Manufacturing Expert System Development Guidelines in a Medical Device Manufacturing Company

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Abstract — The medical device manufacturing company as well as other regulated industries can only perform manufacturing activities in a strictly controlled environment working area controlled by complex systems that combines pumps, chillers, valves, several types of sensors devices, etc. The tightly integration of those individual components including proper equipment maintenance requires workforce personnel with knowledge in several technical areas of expertise. Recent advancement in computational system capabilities have allowed to develop very complex software programs capable of storing a huge amount of information and later analyze the information to identify patterns, relationships or repetitive events. An expert system is a software solution that has been implemented in different fields like; medicine, law and accounting, to reduce the time to perform troubleshooting and diagnostic. This article presents development guidelines to implement an expert system capable of reducing the business downtime caused by failures in the air handling and chilled water system.

Key Terms — Air Handling and Chilled Water System (AHU/CWS), Expert Systems, Inference Engine, Rules.

INTRODUCTION

Organizations today are making every effort to improve their products and services while controlling costs and increasing the quality of their products. Achieving such goals requires the elimination of non-value added activities and increasing the reliability of their products and services. The use of equipment automation, mechanization and implementation of automated

systems and software is a common and proven successful techniques frequently used to achieve those objectives. Performing those complex tasks requires the know-how of the organization's experts Furthermore, maintaining such and specialists. systems required a vast amount of accumulated knowledge mostly acquired via experience even including trial and error in some cases which is a common situation in an Air Handling and Chilled Water loop control system. Medical Devices Manufacturing processes are mostly executed in a controlled environmental controlled Maintaining the areas within the specified environmental parameters (temperature, humidity, and pressure) is hence vital to disruption to the manufacturing process. Complying with such precise parameters requires the interaction of several mechanicals sensor's controlled and other type of equipment. The combination of those systems working in sync is commonly known as the Air Handling and Chilled Water System (AHU/CWS). The unavailability of an automated, custom made or critical system/equipment due to a malfunction represents a negative impact to the Medical Device Manufacturing industry. Therefore, well trained and experienced personnel are critical to reduce such impact. Unfortunately, there is usually a shortage of such people and their knowledge is almost always locked away in their heads. Leaving the organization means to take their knowledge with them. Consequently, competitiveness and business survival requires capturing and automating their knowledge to make it available immediately in order to avoid business process interruptions due to an AHU/CWS malfunction. Today's exponential improvements in computer systems processing power including new software programming techniques have help developed "Expert Systems" application that can be used to business knowledge functional vault. Since it is not possible to clone your experts, you must find another way.

RESEARCH OBJECTIVES

This research will focus in the following areas:

- Define expert systems application features and requirements needed to implement an AHU/CWS support expert system.
- Define general approach methodology to select AHU/CWS data collection methodology to feed the expert system.
- Define a methodology and/or process to maintain functional AHU/CWS incorporating equipment and process changes due to equipment replacement and AHU/CWS control systems improvements.

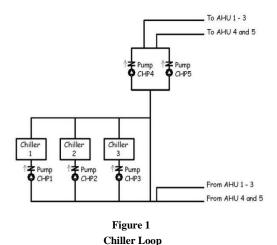
Expert Systems have been developed and are currently available to be implemented in a variety of business flavors (medicine, customer services, lawyers, etc.). This research will exclusively concentrate in the AHU/CWS expert systems associated to the Medical Device Manufacturing industry needs.

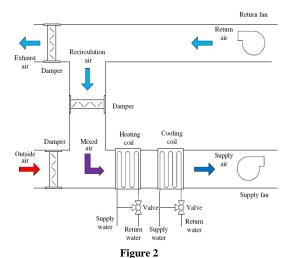
RESEARCH CONTRIBUTIONS

This research provides a clear, concise and defined methodology to be applied in the development of a Medical Devices Manufacturing Expert System Development Guidelines specifically related to AHU/CWS systems. The guidelines criteria will take into consideration the following areas; business impact due to AHU/CWS equipment downtime, effective troubleshooting time, repetitive equipment failure events, and support department/knowledge expert response time among other criteria. Cost vs. Benefits, Return of Investment (ROI), and other financial guidelines will be also included. The ultimate goal is to provide the Medical Device Manufacturing industries a sounding guideline to develop and implement an effective and efficient Expert System concentrated in the AHU/CWS area. Furthermore, the Medical Devices Manufacturing Industries will increased the competitiveness by reducing the operational impact costs associated to AHU/CWS equipment downtime events severely impacted by the lack of immediate and effective technical knowledge support.

RESEARCH BACKGROUND

Most Medical Devices Manufacturing process generally conducted in environmental Common controlled areas. controlled environmental parameters are temperature. humidity, room differential pressure and air cleanliness [1]. Maintaining such parameters during the manufacturing processes help reduce variations associated to components physical dimensional changes (length, wide, etc.), material curing process, material chemical properties, etc. Maintaining tight manufacturing a environmental control is achieved by combining several mechanical (Chillers & pumps), electrical (heaters), electronics and sensors devices (these devices are combined to create a "Chilled Water System" or CWS (Figure 1) required to product a constant water flow and temperature utilized to feed an Air Handling Unit or AHU (Figure 2). A chilled-water system uses chilled water to transport heat energy between the airside, chillers and the outdoors. An AHU, sometimes called an air handler, is a piece of equipment that is used to condition and circulate air as a component of a heating, ventilating and air conditioning system. This handler is usually a large metal box that contains a blower, heating and cooling elements, filter chambers, sound attenuators and dampers. The air handler connects to ductwork that in turn, distributes the conditioned (and heated or cooled) air throughout the building before returning it to the AHU [2].





All mechanical, electrical and electronics components are controlled via a Management System (BMS). The BMS decides the operational requirements of each subcomponent in order to meet the established environmental parameters setup by the user. The BMS operates based on the principle of the Psychometric chart when achieving a given temperature/humidity. Due to the inherent complexity of the overall system, an AHU/CWS system component failure prevents the BMS to properly maintain the established environmental parameters therefore impacting the environmental control areas manufacturing process Seasoned and experienced technicians are [3]. in commonly used the Medical Device Manufacturing industry to repair such systems due

Schematic Diagram of an AHU

its complexity and to reduce the troubleshooting time associated to the repair and adjustment process. Not having a medical device manufacturing area fully operational causes a negative business profit impact that can be easily quantified.

An expert system is a computer system that incorporates a series of defined rules, algorithms and accumulated data that emulates the human decision-making evaluation process. An expert system differs from traditional programming due to its unique structure; a fixed portion called the inference engine and a variable portion called the knowledge base. One major benefit of an expert system is that new information, findings or learned event can be incorporated into the system and later used as part of the decision-making algorithm. The knowledge base main purpose is to accumulate rules and problem solving knowledge. Rules are usually define in the form of "IF" condition "THEN" actions. The condition portion of the rule is usually a fact; IF Day = raining, means that it is a fact the raining condition is present and it is confirmable. The action portion is the expected consequences of a present condition, ex: IF Day = raining THEN road is wet. Rules can be specific, can be chained together, and can be heuristic (based on known facts) [4]. The inference engine is responsible to evaluate and determine the action to be executed when a rule containing it is identified.

When equipment breaks it needs to get fixed as quickly as possible. If it is part of a production line it can disrupt manufacturing and in some instance requires overtime to comply with the scheduled manufacturing quota. If it is a product that was sold to a customer, the ability to get it fixed quickly and correctly will strongly influence the customer's satisfaction and influence potential future sales. Either case, it is measurable negative cost impact that will be eventually affect the business profit.

Typically a company has a few highly talented experts that can very quickly diagnose the cause of a problem and fix it. They have the ability to rapidly recognize the various possible causes, and the subtle differences that enable them to identify

the underlying problem. This is a common scenario for experienced AHU/CWS facilities technicians. However, this level of knowledge is scarce since it is based on many years of experience. Even worse, some employees are not willing to share their accumulated knowledge with their peers and coworkers. If they leave the company, they carry it with them and the company will probably have to spend in training expenses to develop the expertise required to reduce a potential downtime impact.

Diagnostic reasoning is often complex. An expert knows that a particular combination of symptoms indicate one cause, but slightly different symptoms might indicate a totally different cause. It is very lengthy and time consuming process to teach this type of reasoning to a new employee or an inexperienced person since it is based on so many independent factors that have to be combined to reach a conclusion and often acquired by direct observation or trial and error troubleshooting experience.

RESEARCH METHODOLOGY

The methodology will be based on the following phases:

- Requirement
- Selection and Design
- Implementation
- Verification
- Maintenance

The successfully completion of each of those activities will be essential to effectively achieved the realization objective.

During the Requirement phase research will be conducted which includes brainstorming about the type of Expert Systems software capabilities, functional requirements, operational requirements, etc. a matrix will be developed to maintain track of the available Expert System software packages user interface capabilities, hardware requirements, OS requirement, networking environment requirements, level of programming and/or customization degree, etc. Additionally, a brainstorming section will be conducted in

conjunction with the AHU/CWS technicians and system experts to discuss AHU/CWS configuration and interaction. AHU/CWS recorded failures and repairs will be listed, discussed and finally categorized based a criteria to be defined the AHU/CWS subject matter experts from the team. The end goal of the Requirement phase will be; list available Expert System software packages feature and capabilities, categorized AHU/CWS equipment failures by categories.

During the Selection & Design phase emphasis will be given to match the Expert System software packages functionality matrix versus the compiled AHU/CWS system requirements needs. The compiled AHU/CWS equipment failures and repairs list will be analyzed in order to determine a suitable data collection mechanism that will contained the necessary information require to be feed into the selected Expert System.

The Implementation phase will incorporate the design outcome into the selected Expert System software package. All listed requirements shall be properly integrated into the selected solution and verify against the original requirement list. A manual AHU/CWS data collection form shall also be implemented to guarantee that the Expert System inference engine can be feed at a later moment in case the Expert System is unavailable.

The Verification phase will focus on the Expert System testing phase. The testing phase will compare the Expert System response against a known outcome. Both shall match. Expert System modification and/or programming changes will be implemented, documented and re-tested until the acceptance criteria is met.

Maintenance phase will contain all necessary forms, procedures and techniques to guarantee that any AHU/CW system and equipment changes will be capture and incorporate into the Expert System accordingly. A maintenance and/or change event log will be used to maintain records of Expert System changes.

The following is graphic representation of the phase's interaction.

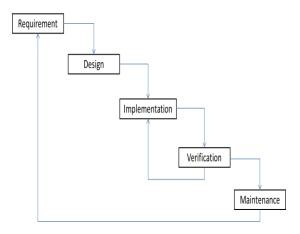


Figure 3
Implementation Development Process

It is important to establish that the methodology utilized is considered a living process since any or all phases can be accessed as long as the Expert System is in used.

RESEARCH RESULTS

Expert systems found broad application in fault diagnosis from their early stages because an expert system simulated human reasoning about a problem domain using heuristic knowledge rather than precisely formulated relationships, in forms that reflect more accurately the nature of most human knowledge. The successful implementation of an AHU/CWS Expert System solution can be achieved by completing all the established implementation development process phases.

Requirement Phase

The process of diagnosing faulty conditions varies widely across to different approaches to system diagnosis. Most of the past applications have been rule based while the automation of the diagnostic process including real-time data and/or modeling techniques added a new dimension to diagnostic tasks by detecting and predicting faults on line. A variety of fault detection and diagnosis techniques have been developed for the diagnostic problem solving process. Actual expert systems are based on separation of domain knowledge and general reasoning knowledge knowing as inference engine. Inference engine uses different computational algorithms search techniques such as backward and forward changing. Some expert systems are based on rule-based model while the most recent systems utilize model-based approach.

Rule-based expert systems have a wide range applications for diagnostics tasks where expertise and experience are available but deep understanding of the physical properties of the system is not available or too expensive to obtain. In the rule-based systems, knowledge is represented in the form of production rules, and a rule describes the action that should be taken if a symptom is observed. The association between premises and conclusions in the knowledge base is the main characteristic. These associations describe the cause-effect relationships to determine logical event chains that were used to represent the propagation of complex behavior. The following figure (Figure 4) represents the general architecture of these systems including domain independent components like the rule representation, inference engine and the explanation system.

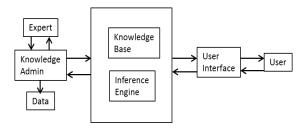


Figure 4
Simplified Structure of a Rule-Based Expert System

It is important to point out that this expert system model requires domain specific knowledge formatted in a suitable knowledge representation scheme and an appropriate interface for the human-system dialogue. The rule-based approach has a number of weaknesses like poor handling of novel situations and lack of generality but on the other hand, it offers efficiency and effectiveness for systems operating within a fixed set of rules. A decision tree is the main technique that defines the logical paths that knowledge base must follow to reach conclusions. Therefore, problems that are easily represented in a form of a decision tree are

usually good candidates for a rule approach expert system model. Rule-based expert system do requires a multitude of rule to cover all possible fault scenarios. It has a limitation to represent time-varying and spatially varying situations and has a limitation to learn from errors without the intervention of the knowledge Administrator to feed the system with the new acquired knowledge.

In model-based expert systems, a model (heuristic or mathematical) is employed to describe the monitored system nominal behavior. differences between the model's output and the measured process are interpreted and evaluated to determine and isolate the faults. Model-based system has eliminated the limitations of early expert systems because this model diagnosis uses knowledge about structure, function and behavior and provides device independent diagnostic procedures. It also has the potential of early detection of slowly accumulated developing faults. Fault detection is identified after checking some measurable variables of a system in regard to a predetermined tolerance of the normal values and taking appropriate action when a limit value is exceeded. Residuals are generated by comparing the sensed measurement to the predicted output of the model. Therefore, the residuals are expected to be zero or close to zero in non-fault cases, but are different from zero when a fault is present. Figure 5 represents the diagnosis process using a modelbased expert system.

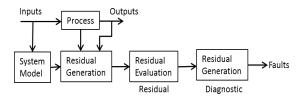


Figure 5
Diagnosis Process using a Model-Based Expert System

The model-based expert system requires computational power systems to successfully performed system modeling in almost real time. This model also usually makes use of measurements from process instrumentation that is not always necessary installed for this purpose.

Therefore, the instrument may not be sensitive enough to detect small process changes affecting the overall system.

On-line expert systems usually use a combination of quantitative and qualitative methods for fault detection. This system allows interaction and evaluation of all available information sources and knowledge about the technical process. An important characteristic of the on-line expert system is that a data base exists with information about the present state of the process in parallel with a knowledge base of a traditional expert system. The inference engine combines both heuristic reasoning with algorithmic operations in order to determine a specific conclusion. Table 1 summarizes the main advantages and disadvantages of each expert system.

Table 1
Expert Systems Technologies Comparison

	Advantages	Disadvantages			
7	A process model is not required	Development and maintenance is expensive			
Knowledge-based system	Rules can be added, deleted and modified	n			
e H	easily	Poor handling of unknown situations			
ledge-l	Effectiveness in fault detection when apply to	Difficult to acquire reliable knowledge from			
<u> </u>	stable processes	experts			
2	Deduction and Induction process is easy to				
	determine	Inability to learn from errors			
-	Dynamic fault detection	Faults isolation difficulties			
Model-based system	Device independent diagnosis	Domain dependent			
del-bas system	Deal with unexpected situations	Knowledge bases are quite demanding			
Mo	Ability to diagnosing incipient faults				
	Knowledge acquisition is not required				
pes	Fast Computation	Computationally demanding			
line ba system	Ability to handle dynamics processes	Require vast amount of data			
On-line based system	Real time fault diagnosis	Difficult to determine reasoning process			
ō		Domain dependent			

Several expert systems are available and are customizable for different applications and scenarios. Some popular expert systems packages are:

Exsys Corvid® - Aimed at non-programmers, with system rules written in English and algebra. The Inference Engine supports "Backward Chaining", which is a way to breakdown a problem into small sub-tasks that are automatically used as needed. This allows the configuration logic to be defined in relatively simple, detailed rules on specific aspects of the design. Corvid® systems can also interface to sensors, databases or measuring equipment to provide information needed by the

systems that automatically monitor processes and watch for developing problems.

Vanguard Knowledge Automation System® - Combines expert system decision-making technology with quantitative methods. Drastically reduce the time needed to build highly complex expert systems by using point-and-click development along with built-in Wizards. It provides a tree window for visualizing the decision process, a definition window for writing scripts and a form window for building the user interface [5].

Gensym G2® - Expert system designed for integration with on-line, real-time data. Support bidirectional links to databases, enterprises system, control system and other systems. The system support advanced features like; Real-time reasoning, Natural language rule definition, Object modeling, Task priority scheduling [8].

Fully capturing the domain expert's decision making logic and process is essential to building a system that can provide advice comparable to the expert. The rules in a system must be able to completely describe how the expert makes the decision. Many problems can seem simple at first, but when examined in detail have aspects that are subtle, complicated or probabilistic. The key to fully capturing the expert's decision making logic is to describe it in the same way the expert thinks about it [6]. In order to capture all information pertaining to the chilled-water system, it is necessary to identify both the chilled-water system expert(s) and to have a detailed understanding of the chilled-water system design specifications. A brainstorming section shall be conducted in conjunction with the AHU/CWS technicians and system experts to discuss AHU/CWS configuration and interaction between the chilled-water system different components, equipment and sensors. A collection of past events chilled-water system symptoms and solutions will be prepared to be later feed into the expert system. The gathered information will be used during the design and implementation phases

Selection and Design Phase

The successful selection and design of the expert system should take into consideration several factors not only related to the expert system capabilities but also related to the system user and company environment. The following are some questions that must be taken into consideration during the selection process:

- Who will use it?
- How it will work?
- Where it will be used?
- When it will be used?
- How it will be made available?
- What hardware will be required?

In addition, the selection process shall also address the following areas:

- Level of expertise required to add new data, rules, etc.;
- Knowledge expert mechanism utilize to gather information from the chilled-water system experts;
- Level of expertise required to maintain the expert system;
- Incremental cost related to software maintenance and upgrades.

The answer to these questions will be compiled and added to the list of the system attributes to be evaluated [7]. Finally a matrix of requirements versus the compiled chilled-water system needs will be created in order to evaluate the expert system attributes such as:

- The definition of the user interfaces;
- What constitutes an error and how errors shall be handled?;
- Operating environment, including any required hardware and software configurations, all software versions, and utilities;
- User operation and execution requirements;
- Required response times;
- Startup and shutdown procedures;
- Software driven alarms, warnings and operator messages;

- Security requirements, including those related to compromise of sensitive information;
- Software manufacturer support;
- User maintenance requirements;
- Design constraints such as: programming language(s) and/or program size(s);
- Memory requirements.

During the Selection and Design phase emphasis will be given to match the Expert System software packages functionality matrix versus the compiled AHU/CWS system requirements needs. The compiled AHU/CWS equipment failures and repairs list will be analyzed in order to determine a suitable data collection mechanism that will contained the necessary information require to be feed into the selected Expert System. The software selection process and be divided in four major areas such as:

- Planning and Budgeting This is the initial cost to buy the software. Although there are as many ways to price software as there are vendors, the software license is typically calculated by estimating the number of users that will be using the system and multiplying that by a per-user license cost. The vendors may also charge a fee for the various modules or areas of functionality that you purchase. You also need to include the software maintenance cost which is the annual fee that you pay the software vendor for updates, upgrades, and some level of support.
- Software Vendor Research his phase focuses on how to start with a long list of vendors and efficiently evaluate them to select the three tops candidates. Perform thorough research on vendors using as many resources as possible including independent studies, articles, web sites, and consultants.
- Software Demos The most important part of this phase is to develop a quasi-functional demo script. The script should target the following areas; allows you to see how the vendor will solve your specific requirements and let you to schedule your potential user to

- observe the software functionality. Finally, it allows you to compare the vendor's response under same conditions.
- Software Contract Make sure that the terms of the contract are specifically defined up front. Pay close attention to the definition of a "user", "installation", "go-live", etc. "installation" mean loading the software onto the server, or it can mean completed implementation? Define when progress payments will be made. Make sure that you negotiate the Statement of Work (SOW) before you sign the contract. Software contract negotiation is one area where it can be very helpful to have a consultant involved.

Finally, the design phase should focus in the following deliverables:

- Interconnection to AHU/CW system;
- Mechanism to acquire AHU/CW system events and solutions to populate the knowledge base;
- Completed prototypes of screens, reports and dialogues, system indicators, system alarms, etc.

Implementation Phase

This phase will incorporate the design outcome into the selected Expert System software package. All listed requirements shall be properly integrated into the selected solution and verify against the original requirement list. A manual AHU/CWS data collection form shall also be implemented to guarantee that the Expert System inference engine can be feed at a later moment in case the Expert System is unavailable. A requirement vs. deliverable matrix can be utilized to keep track of requirements fulfillments and changes as seen in Table 2.

In this phase, the expert system application is installed in the production environment. While installing the system, the Implementation Team should keep the configuration information updated by an established Configuration Management Plan previously defined in the Design Phase.

Table 2
Requirement vs. Deliverable Matrix

ID	Business Requirement	Status	ES compatible Feature/Function Document	Technical Specification	Software Module(s)	Test Case Number	Tested In	Implemented In	Verification	Additional Comments
001										
002										
003										
004										
005										
006										
007										
008										
009										

It is important to review the project implementation phase performance to assess whether the project delivered promised benefits, met the objectives, operated within scope, and produced the promised deliverables on time, within budget, and using the allocated resources. Assess how the project performed against each of the targets defined during the Requirement, Selection and Design phases. Identify whether the project:

- Delivered the business benefits;
- Remained within the original scope;
- Met the quality targets;
- Was completed within the planned project schedule;
- Delivered within the budget defined in IT Project Request and any approved changes.

Verification Phase

The Verification phase will focus on the Expert System testing phase. The testing phase will compare the Expert System response against a known outcome. Both shall match. Expert System modification and/or programming changes will be implemented, documented and re-tested until the acceptance criteria is met. This process is iterative and regressive to detect any new defect introduced by the correction of a previously detected and corrected defect(s). Interactions of hardware and software components are to be considered when testing the expert system against a known AHU/CW system response. For example, a known failure can be induced and the expert system diagnosis response should be able to correctly identify the induced failure. Otherwise, the expert system inference engine rules and definition shall be evaluated for accuracy. The process is repeated again. Once the integrated system software has passed the verification, the software is to be "locked", to prevent changes and possible introduction of new defects.

Maintenance Phase

Maintenance phase will contain all necessary forms, procedures and techniques to guarantee that any AHU/CW system and equipment changes will be capture and incorporate into the Expert System accordingly. A maintenance and/or change event log will be used to maintain records of Expert This is an important role System changes. particularly if the expert system have direct interface to the AHU/CW system sensors and other hardware (valves, monitor devices, etc.). AHU/CW system repairs can imply a component replacement from a particular supplier to a different one due to several factors like parts unavailability, obsolesce, Different supplier's component cannot guarantee the same device operating performance along the operational range. Even yet, the same component part number from the same supplier may have a slightly operational curve. Therefore, establishing a robust change control program is extremely important to keep track of all changes and determine if the expert system parameters, rules and definition require modifications. The maintenance phase also includes expert systems as well as AHU/CW system new functionality upgrades. Because of the known nature and their significant impact, these upgrades should be managed in the same way that the initial system integration occurred. New control system functionality requires that previous deliverables be updated.

CONCLUSIONS

As expert system techniques matured into a standard information technology since the 1980s, the increasing integration of expert system technology with conventional information technology has grown in importance. Today's systems are capable to deduce faults and suggest

corrective actions for a malfunctioning device or process.

Benefits of expert systems include:

- A speed-up of human professional or semiprofessional work.
- Within companies, major internal cost savings.
 These cost savings are a result of quality improvement, a major motivation for employing expert system technology.
- Improved quality of decision making. In some instances, the quality or correctness of decisions evaluated after the fact may represent a ten-fold improvement.
- Preservation of scarce expertise such as: knowhow in organizations, individuals who are retiring, and to preserve corporate know-how so that it can be widely distributed to other company sites.

Many large buildings, campuses, and other facilities have specialized plants that make chilled water and distribute it to air handling units and other cooling equipment. The design operation and maintenance of these chilled water plants has a very large impact on building energy use and energy operating cost. Advancement in AHU/CW process control systems and sensors technology requires well trained and experienced personnel to maintain the system fully operation and operating at peak conditions. Technical knowledge proficiency in such systems requires time and money therefore; experienced personnel are highly valuable, paid but prone to move to other companies and or industries.

In the case of the medical device industry, the manufacturing area environmental conditions shall be maintained within the established environmental applicable parameters as per regulations. Therefore, no manufacturing activities shall be conducted until the area complies back with the defined environmental requirements. Consequently, the business is severely impacted every time the AHU/CWS system is not operating Both the repair and troubleshooting properly. activities shall be performed is the minimum amount of time in order to reduce such impact.

The utilization of an expert system to accomplish this reduction is a proven fact. Expert application System has been successfully implemented in several areas and fields such as; process control, accounting, law, medical diagnosis, Advancement in computer hardware raw power and new programming methodologies have provided the way to develop new expert systems with real time analysis capacity, ability to communicate to massive databases and the capacity to connect to process sensors and devices among other features. As AHU/CWS systems have become more complex for the medical devices manufacturing industry, the need to perform repair and diagnostic reasoning can be quite challenging. The right selection and utilization of an expert system will prove to be a valuable tool to reduce cost, keep competitive reduce "human factor expertise" dependency.

Finally, this paper emphasizes the development guidelines of an expert system implementation for fault diagnosis in the medical industry AHU/CWS system. A successful implementation will generate immediate benefits by reducing the overall downtime, minimize productivity impact and provide mitigating of site knowledge lost due to site expert's departures.

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