Safety in Medical Signal Analysis

André Fabio Kohn and
Sérgio Shiguemi Furuie
University of Sao Paulo

The art of medical diagnosis has increasingly been aided by the development of equipment and techniques based on electronics, physics, signal analysis, and computer science. In particular, methods and concepts from signal analysis, i.e., signal and image processing, pattern recognition and knowledge-based procedures, have been responsible for the development of many of today's medical instruments.

But are signal analysis techniques safe for medical applications? Can any technique be used without concern for erroneous results that may lead to a wrong diagnosis or an inadequate decision? If the medical device permits the operator to select certain parameters (e.g., filter characteristics, temporal or spatial sampling interval), then there is always a possibility that certain choices lead to severe artifacts or distortions, or undesirable behaviors in a closed loop system, and therefore to a wrong diagnosis. The first step in analyzing such systems is to define the meaning of the "safety" of a signal analysis technique.

One could declare a signal analysis procedure safe if the probability of an incorrect interpretation or decision, attributable directly to the procedure itself, is below a certain value. A signal analysis technique may produce graphs, images, numbers, or tables to be analyzed by either a physician or a machine. Errors in interpretation caused by signal analysis artifacts or distortions may be due to implementation problems, such as unexpected overflow/roundoff error and program code error, or due to the signal analysis method itself.

Finite register length effects are easy to control during the design phase; but, on the other hand, programming errors are quite difficult to avoid and to detect, and pose a serious threat to equipment safety. Software safety is a complex issue in computer-based medical equipment, and needs to be addressed by a variety of means [1, 2].

However, the most subtle source of artifacts is the signal analysis method itself. An example is the use of a filter to attenuate interference when the (unidimensional) signal of interest contains wavelets. The output wavelets may be distorted by the filter in such a way that their interpretation leads to an incorrect diagnosis. In medical imaging, peripheral hot spots and sunburst streaking in computed tomography [3], blurring of tomographic reconstruction of cardiac images (as in SPECT) due to organ movement, and artifact due to image enhancement are among the difficulties introduced by signal analysis methodology. Hence, special care is required in interpreting the image. Signal analysis artifact or distortion may arise in at least three ways: 1) when the designer has not predicted the gamut of the input signals; 2) when external factors, such as organ movement, electrical interference and noise, significantly modify the normal operating conditions; and 3) when improper parameter settings are used by the operator.

It is quite difficult to study the possibility of artifacts generated by the signal analysis method itself. In some cases, an in-depth knowledge of the relevant signal analysis theory may be sufficient to pinpoint the cases in which a technique may give rise to artifact. In other cases, there is no other way but running a large number of trials with different inputs. Knowledge from (i) the particular biological signal, and its generators and characteristics in normal and pathological states, as well as in various recording situations; and (ii) the theory of the signal analysis technique employed, usually provides some hint as to the different signals one should apply to test for possible artifacts or distortions. Still, the problem of selecting a broad range of test signals that is representative of the input signal space is a major challenge.

But how should the outputs of a signal analysis technique be evaluated in terms of the potential to cause a wrong diagnosis or an inadequate decision? Unfortunately, not all artifacts or distortions will lead to an erroneous result. Therefore, the final step in the testing for malfunction should involve the decision maker, i.e., a physician or a machine. In the case of a human decision maker, one should use a sufficient number of people to ensure statistical significance, giving preference to specialists from different medical centers to avoid possible correlation between judgments. An interesting example on the use of humans to evaluate pattern recognition techniques can be found in [4]. One application of a machine decision maker where the safety issue is extremely relevant is in closed-loop systems, where signals from the patient are analyzed by the machine, which then issues command signals for actuators.

The issues raised in this article are easy to understand but difficult to confront. Nevertheless, some general recommendations can be put forward:

- Besides defining norms for hardware and software quality, the problems of signal analysis safety must also be considered. For systems where interpretation is done by physicians, proper statistical analysis procedures should be employed to assure a reliable estimation of the safety of the signal analysis technique.
- A thorough testing should be carried out during development to see if the combination of parameters chosen by the operator, and/or atypical input signals (e.g., spikes) can lead to the generation of dangerous artifacts or distortions. The system should produce diagnostic messages for any potentially dangerous operator inputs. It should also give advice on adequate choices of parameters, perhaps illustrating with pre-recorded signals the effects of any parameter set.
- Data bases with interpreted signals (by experts in the field) for normal and pathological subjects, under different experimental conditions, are extremely valuable for testing signal analysis techniques and should be widely available. One example of such a data base is that developed by MIT/BIH for ECG signals. Simulated signals, based on physiology and pathology or on fitting techniques, may also be very useful for testing different signal analysis methods.
- In cases where a machine is the "final user" of a signal analysis procedure in a closed loop system, one should look at the experience of people involved in evaluation of the reliability of real-time algorithms and software in complex control systems.

It is clear that biomedical engineers have important tasks with respect to the issues raised here. These include: evaluating the

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Academy of Dermatology Task Force on DERM/DDX, which has developed an on-line differential diagnosis system for dermatologists. He is president of Stoecker Moss & Co., which develops medical computer vision systems. His research interests include artificial intelligence in medicine, computer vision in medicine, and diagnostic problems in dermatology. Dr. Stoecker is an associate editor of *Computerized Medical Imaging and Graphics*. He is a member of the UMR Chapter of Sigma Xi.

References

1. **Umbaugh SE, Moss RH, Stoecker WV:** Automatic color segmentation of images with application to detection of variegated coloring in skin tumors. *IEEE Engineering in Medicine and Biology* 8(4) 43-52, 1989.
2. **Genesereth MR, Nilsson NJ:** *Logical Foundations of Artificial Intelligence*. Morgan Kaufman, Palo Alto CA, 1988.
3. **Kopf A, Rigel DS, Friedman R:** The rising incidence and mortality of malignant melanoma. *Journal Dermatol Oncol* 8:760-1, 1982.
4. **Tanimoto SL:** *The Elements of Artificial Intelligence*. Computer Science Press, Rockville, Maryland, 1987.
5. **Devijver PA, Kittler J:** *Pattern Recognition: A Statistical Approach*. Prentice-Hall International, London, 1982.
6. **Thomas W, Hapgood W:** *1st-Class Fusion*. 1st-Class Expert Systems, Inc., Wayland Mass., 1987.
7. **Quinlan JR:** Learning efficient classification procedures and their application to chess end games, in Michalski RS, Carbonell J, and Mitchell TM (eds.): *Machine Learning: An Artificial Intelligence Approach*, Morgan Kaufman, Los Altos CA, 1983.
8. **Price K:** Anything you can do, I can do better (no you can't)... *Computer Vision, Graphics, and Processing* 36(3):387-391, 1986.
9. **Koh NH, Lew RA, Prout MN:** Screening for melanoma/skin cancer: theoretic and practical considerations. *J Am Acad Dermtol* 20:159-172, 1989.
10. **Friedman RJ, Rigel DS, Hopf AW:** Early detection for malignant melanoma: the role of the physician and self-examination of the skin. American Cancer Society Pamphlet, 1985. Reprinted from: *A Cancer Journal for Clinicians* 35(3) 130-151, 1985.
11. **Stoecker WV:** personal interview by Scott Umbaugh on 9/30/89 at the University of Missouri-Rolla.
12. **Umbaugh SE:** Computer Vision in Medicine: Identification of Variegated Coloring in Digitized Skin Tumor Images. MS thesis, Electrical Engineering Department, University of Missouri-Rolla, 1987.
13. **Umbaugh SE:** Computer Vision in Medicine: Color Metrics and Image Segmentation Methods for Skin Cancer Diagnosis. Ph.D. Dissertation, Electrical Engineering Department, University of Missouri-Rolla, UMI Dissertation Services, Ann Arbor MI, 1990.
14. **Jain AH, Dubes RC:** *Algorithms for Clusterina Data*. Prentice-Hall, Englewood Cliffs NJ, 1988.

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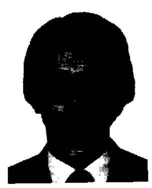
safety of signal analysis techniques proposed for medical equipments or systems; devising safer signal analysis techniques; developing corrective measures for existing techniques to improve the overall safety; and providing guidance to medical personnel in the use of complex medical equipment.

André Fabio Kohn was born in Sao paulo, Brazil. He received the B.S. and M.S. degrees in electrical engineering from the Escola Politecnica, Universidade de Sao Paulo, and the Ph.D. degree in engineering from the University of California, Los Angeles, in 1973, 1976 and 1980, respectively. He has worked in medical instrumentation, biomedical signal processing and pattern recognition, quantitative neurophysiology, and neural modeling. He directs a biomedical engineering laboratory at the University of Sao Paulo that he founded in 1981. Presently, he teaches pattern recognition, signal processing and neural modeling. He may be reached by e-mail at either andfkohn@brusp.bitnet, or, alternatively, andfkohn@brusp.ansp.br; or at the Universidade de Sao Paulo, Escola Politecnica, DEE, Av. Prof. Luciano Gualberto, Trav. 3, 158, Sao Paulo, S.P., Brazil.



Sérgio Shiguemi Furuie was born in Sao Paulo, Brazil, in 1954. He graduated in electronic engineering from the Aeronautics Institute of Technology (1977). He received the M.S. degree in biomedical engineering from COPPE/UFRJ, Rio de Janeiro, in 1980, and the Ph.D. degree from Escola Politecnica, Universidade de Sao Paulo, in 1990. Since 1981, he has worked at the Heart Institute of the University of Sao Paulo. His research interests include biomedical signal processing, tomography, pattern recognition, PACS and general image processing. He may be reached by e-mail: furuie@incor.hc.usp.br

References

1. **Dettmer R:** Making software safer. *IEE Review* 34(8):321-324, 1988.
2. **Hyman WA, Brannigan VM, McDermott JJ, Willingmyre GT, Estrin NF:** Regulatory and other public policy issues. *IEEE Engineering in Medicine and Biology Magazine*, 8(3):33-40, 1989.
3. **Oppenheim BE, Appledorn CR:** Single photon emission computed tomography. In: Gelfand MJ, Thomas SR (Eds): Effective Use of Computers in Nuclear Medicine, McGraw-Hill, New York, 1988.
4. **Siedlecki W, Siedlecki K, Sklansky J:** Experiments on mapping techniques for exploratory pattern analysis. *Pattern Recognition* 21: 431-438, 1988.