

**Information Dynamics view
Of
High Confidence Medical Device Software and Systems**

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Information dynamics is a study of the basic nature of information, and its implications to the design, implementation, operation and use of systems of today and tomorrow. The starting point in this study is the recognition that information is distinct from its representation, and information can only be handled by sentient beings. All mechanical devices can only use representations of information and not the information itself. Further, any information maintains a LOT of relationships with other information. When a representation for the information is created only those representations which are explicitly captured are retained. When A wants to send some information to B, it has to create a representation based on its context – we use the term Perceived Reality for it. The representation so created is sent to B in the form of a message which, when received by B has to be converted by it to information using its perceived reality. As the two perceived realities are different there can be very little assurance that the B got the information that A was sending!!

Information Dynamics provides a framework within which we can examine many of the system issues. It relies extensively on the use of models by the entities. For example, when A and B interact each keeps within its perceived reality a model of the other. The model is used in deciding what action to take as well as in assessing the responses received. Within this framework the actions are carried out by entities using the resources available with them and use physical and well as information inputs. In particular, each action chain has to be triggered by some information. We believe that the Information Dynamics framework is well suited for examining the High Confidence Medical Device Software and Systems.

Medical device software and systems (MDSS) may be viewed as a collection of autonomous entities – including humans – which carry out a coordinated set of actions to achieve a goal which may be the treatment of a patient Each entities in this system may have a well defined role which may be as an

- Information collection agent – which may be a sensor, or a test facility
- Information storage agent
- Information processing agent – which may process, transform or reduce the information
- Information movement agent/facility – which is responsible for moving the information from one location/entity to another location/entity

- Action agent – capable of carrying out some defined actions when instructed/authorized/triggered to do so.

We recognize that any such system only handles represented information and not the actual information which may only be handled by a human being. There may be multiple representations of any information and for us to extract the actual information additional tags/descriptors/metadata may have to be attached to the data so that a machine can recognize and understand the represented information. In order to design a flexible, high confidence medical system we believe that we have to explicitly recognize the distinction between the information and its representation and design the system so that it can carry out the appropriate processing and handling of the represented information which has a meaning at the information level.

The basic building blocks for carrying out any complex operation are a collection of primitive steps/actions. A complex operation can then be carried out by executing the primitive actions in a properly coordinated manner. The coordination of any such actions has to be done at a location and time. Therefore, in addition to information, location and time also become important attributed of such a system.

While the current architecture of the Internet focuses on the movement of data, (a collection of bits structured as a packet), and delivers it from one location to another location without any concern for the content or meaning of the data it is moving, we believe that the MDSS has to move information representations and by keeping enough tags and descriptors/tags with the data in a form and format which can be uniformly interpreted, we can eliminate a number of problems of data movement. Further, as the information movement facilities may be shared for the movement of a variety of information with different degree of priority, importance and criticality, if the information movement infrastructure could recognize the nature of information it is moving, it may be able to carry out a more effective resource management and thereby deliver a consistent and desirable performance.

When we have to plan a sequence of actions which use a number of resources which are shared not only by the entities participating in these actions but also by other entities, we not only need accurate timing information but also the location information. Note that for any two entities to exchange any physical entity, the two have to be at the same place at the same time. Some of the temporal matching can be provided by the use of buffers but any such use of buffers always implies a delay or wasted time.

While a large number of tools, techniques, algorithms etc. have been developed to handle a variety of problems which appear in MDSS, what we require is an integration framework which not only permits the integration of diverse devices, algorithms, procedures, and operations but supports an open environment which is well suited for a continued incorporation of new techniques which maintaining a high degree of confidence in its operations.

Bio of Prof. Ashok K. Agrawala

Dr. Agrawala is a Professor of Computer Science at the University of Maryland. In 2001, he started the Maryland Information and Network Dynamics (MIND) Lab which carries out research and development activities in partnership with the industry. He received a BE degree in 1963 and a ME in 1965 from the I.I.Sc, Bangalore; and a Master of Arts and a Ph.D. degree in Applied Mathematics from Harvard University in 1970. Prof. Agrawala is the author of seven books, 6 patents (awarded or pending), and over 240 papers and is a well recognized for his contributions to the research and use of the management of time in real-time processing and clock synchronization applications. He has developed a few location determination techniques and several other innovative technologies for systems and networks which are in different stages of deployment. Prof. Agrawala is a Fellow of the IEEE and Senior Member of the ACM.