers remote home monitoring capabilities on a UHF frequency outside the MICS band. Ironically, Medtronic manufactures the system depicted in the video supplied by Biotronik. *See* Biotronik ex parte presentation, FCC file PG6BA0T, Mar. 14, 2003 (providing videotape of newsclip profiling Medtronic "Chronicle" remote medical telemetry system).
It is not possible to "turn off' period scheduled transmissions. "Biotronik cannot "turn off" periodic transmission mode independent of other modes of transmission, [and] doctors have been unable to implant Biotronik's devices in cardiac patients since the Commission's February 25, 2003 Order." Biotronik Reply Comments at 2 n.6. "It is not possible for Biotronik to use its cardiac implant devices in the manner contemplated by the Commission for 8 to 12 months." RfW at 2 n.4. To comply with the FCC's decision requiring Biotronik to "turn off" periodic transmissions, requires the company to "rewrite the implant device's firmware, …validate all of the software," and re-request FDA approval. *Id.*	Biotronik's own user manual for the implants explains that the "Home Monitoring function can be switched ON or OFF" independent of the other RF modes. *See, e.g.,* Philos Technical Manual at 5, 8, FCC ID: PG6BA0T. In addition, Biotronik's April 8, 2002, filing requesting reconsideration of the initial adverse OET Letter Order states that: "Scheduled messaging is programmable as ON or OFF," demonstrating that at least as early as April 8, 2002, Biotronik was able to turn off scheduled messaging and comply with OET's order, but chose not to. *See* Biotronik Inc., Petition for Reconsideration or Waiver, Biotronik Inc. Grant of Equipment Authorization for the Medical Implant Communications Service, FCC ID PG6BA0T, Ref. No. 1300F2, Apr. 8, 2002. Biotronik also implies disingenuously that it has just learned that its periodic transmissions are non-compliant, when it has known this since March 2002. *See* RfW at 2 n.4.

Biotronik's Request for Waiver says …	When in reality …
Frequencies proposed by Medtronic (e.g., 433 MHz under Part 15) for transmit-only operation are not available internationally. "[T]he alternative bands Medtronic proposes are not [available internationally]." Biotronik Reply Comments at 9.	The 433 MHz band, which is available in the U.S. under Part 15 of the FCC's rules, is also available overseas. Without a waiver of the MICS rules, Biotronik would be able to operate its transmit-only device at 433 MHz. Several other non-life critical medical devices operate from within the human body on a transmit-only using Part 15. *See* Medtronic Opposition, ET Docket 03-92, June 11, 2003 (describing transmit-only medical devices, the "M2A Capsule" and Medtronic Bravo Unit).
Biotronik is working on implementation of a compliant device. "While Biotronik continues to work on developing a bi-directional circuit, implementation of a compliant device will require an extended period of time … . In the interim, Biotronik's [] system [] will [help] in the treatment of cardiac patients." Biotronik Reply Comments at 6. *See also* Biotronik Comments at 4.	There is no need to grant the unlimited open-ended waiver that Biotronik has requested because the company is developing a MICS-compliant system. Medtronic has even identified for Biotronik vendors of MICS-compliant solutions. Accordingly, no waiver is needed, but if one were to be granted, it should be limited in time and to operation of the current Philos DR-t and Belos implant devices – not to the broad class of all cardiac or other implant devices.

Biotronik's Waiver Request: Prescription for Congestion

The Commission should not grant Biotronik's request to waive the requirements that implant devices in the Medical Implant Communications Service ("MICS") "listen before transmitting" ("LBT"). First, Biotronik's waiver request essentially asks the FCC to create a medical CB band with all the uncertainties regarding interference, band growth, and reliability; allowing Biotronik's "transmit-only" approach will severely compromise the band's long-term medical usefulness. Second, the request is inconsistent with sound spectrum management and the forward-looking direction that the FCC is taking with encouraging use of state-of-the-art self-regulating radio systems; Medtronic and others have expended considerable time and effort developing fully MICS-compliant systems. Third, there is no sound reason for granting the request because (i) alternative spectrum is available for Biotronik's application, and (ii) LBT systems for MICS-compliant operation at 402-405 MHz are available today. Fourth, NTIA, which warns about the possibility of harmful interference, does not support Biotronik's request as proposed, and Biotronik has balked at NTIA's suggested conditions. Fifth, Biotronik should not be rewarded for its duplicitous behavior with both the Commission and the medical community.

Grant of Biotronik's waiver will essentially create a medical CB band and severely compromise the long-term usefulness of the MICS band.

- The FCC required LBT for a reason – to offer a reliable medical service that avoids receiving and causing harmful interference and effectively increase the number of MICS devices and applications operating in close proximity to each other. The Commission intended to create a reliable service for advanced two-way RF medical implant devices supporting life-critical applications.

- Transmit-only devices will interfere with MICS-compliant devices, and the harm to MICS operation will encourage continued use of old technology, impeding development of MICS-compliant equipment incorporating smart transceivers.

- While the power levels stated in the waiver request are less than allowed under MICS, Biotronik has requested unlimited authority to transmit at maximum power with no limit on the number of transmissions, the transmission duration, or the frequency of transmissions. In addition, if the Commission blindly grants a waiver of Section 95.628(a), as Biotronik requests, the company would be allowed to develop an external controller that operates on a transmit-only basis.[1]

- The promise of MICS will be lost should the FCC grant Biotronik's waiver. Biotronik's approach is not only admittedly unreliable but also inconsistent with the

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[1] Biotronik's request impacts the MICS rules that apply to implant transmissions, *i.e.*, Sections 95.628(b), 95.1209(b), and 95.1211(b), but the waiver request only cites Section 95.628(a), which governs the operation of the external programmer/controller. Notably, Biotronik's waiver requests coverage only for its implanted devices, and NTIA explicitly requests that any waiver be restricted to implanted devices.

forward-looking direction that the FCC is taking with regard to efficient spectrum use. Also, contrary to Biotronik's assertion, MICS-compliant implants that incorporate LBT are within the state-of-the-art.

Alternative spectrum for Biotronik's application is available in the U.S. and internationally.

- Transmit-only medical devices for non-life critical transmissions, similar to Biotronik's devices, operate from within the human body under Part 15. And, contrary to Biotronik's assertion, these frequencies are available internationally (*e.g.*, 433 MHz).
  - ❖ A recent FCC paper on unlicensed devices describes the "M2A Capsule," a transmit-only device that sends internal images of the digestive tract.
  - ❖ Medtronic also offers a medical device that transmits pH levels from within the digestive tract to an external receiver at 433.9 MHz.
- Biotronik's transmit-only operation is inherently unreliable and admittedly not suitable for life-critical applications. Transmit-only operation, which can impact MICS-compliant systems providing life-critical communications, should operate outside of the MICS band.

Far from having "no objection" to the waiver, NTIA warns of the "real risk" of interference from METAIDS and offers conditions that Biotronik has rejected.

- NTIA has recommended that any possible waiver be limited to the current "device characteristics (*i.e.*, peak power, periodic transmission duration, and transmissions per day)," yet Biotronik objects to this condition.[2] And, remarkably, Biotronik has delegated to the FCC the task of telling NTIA that this condition is unacceptable.

A company that ignores clear FCC orders, flouts long-standing rules, and makes misleading statements should not be rewarded with a waiver of the LBT rules.

- Biotronik never complied with the March 8, 2002, OET order to modify its devices by deleting the periodic transmission feature used to support its "Home Monitoring" application.
- Instead, Biotronik launched a broad-based marketing campaign announcing the availability of the Home Monitoring capability of its RF implants in the United States – in specific contravention of FCC's rules governing the marketing of unauthorized equipment. (Biotronik implies in its latest waiver request that it just learned that the

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[2] Biotronik asserts that the conditions are not necessary because its "cardiac implants have gone through rigorous, FDA-approved testing" showing that they are not susceptible to interference from METAIDS. However, the standard tests that Biotronik cites bear no relation to the susceptibility of Biotronik's transmissions to METAIDS interference –the FDA does not conduct any tests with interfering signals in the MICS band.

feature is not authorized and that it needs time to come into compliance – despite the fact that the company has known for well over a year that its periodic transmissions do not comply with the MICS rules.)[3]

- Biotronik also applied for and received several experimental authorizations to "test" the periodic transmission capability. Under cover of these authorizations, it has:

  - ❖ sold unauthorized implant devices in specific contravention of the Commission's rules; and

  - ❖ marketed the devices' unauthorized periodic transmission capability – again in direct contravention of Commission orders and rules.

- Biotronik also steadfastly refuses to inform doctors and patients that the FCC has not authorized the "experimental" periodic transmission capability and that its use is limited to two years. According to Biotronik, having to so inform doctors and patients would harm such impermissible "experimental" sales.

- Biotronik also claims that it "cannot 'turn-off' periodic transmission mode used for Home Monitoring independent of other modes of transmission." Reply Comments of Biotronik at 2 n.6. However, Biotronik's user manual for the implants explains that the Home Monitoring feature can be set on or off, independent of the other RF modes. *See, e.g.,* Philos Technical Manual at 5, 8, FCC ID: PG6BA0T ("The Home Monitoring function can be switched ON or OFF . . . The patient activated message can also be programmed ON or OFF.").

- Biotronik's waiver request ignores the reality that its implants will be used in nursing homes, hospitals, and clinics, in an attempt to mask the real risk that the non-compliant transmissions will be susceptible to interference and cause interference in these locations. Particularly when the patient is in a hospital or clinical setting the attending physician will likely want to step up monitoring, and, thus, the number of transmissions from the RF medical equipment, thereby increasing the likelihood of interference.

- Biotronik continues to ignore FCC directives and to play fast and loose with the Commission's rules. Grant of the requested waiver would encourage equipment makers to follow Biotronik's full steam ahead marketing and sales approach, and develop transmit-only implants that can be placed on the market cheaply and quickly to the harm of the public interest and long-term growth of the MICS band.

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[3] During the development of the FCC rules, ITU Recommendation, and ETSI Standard – all requiring implementation of LBT – Biotronik made no objection, nor did it offer any input, while knowing that the equipment it was developing did not meet the requirements being promulgated.

THE FUTURE OF THE MICS SERVICE

TWO CRITICAL ISSUES

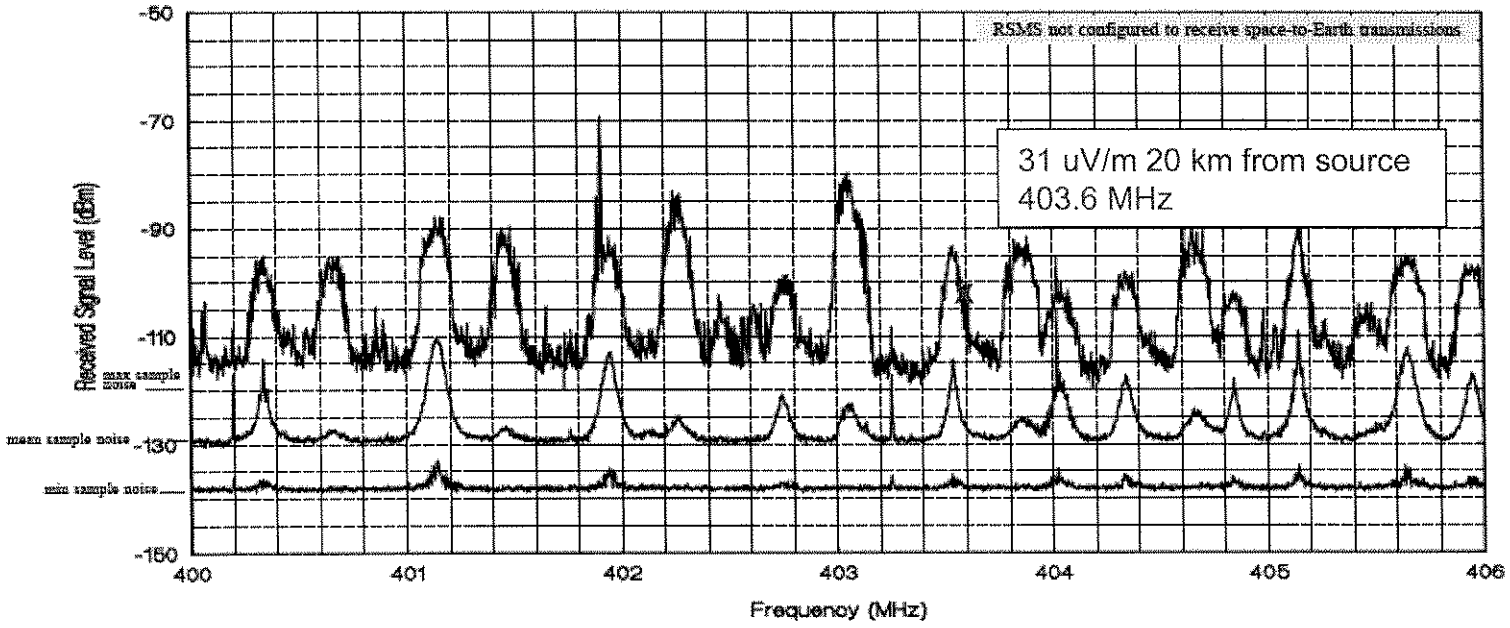
- Frequency monitoring in the band is required.
  - LBT is critical to avoid interference from ambient emissions whatever their source.
  - The RF environment demands LBT to ensure a reliable communications service.
- Interference control between MICS devices.
  - A single device has the potential to interfere with other MICS systems.
  - Proliferation of non-LBT devices will cause interference to and from MICS devices

THE NEED FOR LBT AMBIENT RF LEVELS 3 SCENARIOS

- General Environment in a broad geographic area (San Francisco) from NTIA files.
  - 2 different locations, scanning downtown from 5 km & 20 km distances
- Home environment
  - 3 different digital systems,
- Medical Facility environments
  - Scans of ambient EMI at 6 locations

GENERAL ENVIRONMENT

San Francisco Area, 1st Location
Biotronik Philos System potentially blocked
20 km from source for Rx and Tx at 3m separation

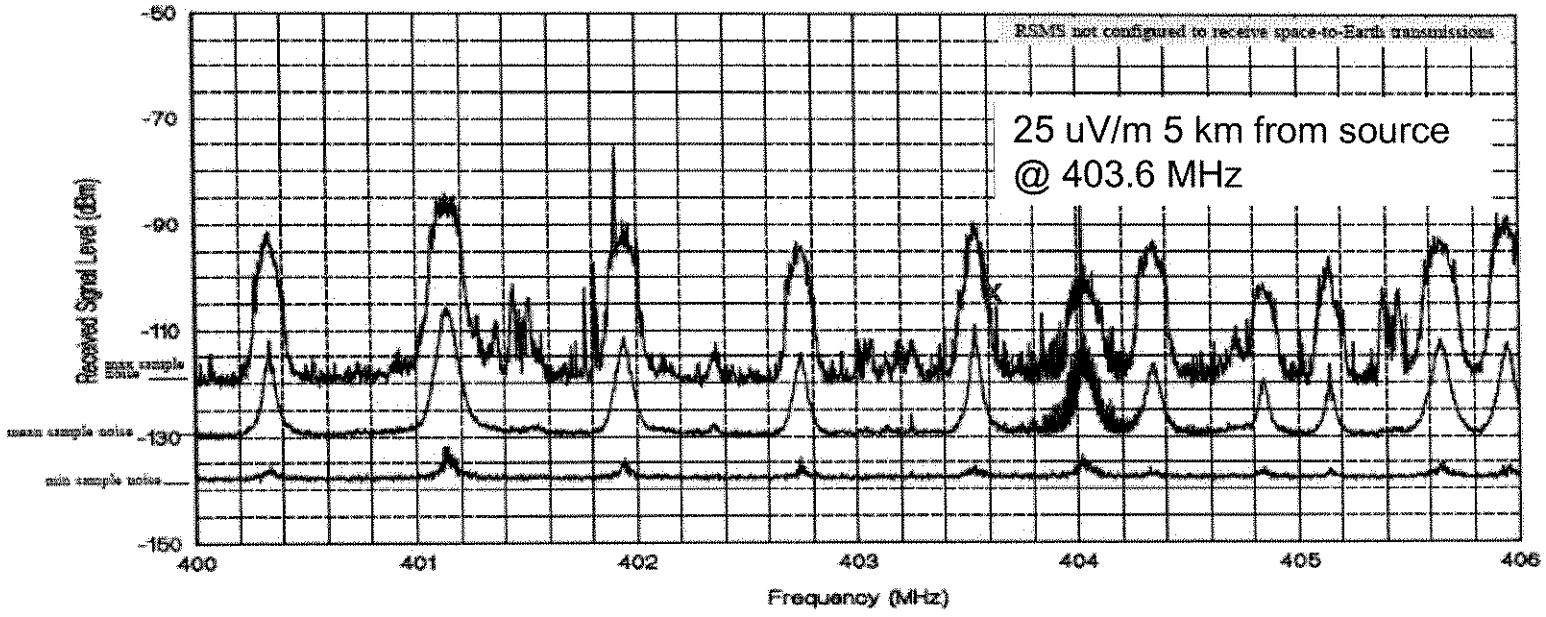


1. STANDARD FREQUENCY AND TIME SIGNAL-SATELLITE (400.1 MHz ±25 kHz).
2. 400.15-401 MHz: METEOROLOGICAL-SATELLITE (space-to-Earth).
3. 400.15-401 MHz: SPACE RESEARCH (space-to-Earth), MOBILE-SATELLITE (space-to-Earth), Space Operation (space-to-Earth).
4. 401-402 MHz: SPACE OPERATION (space-to-Earth), Earth Exploration-Satellite (Earth-to-space), Meteorological-Satellite. (Earth-to-space).
5. 402-403 MHz: Earth Exploration-Satellite (Earth-to-space), Meteorological-Satellite (Earth-to-space).

Figure 17. NTIA spectrum survey graph summarizing 1,320 sweeps across the 400-406 MHz range (System-1, band event 16, swept/m3 algorithm, sample detector, 3-kHz bandwidth) at San Francisco (Grizzly Peak), CA, 1995.

ALTERNATE LOCATION

San Francisco Area, 2nd Location
Biotronik Philos System potentially blocked
3.1 km from source for Rx and Tx at 3m separation



1. STANDARD FREQUENCY AND TIME SIGNAL-SATELLITE (400.1 MHz ±25 kHz).
2. 400.15-401 MHz: METEOROLOGICAL-SATELLITE (space-to-Earth).
3. 400.15-401 MHz: SPACE RESEARCH (space-to-Earth), MOBILE-SATELLITE (space-to-Earth), Space Operation (space-to-Earth).
4. 401-402 MHz: SPACE OPERATION (space-to-Earth), Earth Exploration-Satellite (Earth-to-space), Meteorological-Satellite (Earth-to-space).
5. 402-403 MHz: Earth Exploration-Satellite (Earth-to-space), Meteorological-Satellite (Earth-to-space).

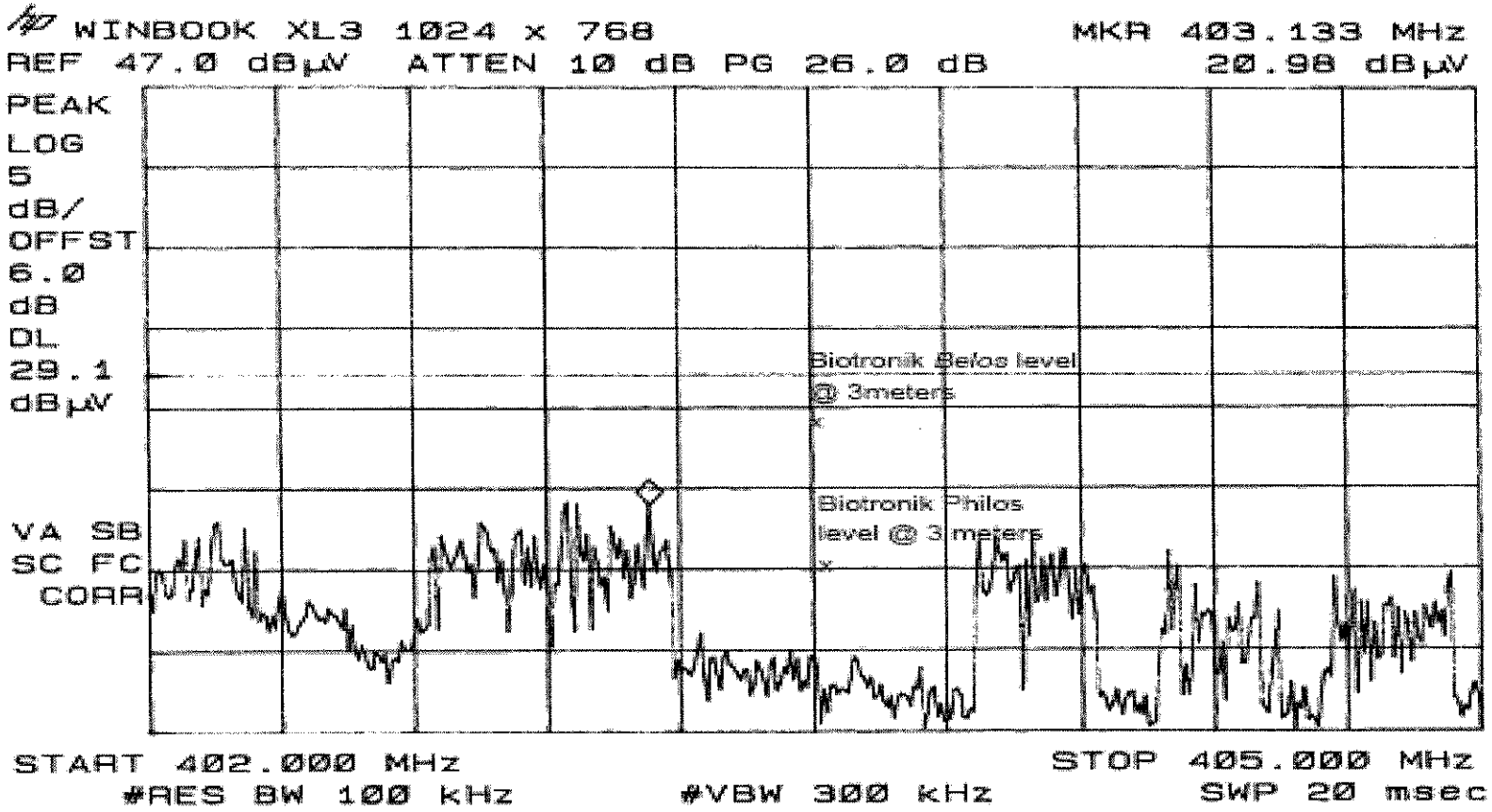
Figure 18. NTIA spectrum survey graph summarizing 1,740 sweeps across the 400-406 MHz range (System-1, band event 16, swept/m3 algorithm, sample detector, 3-kHz bandwidth) at San Francisco (Yerba Buena), CA, 1995.

FREQUENCY MONITORING IN THE GENERAL ENVIRONMENT

- Allowing 12 dB for wall attenuation, without LBT, the Biotronik Rx C/I ratio of 14 dB could not be met at distances <6 km along one radial and along the other radial at distances <1.25 km with the Philos implant Tx separated from the Rx by 3m inside the home.
- With LBT for frequency selection and wall attenuation, inside the home the C/I ratio of 14 dB as above could be met with virtually no potential for any interference to the Biotronik communications link from these sources.
- RELIABLE communications link not possible with Biotronik transmit only system.

HOME ENVIRONMENT

1ST UNIT



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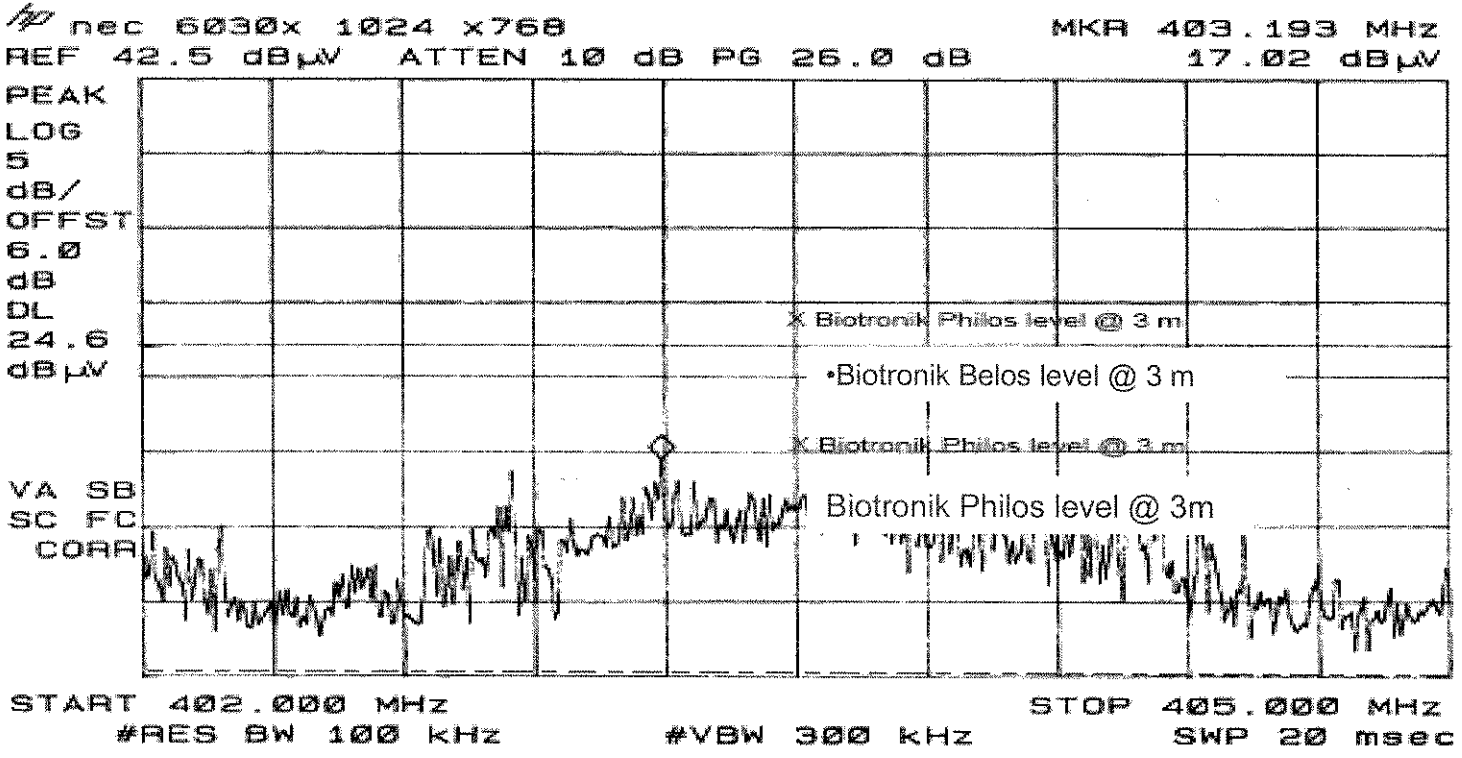
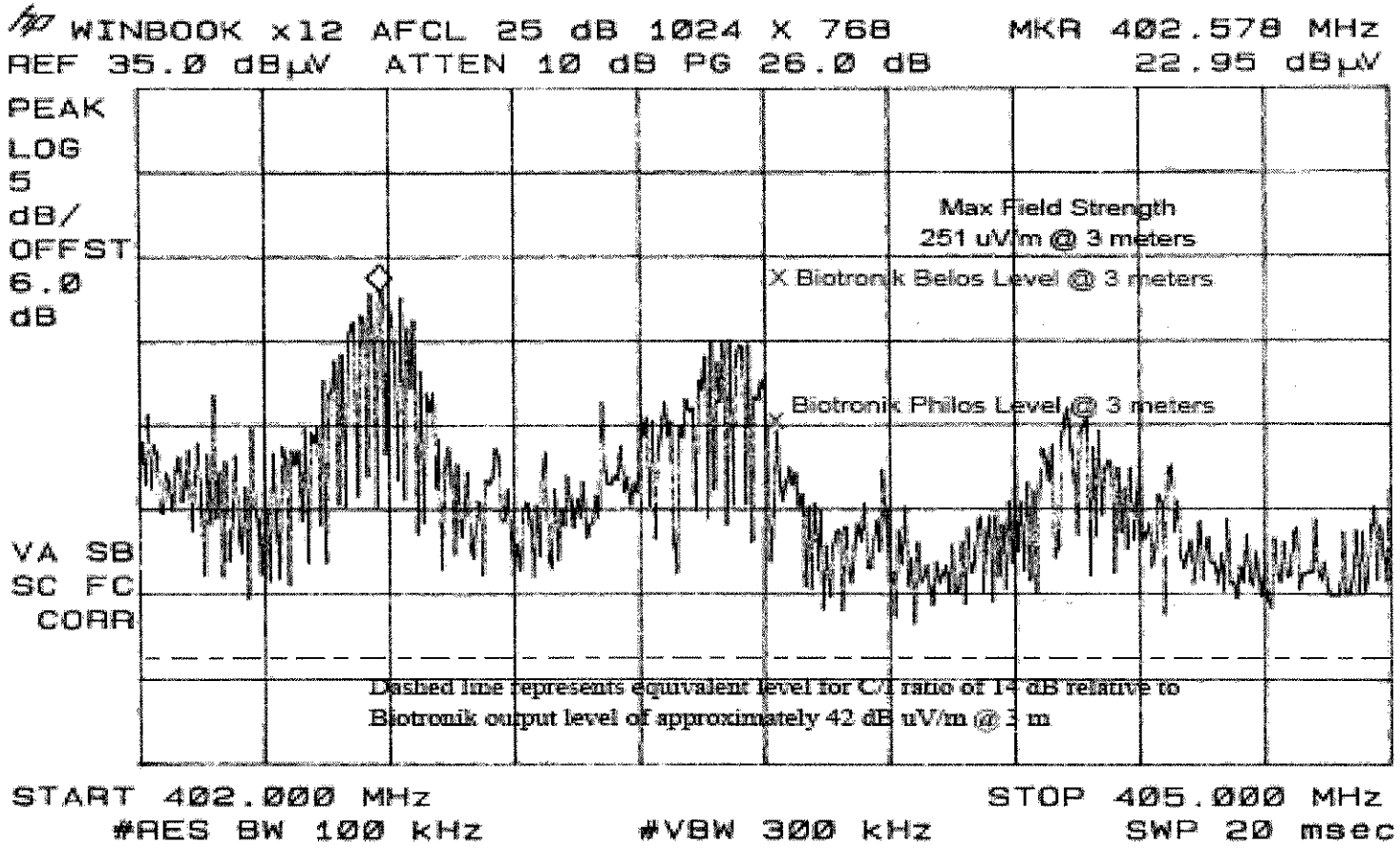
2nd unit



CONTINUED

3rd unit



FREQUENCY MONITORING IN THE HOME

- The Philos system will not function at 3 meters separation if its Rx is within 3m of any of the digital devices. To function in this case the Philos Tx must be <0.5m. Not likely at 2:00 am.
- With LBT and frequency selection the Philos device could function at approximately 1.5m in all 3 scenarios.
- The Belos-T devices will not function at 3 meters in the presence of two of the units. To function in the latter case they must be within 1.9m.
- With LBT and frequency selection the Belos device could function at 3m in the presence of all 3 units.
- Again, reliability is the issue.

MEDICAL FACILITY ENVIRONMENT

- Ambient measured at multiple locations at several different medical facilities.
- Levels show that ambients are above threshold level in many locations, only 2 or 3 channels below threshold available in some medical facilities.

FACILITY 1

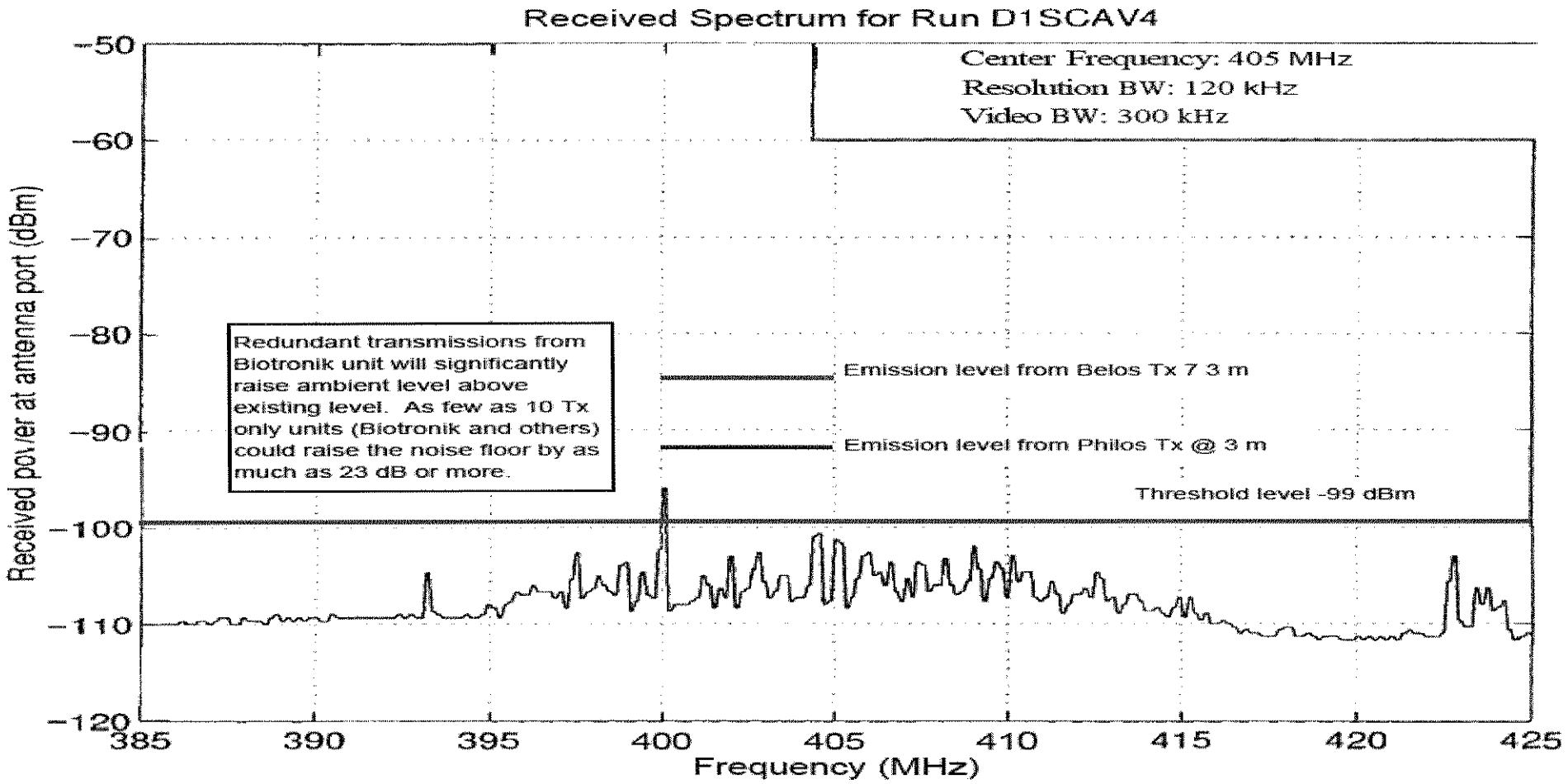


Figure 109: An average standard spectrum scan

FACILITY 2

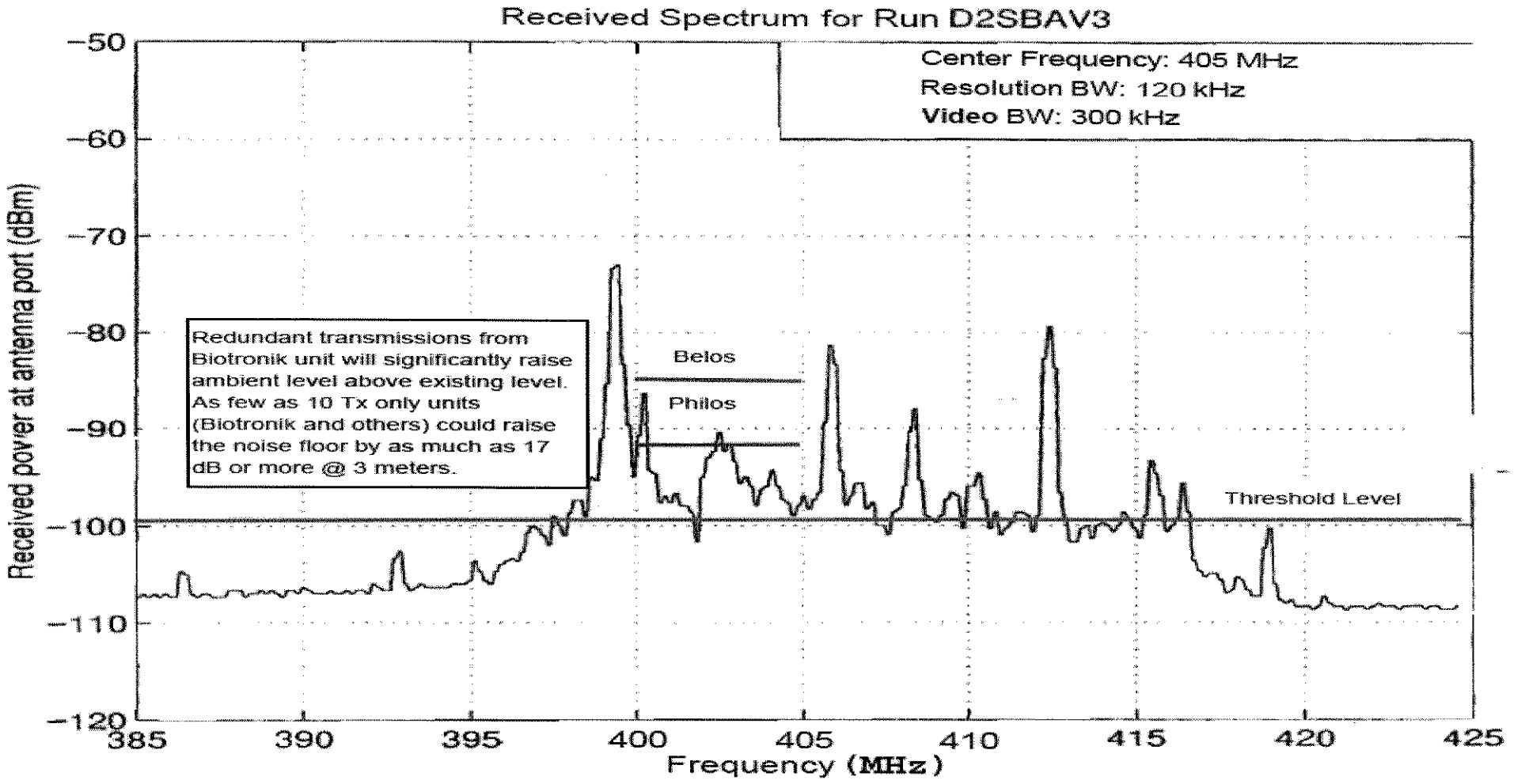


Figure 149: An average standard spectrum scan

FACILITY 3

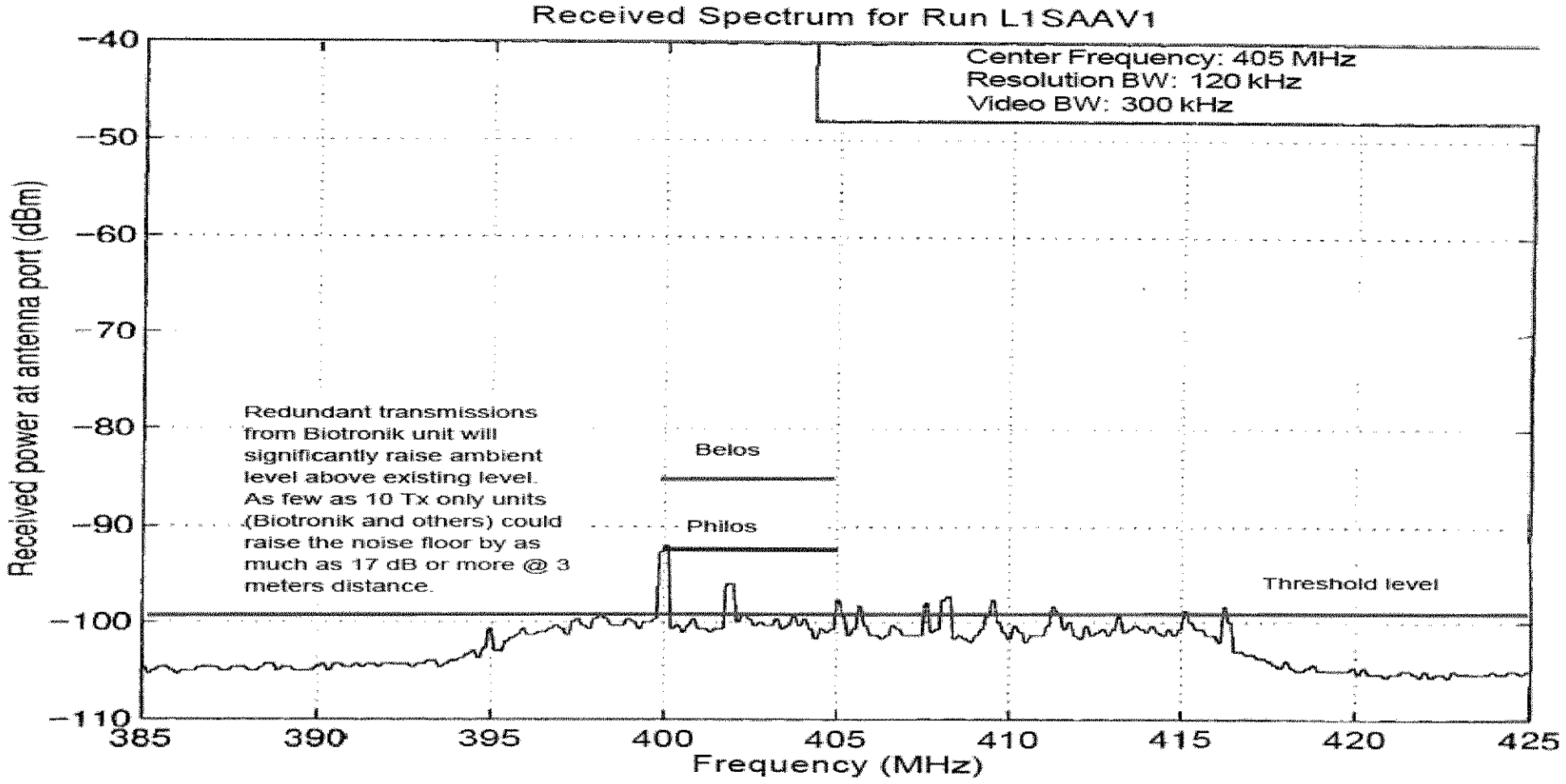


Figure 169: An average standard spectrum scan

FACILITY 4

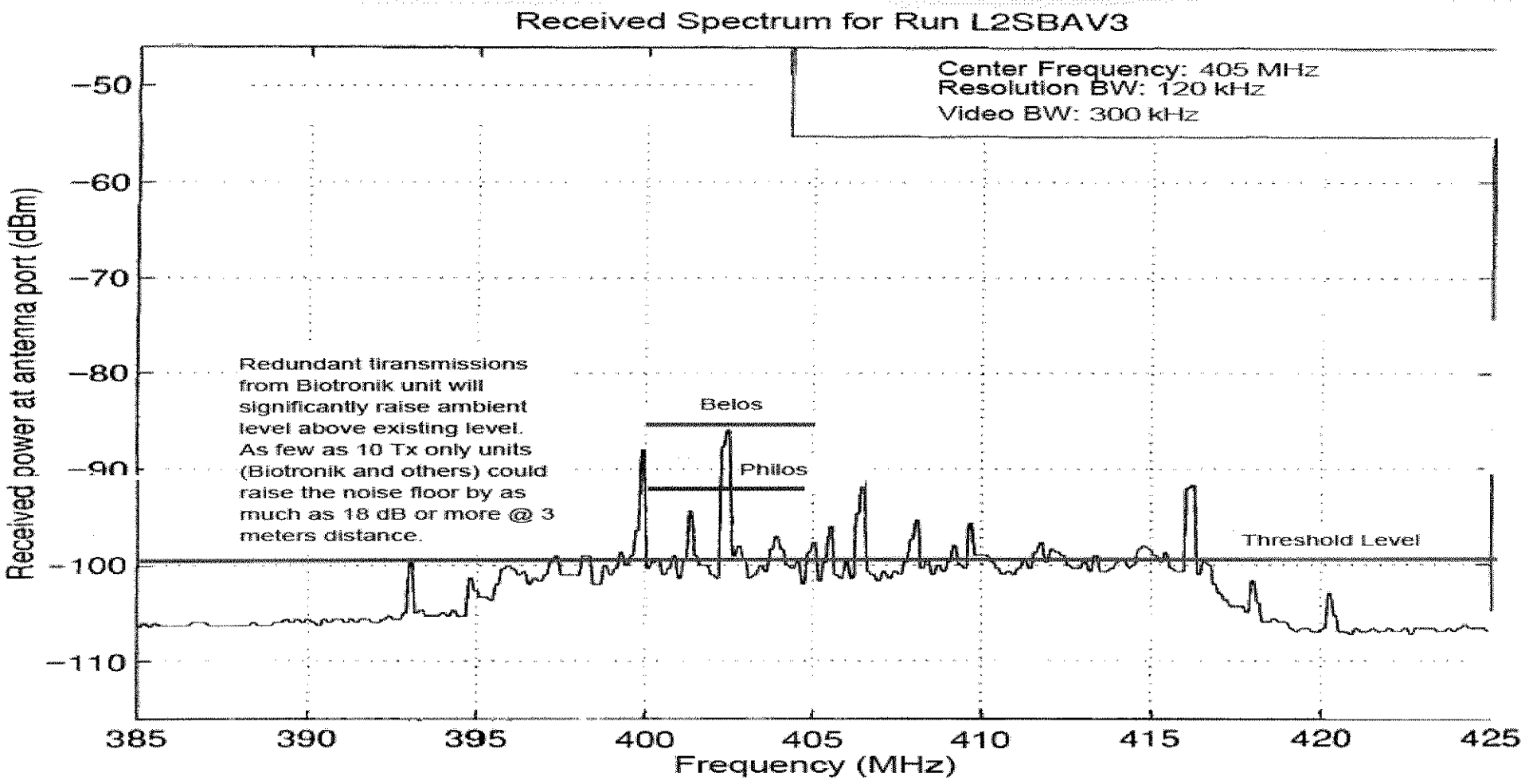


Figure 227: An average standard spectrum scan

FACILITY 5

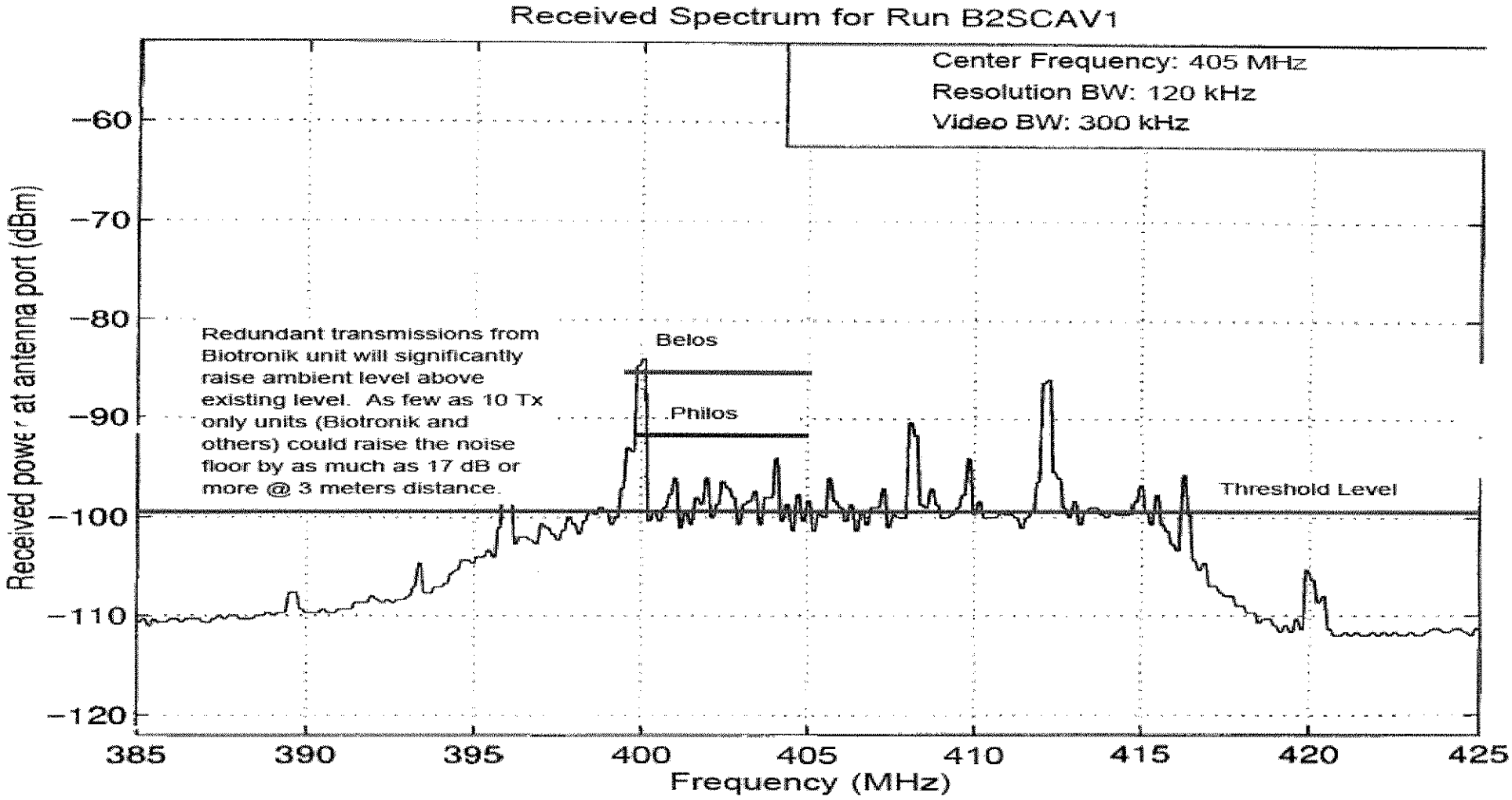


Figure 343: An average standard spectrum scan

FACILITY 6

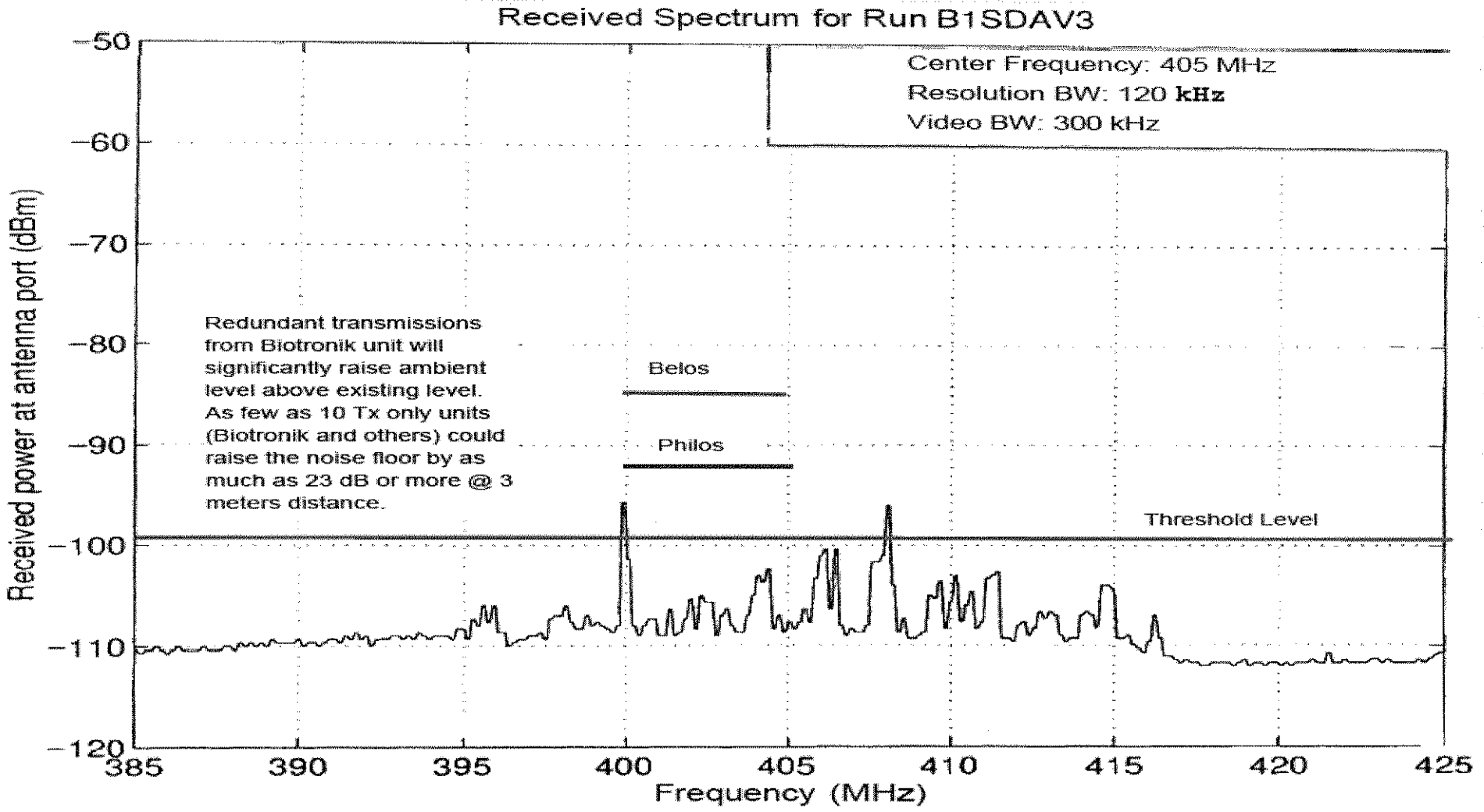


Figure 293: An average standard spectrum scan

FACILITY 6 (PEAK)

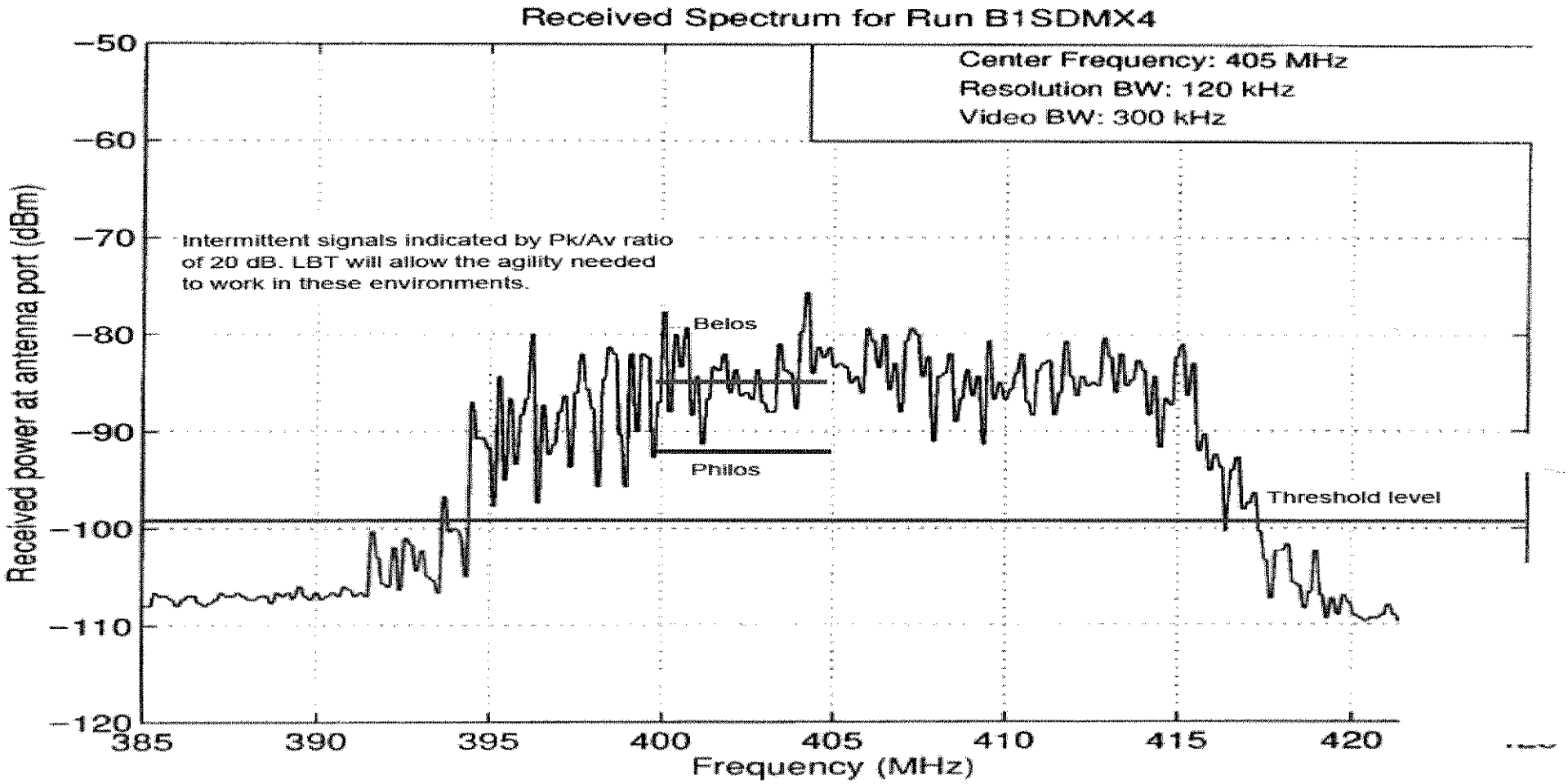


Figure 294: A max hold standard spectrum scan

FREQUENCY MONITORING IN A MEDICAL FACILITY

- Average levels computed by summing the measured levels in a given bin and dividing by the number of sweeps (Video Averaging).
- Frequency monitoring and selection will permit channel selection at or below threshold level.
- FM&A using LBT makes MICS a reliable service.
- Redundant Biotronik emissions are well above threshold levels. Such emissions serve no purpose but will add to the noise floor.
- Potential to cause interference in the Medical Facility is clear.

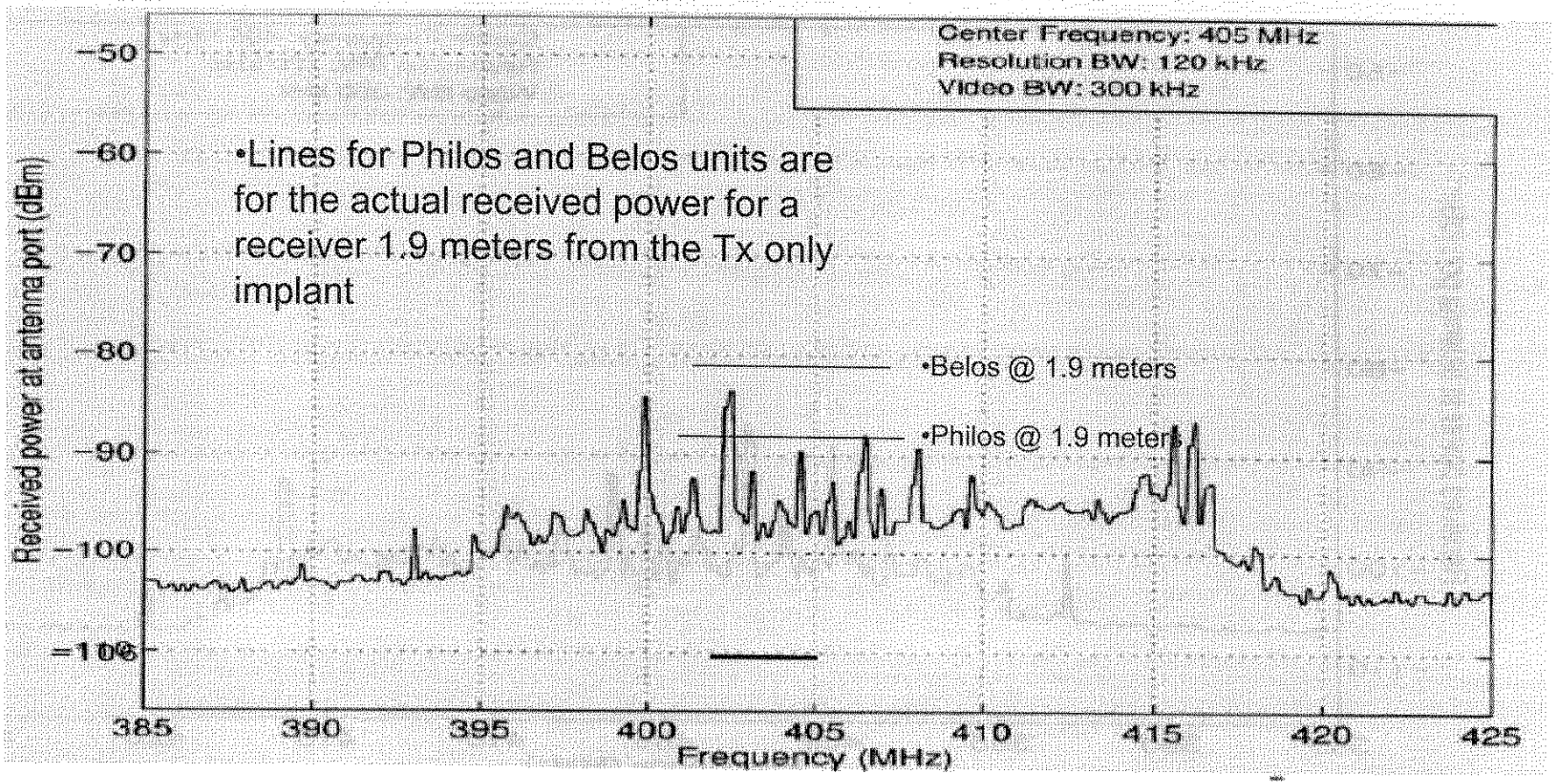
TX ONLY IMPLANT TO MICS SYSTEM INTERFERENCE

- Separation distances less than 18 meters, there is a significant threat of interference with devices of equal power
  - Assisted living homes, nursing homes, hospital wards, physician waiting rooms, etc.
- "Worst case" condition (high power Tx only implant or programmer), the separation distance is approximately 170 meters
  - Applies to individual apartments, residential developments, etc.
- Potential interference effects on threshold level out to 25 to 30 meters radius
  - Applies when existing ambient is near threshold level

INTERFERENCE FROM NON-LBT SYSTEMS

- Biotronik inaccurately portrayed their additive noise in a hospital environment by 20 to 30 dB @ 1.9 meters!
- From Johnson and Jasik, "Antenna Engineering Handbook", $P_r = (\lambda/4\pi R)^2 G_t G_r P t$.
- Using parameters from the FCC Files.
  - FCC ID:PG6BOAT, noise power into receiver at 1.9 meters = 89 dBm.
  - FCC ID: PG6BELOS-T, noise power into receiver at 1.9 meters = 81 dBm.

TRUE BIOTRONIK POWER LEVELS



BIOTRONIK'S RfW

- Biotronik requested waiver of the frequency monitoring provisions of 95.628(a)
  - If rules are waived as requested, a PROGRAMMER without LBT could be CERTIFIED
- Biotronik objects to the operating parameter condition listed in NTIA's letter stating;
  - "Obviously, Biotronik did not, and could not, describe the specific operating characteristics of such future devices in its waiver request."
- Would "future devices" use additional redundant transmissions, longer pulse durations, higher power (-7dbm)?
- NOTE: Biotronik was issued a Canadian Developmental License, Tx & Rx system, at -37 dBW or –7 dBm (8 times higher power than permitted by Part 95).

LIFE THREATENING ISSUES & Radiosondes

- Biotronik asserts that the MICS link "cannot be used for the purpose of immediate response to life threatening situations".
  - Their implants have the ability to recognize a "cardiac event" and automatically transmit. Thus, it seems reasonable to expect immediate response to a "cardiac event" if such an event is transmitted
  - A radiosonde is not likely to know the difference between a "cardiac event transmission " or "scheduled transmission".
- MICS compliant implants will transmit similarly, however, the two-way capability of a MICS implant permits instant recognition of message failure and immediate retry.

PROLIFERATION

- Cardiac implants total about 3 to 5 million
  - With no waiver sunset many could be transmit only.
- Critical Type 1 diabetes patients total more than 1 million with Type II patients another 10 million
  - 1 million are immediate candidates for RF implants, a significant number of Type II patients may benefit
- Other uses are in treating epilepsy, Parkinsons, incontinence, bone stress, etc.
- In the near future as many as 2 million patients could vie for access to MICS spectrum.

BAND MANAGEMENT IS REQUIRED

- Demand for medical telemetry from implants is here now and will grow in the future.
- Deployment rates will be rapid as technology evolves.
- Demands on the band will come from many directions.
- Interference avoidance can be addressed by frequency monitoring and selection.

Summary

- Home, medical facility, and general environments all require frequency monitoring and frequency selection for reliability.
- Low power transmit only devices will cause harmful interference to other transmit-only devices and compliant devices.
- Redundant transmissions – whose only purpose is to attempt to correct a reliability deficiency – deny spectrum access to others and raise the noise floor.

Summary (cont.)

- An FCC misstep will take years to correct
- Reliability of the MICS service is the key issue. LBT to avoid interference is needed.
- The FCC should not "eviscerate" the MICS rules by granting Biotronik's waiver.