A Case Study of the Systems Engineering Process in FDA Class II Medical Device Design

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Table of Contents

Abstract

A systems engineering approach was used to develop a new Food and Drug Administration (FDA) Class II medical device. Development efforts spanned the system life cycle and involved project stakeholders. Requirements were developed and alternative designs were conceptualized. The best alternative design concept was selected based on research and analysis in view of the requirements. A detailed design was embodied in a prototype system that was tested and found not to meet requirements. The design was revised, including a tradeoff where total system cost was increased to satisfy a constraint requirement regarding compliance with federal Food and Drug Administration (FDA) regulations. The revised system design was validated and approved by the project stakeholders within the company. The project progressed through the production stage and into the utilization stage, where the design was validated and approved by project stakeholders outside of the company, including the FDA, and it was successfully operated by end-users. A support system was developed to facilitate proper operation and maintenance of the system.

The purpose of this paper is to present a case study of the systems engineering process and how was used to ensure that a medical device design met all project stakeholder requirements, including a requirement for regulatory compliance.

INTRODUCTION

Fischer Industries, Inc. was one of several manufacturers of tabletop x-ray film processing systems for medical diagnostic imaging applications. These systems are typically used in the offices of dentists, doctors, and chiropractors to develop films taken of patients under treatment. They develop x-ray films by automatically transporting it through a series of chemical baths, a water bath, and a dryer. As medical diagnostic imaging equipment, x-ray film processors are regulated as Class II (moderate risk to health and safety of patients) medical devices by the FDA.

The industry was highly competitive and manufacturers strove to design x-ray film processing systems with the quickest film throughputs possible. This was done by increasing film transport speed coupled with adding complicated subsystems with expensive components like heaters, pumps, sensors, solenoid valves, microprocessor controls, and user interface panels. End users were able to develop more film in a given time period, but their film processing systems were more costly to purchase, required plumbing connections within the darkroom, a minimum 15-amp electrical receptacle, and specialized skills and training to install and service. This limited sales to large practices, with expensive darkroom facilities, within reach of the Fischer Industries dealer network.

In a radical move, the Marketing Department at Fischer Industries determined through market studies that a new simple, low-cost film processor system design would open up a new market for the company. This new market consisted primarily of smaller practices that lacked the capital to invest in even the least expensive film processor system that Fischer had to offer. Many of these practices were in the rural US and in less developed foreign countries, far away from the Fisher Industries dealer network. Most of these practices where hand developing only a few x-ray films per day, using trays of chemicals and water.

This paper describes the process used to define system requirements and the system boundary for this new film processor system design in view of the limitations of existing designs. This paper also describes the activities and interactions within the system life cycle engineering process, including: concept, development, production, utilization, and support.

THE SYSTEMS ENGINEERING PROCESS

Systems engineering is basically good engineering where the system is viewed as a whole. It uses a top-down approach to gain the necessary overview and understanding of how system components perform together as a whole. There is a life-cycle orientation that addresses all stages of the design project. In systems engineering, there is a better and more complete effort regarding the initial definition of system requirements. The goal is to create systems requirements that are well-defined, well-specified, and traceable. Once defined, these requirements are related to specific design criteria. A team approach is used throughout all stages of the system development to ensure that all design objectives are efficiently and effectively met [Blanchard, pp. 18 – 19].

Systems engineering should not only clarify the overall requirements and objectives of the system, but should do so for operation within the system's defined operating environment. Furthermore, continuous monitoring should be done of both the environment and the system over the system life cycle to ensure that the system meets the requirements [Fairbairn, p. 2/7].

Table 1A of the Appendix shows the stage model of the system life cycle used in the development of the new film processor model. This model was similar to they system life cycle model described in ISO/IEC 15288:2002, Annex B and D. Each system life cycle stage was performed according to the Waterfall Sequential Model shown in Figure 1A of the Appendix. The model is arranged essentially like a Gantt chart, where each system life cycle stage is performed sequentially [Kanefsky, p. 4]. The model is well-suited to simple systems of this nature.

CONCEPT STAGE

At the start of this stage it was decided to create a name for the system (the proposed new film processor model). It was named the "AutoTank™" by the Fischer Industries Marketing Department. The purpose of this stage was to capture stakeholder requirements and determine alternative concepts for the AutoTank™ based on the requirements.

Requirements Development

Requirements are of three basic types: functional, performance, and constraint [Martin, p. 18]. A functional requirement specifies the necessary task, activity, or action that must be accomplished or what the system must do. A performance requirement specifies how well the system must perform along with the conditions under which it must perform. A constraint requirement would, for example, specify compliance with government regulations or industry standards.

Good requirements must be achievable, verifiable, unambiguous, complete, expressed in terms of a need (not a solution), consistent with other requirements, and not be so detailed to the point of constraining possible solutions [Leonard, p. 36].

Before requirements could be identified and captured, it was first necessary to identify the stakeholders in the AutoTank™ project. The stakeholders were determined to be the end users, the US Food and Drug Administration (FDA), and the following Fischer Industries personnel: the General Manager, the Sales/Marketing Manager, the Product Service Manager, the Production Manager, the Materials Procurement Manager, the Director of Manufacturing, the Director of Engineering, and the President/CEO.

A meeting was held with the principal stakeholders at Fischer Industries to define the basic need for the AutoTank™ system. These principal stakeholders were comprised of the General Manger and the Sales/Marketing Manager. During this meeting, the basic need was defined to be: A new x-ray film processing system that will be priced within reach of small practices in the target market and perform satisfactorily within the constraints of the target market. Market study data from the target market showed that:

1. Practices operated with low capital investment budgets. Data showed that a maximum cost of $2400 for the AutoTank™ would be within reach of most practices.
2. Practices tended to have facilities that could not accommodate any of the film processing machines in the current Fischer Industries product line. Most end-users developed up to three x-ray films per day by hand in closets or small darkrooms without:
    a. A potable water supply for wash water bath replenishment.
    b. A sanitary sewer connection for automatic disposal of waste water and used chemical solutions.
    c. Adequate electrical service to allow operation of a film processor that draws more than 10 amps.
3. Most practices were located too far from the Fischer Industries dealer network. Without the help of dealer service technicians, end-users at these practices were unable to install, clean, maintain, and repair any of the film processing machines in the Fischer Industries product line.

Functional and performance requirements for the AutoTank™ had to be defined. This was done by holding meetings with all project stakeholders in view of the basic need definition for the system and market study data.

Discussions with the Fischer Industries project stakeholders revealed the following information:

1. The profit margin for the AutoTank™ would have to be a minimum of 40%. This translated into a maximum production cost of $1,400.00 based on the pricing data in the market study.
2. Tooling, manufacturing setup, and non-recurring engineering (NRE) costs were limited to a total of $75,000.00.
3. Customer support would become very challenging because it would be limited to telephone and email.
4. Service repair parts would be sent via mail which could inconvenience customers in especially remote locations for extended periods of time if the new film processor system was unreliable and prone to failure.

Discussions with project stakeholders at practices within the target market revealed the following information:

1. Only basic hand tools (screw drivers, pliers, wrenches, etc.) were available to most end-users.
2. End users were medical practitioners, not trained technicians with advanced skills in troubleshooting and repairing electro-mechanical devices.

Functional and performance requirements for the AutoTank™ were developed based on the information gathered in the meeting. These are shown prioritized in Table 2A in the Appendix. Stakeholder ownership was assigned to each requirement so it could be traced back to its source. All requirements were dated and approved by each owner with a signature.

It is interesting to note that one constraint requirement was developed based on FDA regulations. The FDA was a requirements stakeholder that was not available for discussion, so careful consideration was given to the FDA regulatory requirements regarding Class II medical devices.

FDA regulations require any new medical device product, not substantially equivalent (SE) to a predicate device (already approved for sale to the public by FDA), to go through an expensive and extremely time consuming testing, clinical trial, and approval process. If a new product is proven to be SE to a predicate device, it can be approved quickly and inexpensively through a Premarket Notification to the FDA. A Premarket Notification (also known as a 510(k)) is a marketing application submitted to the FDA demonstrating that the medical device described within the submission is as safe and effective as a legally marketed device that was or is currently on the US market.

SE is likely to be determined by the FDA if the medical device being reviewed is found to have the same intended use and the same technological characteristics as the predicate device. The device can have different technological characteristics. For example, it may be made up of different materials, have a different design, use a different energy source, rely on different principles of operation, and still be SE to a predicate device. However, it is SE only if it has the same intended use and the submitter can demonstrate that it is as safe and effective as the predicate device. Additionally, the device being reviewed must not raise any different issues regarding safety and effectiveness when compared to the predicate device.

Based on FDA regulations, the AutoTank™ constraint requirement was defined. Ownership for this requirement was assigned to the President/CEO at Fischer Industries, because he was ultimately responsible for regulatory compliance. The requirement was dated and approved with the owner’s signature.

Alternative Concept Definition

After the system requirements were determined and prioritized, alternative AutoTank™ concepts were defined. Conceptual designs were developed from these alternatives for consideration. The objective was to think out of the box, so to speak, and come up with at least two alternatives for consideration.

The first alternative concept for the AutoTank™ would basically emulate the process of developing x-ray film by hand. The system would have three injection molded tanks: one for developer solution, one for fixer solution, and one for wash water. Each tank would be filled and drained manually. The developer tank would be heated with an inexpensive aquarium heater. The tanks would be held together in an assembly and placed next to a dryer compartment on the film processor frame. The exposed x-ray film would be attached with clips to mechanism that would automatically dip the film into the three tanks for developing and washing, move the film into the dryer section, and then carry the dry, developed film outside of the film processor.

The second alternative concept for the AutoTank™ was a low cost derivative of the lowest cost film processor then in the product line. This was the "Classic E™" film processor. The operating principle of the Classic E™ film processor is shown in a process diagram in Figure 2A of the Appendix. The Classic E™ wiring diagram is shown in Figure 3A of the Appendix.

Referring to process diagram in Figure 2A, exposed x-ray film is inserted into the top of the Classic E™ film processor. Acrylic transport rollers engage the film as it is inserted and they propel the film into a heated developer solution bath. The film is then transported through the developer bath and into a fixer solution bath. Rollers transport the film through the fixer bath and into a wash water bath to clean off any chemical residue on the film. Wash water is continually replenished with potable water from a cold water connection while the machine is in operation. Overflow from the water bath is drained to a sanitary sewer. After passing through the water bath, the film is transported by rollers through a dryer that blows heated air across the film to evaporate moisture.

After drying, the film drops out of the bottom of the film processing machine into a tray. Transport speed is constant and carefully timed to properly develop and completely dry the film before it exits the film processor.

To speed up the developing process in the Classic E™, the developer bath is automatically heated to 92°F using a temperature sensor and a temperature control printed circuit board assembly (PCBA). Heat is kept on when the film processor is developing film (Run Mode) and when it is standing by for the next film (Standby Mode). A level sensor PCBA, transformer, control relay, and level sensing float switch are used to automatically shut off power to the developer heater should the developer bath level drop far enough to expose the heating element to air. The developer and fixer baths are kept agitated using circulating pumps. When a film is inserted, both baths are replenished with fresh solution from storage tanks under the film processor. Overflow during replenishment is drained to a sanitary sewer. High cost components in the Classic E™ included circulating pumps, replenishing pumps, the developer bath heater subsystem, and the dryer heaters.

Considering the design of the Classic E™ film processor design in view of the system requirements, the second alternative AutoTank™ concept was derived by:

1. Eliminating developer/fixer bath circulating pumps, developer/fixer solution replenishing pumps, the water solenoid valve, all supply tubing, and the developer/fixer solution storage tanks. Developer solution, fixer solution, and water would be added to the film processor by hand. Because of evaporation, levels in the baths would have to be checked periodically and replenished by hand.
2. Retaining the small (and cheaper) film transport roller racks of the Classic E™ but using them in a deeper tank assembly and frame from a larger film processor

model (the 4000M™). This deeper tank would provide more volume for the developer, fixer, and water baths. This would extend the useful life of the chemical baths and the wash water bath, since they would no longer be automatically replenished and drained during processing.

3. Eliminating the developer bath heater, temperature control PCBA, temperature sensor, level detection PCBA, transformer, float switch, and film feed relay. Film would be developed at room temperature, analogous to developing films by hand.
4. Eliminating heaters in the dryer section. Film would be dried by blowing room temperature air across its surface. Heatless drying is effective only if the film transport speed is slow enough.

The second concept alternative is illustrated in the AutoTank™ film processor process diagram shown in Figure 4A of the Appendix.

Figure 4A also shows the system boundary for the concept alternative. This boundary defined the inputs and the outputs of the system and it defined what was to be included and was not to be included in the system development.

DEVELOPMENT STAGE

In systems engineering, the development stage involves analyzing the problem and synthesizing a solution [Martin, p. 29]. Mockups and prototypes are built to check compliance to requirements and to validate design assumptions. This stage ends when the design is fully qualified, all requirements have been complied with, or appropriate deviations have been approved.

Research, analysis, and preliminary design showed that the first concept alternative of the AutoTank™ would be in conflict with three systems requirements:

1. The mechanism to move the x-ray film would be very complicated mechanically and very expensive to design, tool, and manufacture. Projected costs exceeded the $75,000.00 maximum budget requirement.
2. Due to its complexity, the mechanism to move the x-ray film would be prone to fail and difficult for end-users to service and maintain without on-site support.
3. The mechanism to move the x-ray film would require a lot of space within the film processor. The film processor dimensions would exceed the foot print requirement.

Since SE and low cost were prime requirements for the design of the AutoTank™, both alternative concepts would have to be as safe and effective as any predicate film processor models in the Fischer Industries product line, plus it would be logical that they would be designed to have much cheaper and/or fewer components. Furthermore, because one of the primary requirements limited tooling, manufacturing setup, and non-recurring engineering (NRE) costs to a maximum of $75,000.00 it would also be logical that a concept for the AutoTank™ would incorporate as many components from current inventory as possible. With this in mind, the first concept alternative was discarded and focus was turned entirely to the second concept alternative.

For the second alternative concept, preliminary research, analysis, and design showed that cost to manufacture would be about $400.00 below the maximum $1,400.00 requirement. Also, since the second concept alternative used many existing components from the Classic E™ and the 4000M™ film processors, the costs to design, tool, and manufacture the AutoTank™ would be well under the $75,000.00 maximum requirement. The simplified design concept of the second alternative would make the AutoTank™ extremely easy for end-users to set up and maintain. No special tools would be required.

A prototype of the second concept alternative was constructed using components from the Classic E™ and the 4000M™ film processors. Like the Classic E™, the film transport speed was held constant by a fixed-speed drive unit. This drive unit had a gear ratio to produce a total film transport time of around two minutes. The prototype AutoTank™ was placed in a test darkroom for validation. An x-ray machine was used to expose film of a test subject (an unpopulated printed circuit board) and three films were developed each day over a two week period with small variations in ambient temperature over that time. Developer solution temperature was recorded each time a film was developed. The developed films were placed on a light box and visually inspected. Readings were also taken in the same location on each film with a densitometer. Validation testing showed that the AutoTank™ design, as-embodied in the prototype, could not meet the SE requirement, because it was not as effective as a predicate device. Film contrast was found to vary significantly over a small variation (4ºF) in developer temperature.

After careful re-evaluation of the AutoTank™ design it was hypothesized that a variable speed drive unit could compensate for reasonable variations in ambient conditions. In other words, the transport speed could be slowed down for lower developer solution temperatures and it could be sped up for warmer developer solution temperatures. It was reasoned that a “sweet spot” could be found on the variable speed drive unit control setting that would give acceptable film contrast over reasonable variations in room temperature.

Cost analysis showed that a variable speed drive unit would add almost $400 to the total production cost of the AutoTank™. This would bring the cost almost up to the maximum production cost requirement of $1,400.00. The following trade-off was proposed to the project stakeholders at Fischer Industries with an engineering change notice (ECN): Increase the production cost to enable the AutoTank™ design to meet the SE requirement. The trade-off was accepted and the ECN was approved. The design of the AutoTank™ was revised accordingly.

The AutoTank™ prototype was rebuilt to include a variable speed drive unit. It was then placed back in the test darkroom for validation. X-ray films were developed over a range of room temperatures as described for previous tests. After some experimentation with the variable speed unit control settings, a sweet spot was found that provided a 3-minute, 43-second total film transport time for a developer temperature range of 77 to 81ºF. This transport time yielded consistent film density for three films per day over three weeks without changing chemical solutions or water.

All requirements for the AutoTank™ were proven to be met. The AutoTank™ design went through a final design review with project stakeholders at Fischer Industries. The design was approved and the design documentation was turned over to manufacturing. Using the validation test results to show SE to a predicate device (the Classic E™), a Premarket Notification was written and submitted to FDA for approval.

PRODUCTION STAGE

Pilot production inventory was ordered, production assembly procedures were written, and assembly stations were set up. Five pilot production AutoTank™ film processors were built for development testing. Each AutoTank™ was inspected and tested at the end of the production line to verify that they functioned properly.

The AutoTank™ pilot production units were installed at various medical practices in the target market. These practices were given an AutoTank™ free of charge if end-users agreed to evaluate the product for a three month period. Evaluation included documenting ambient temperatures, variable speed drive unit settings, usage of chemical solutions, any problems with film quality, and any difficulties with maintenance. At the end of the three month evaluation period, all of the pilot production AutoTank™ units operated satisfactorily without any significant problems. All end-user requirements were satisfied.

After review of the Premarket Notification, the FDA approved sales of the AutoTank™ because it was SE to predicate devices in the Fischer Industries product. All stakeholder requirements were met. The AutoTank™ went into full production.

UTILIZATION STAGE

Upon delivery of the first AutoTank™ system to a paying customer, the project moved into the Utilization Stage. Systems engineering activities can continue in this stage of the project to support any modification activity that may be required [Faulconbridge, p. 8]. This was the case for the AutoTank™.

For example, some medical practices were found to operate their AutoTank™ film processors where ambient conditions cooled down development temperature to the point where, even at the slowest transport drive unit setting, the films would not develop properly. To solve this problem, an optional low power silicon rubber blanket heater subsystem was developed to adhere to the bottom of the developer bath tank. Validation testing in the lab and in the field proved that the requirement for developer solution heat was met, and the optional subsystem was put into production/utilization.

SUPPORT STAGE

This stage was concurrent with the utilization stage. In systems engineering, the support stage involves developing a means to facilitate proper operation and maintenance of the system. This includes developing a supply chain of consumables and spare parts. It also includes training end-users, maintainers, disposers, administrators, etc. [Martin, p. 29].

During the development of the AutoTank™, the support stage involved preparing instruction manuals, putting together troubleshooting procedures, training product service personnel, and developing an instructional video to show end users how to set up and maintain the AutoTank™.

CONCLUSION

In this case study, systems engineering was used to improve communications between all project stakeholders. This ensured that all requirements were specified in common terms and that none were overlooked. The requirements were used to guide the design process. Throughout the design process, validation testing ensured that all requirements were ultimately met and that all stakeholder needs were satisfied in a timely, cost-effective manner. Systems engineering efforts continued over the entire life cycle to ensure that stakeholder needs continued to be met in view of changing requirements or new requirements.

References

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Appendix

Stage	Purpose
Concept	To capture stakeholder requirements for the system (the proposed new film processor). To define alternative concepts.
Development	To refine requirements for the system. To architect the system solution. To build a system prototype. To verify and validate the system.
Production	To produce the system. To inspect and test the product.
Utilization	To satisfy end-user needs during system operation.
Support	To facilitate proper operation and maintenance of the system.

Table 1A – System Life Cycle Stages for the Propsed New Film Processor

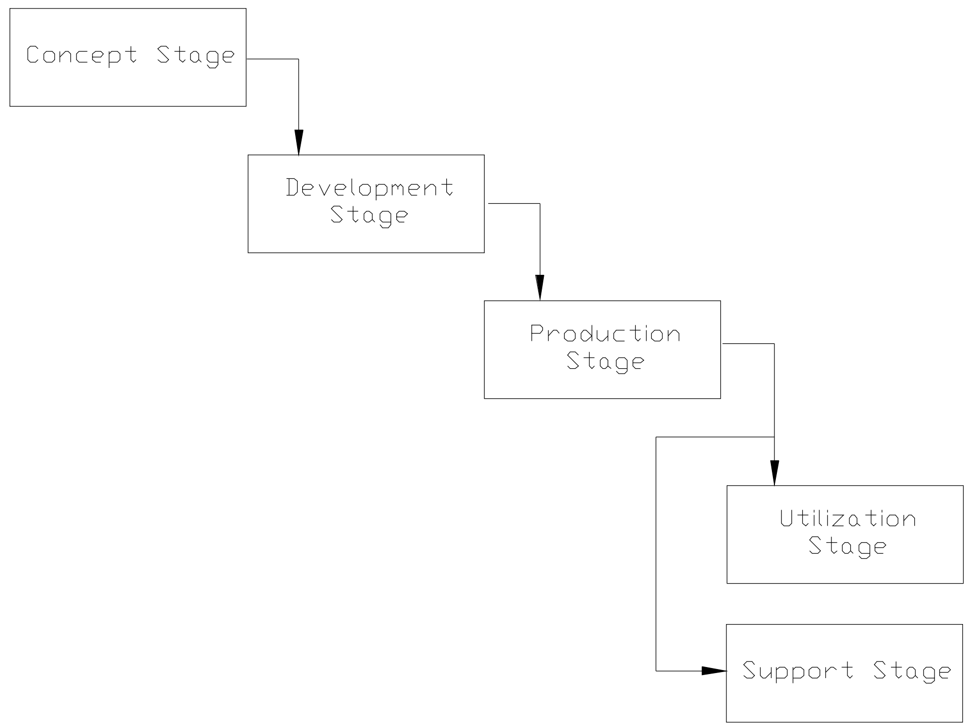

Figure 1A – Waterfall Sequential Model

No.	Requirements	Test Method	Rationale	Owner
1	The AutoTank™ shall have a maximum cost to produce of $1,400.00 per unit.	Analysis	Market studies have shown that customers are more likely to buy a film processing machine if it was priced at less than $2,400.00. Fischer Industry's margin is 40% on all film processor products.	President/CEO
2	Tooling, manufacturing setup, and non-recurring engineering (NRE) costs shall not exceed $75,000.00	Analysis	Funds are limited due to declining sales.	General Manager
3	The AutoTank™ shall be SE to an existing predicate device in Fisher Industries product line.	Analysis/ Measurement	To achieve approval from FDA, via 510(k) Premarket Notification, in a timely and cost-effective manner.	President/CEO
4	The AutoTank™ shall operate on 100 to127VAC or 207 to 253VAC mains power.	Measurement	These voltage ranges are common in the target market.	Sales/Marketing Manager
5	The AutoTank™ shall operate on 50 or 60 Hz mains power.	Measurement	These frequencies are common in the target market.	Sales/Marketing Manager
6	The AutoTank™ shall draw no greater than 10-amps of power.	Measurement	Studies have shown that darkrooms darkrooms in the target market will not have dedicated 15 amp (or greater) receptacles.	Sales/Marketing Manager
7	The AutoTank™ shall operate without a potable water supply.	Inspection	Studies have shown that darkrooms darkrooms in the target market will not have a potable water supply connection for automatic replenishment the wash water bath in a film processor.	Sales/Marketing Manager
8	The AutoTank™ shall operate without a drain to a sanitary sewer.	Inspection	Studies have shown that darkrooms in the target market will not have a connection to a sanitary sewer for automatic disposal of waste wash water and chemical solutions from a film processor.	Sales/Marketing Manager
9	Installation and startup of the AutoTank™ shall be done by end users within 15 minutes of unpacking, without the aid of any specialized tools or training.	Measurement	End users in the target market will have no access to the Fischer Industries dealer network.	Product Service Manager
10	End users shall be able to disassemble and clean the AutoTank™ without the aid of any specialized tools or training.	Analysis	End users in the target market will have no access to the Fischer Industries dealer network.	Product Service Manager
11	The AutoTank™ shall develop sheet x-ray film as small as 4" x 4" and as large as 14" x 17".	Inspection/ Measurement	Market studies show that the AutoTank™ will be used by podiatrists who typically use 4" x 4" sheet film. Other practitioners typically use 14" x 17" sheet film.	Sales/Marketing Manager
12	The AutoTank™ shall occupy a minimum foot print of 24" wide by 18" deep.	Measurement	The AutoTank™ will be compatible with Fischer Industry's existing line of accessories (e.g. film processor stands).	Sales/Marketing Manager

Table 2A – Fischer Industries AutoTank Requirements

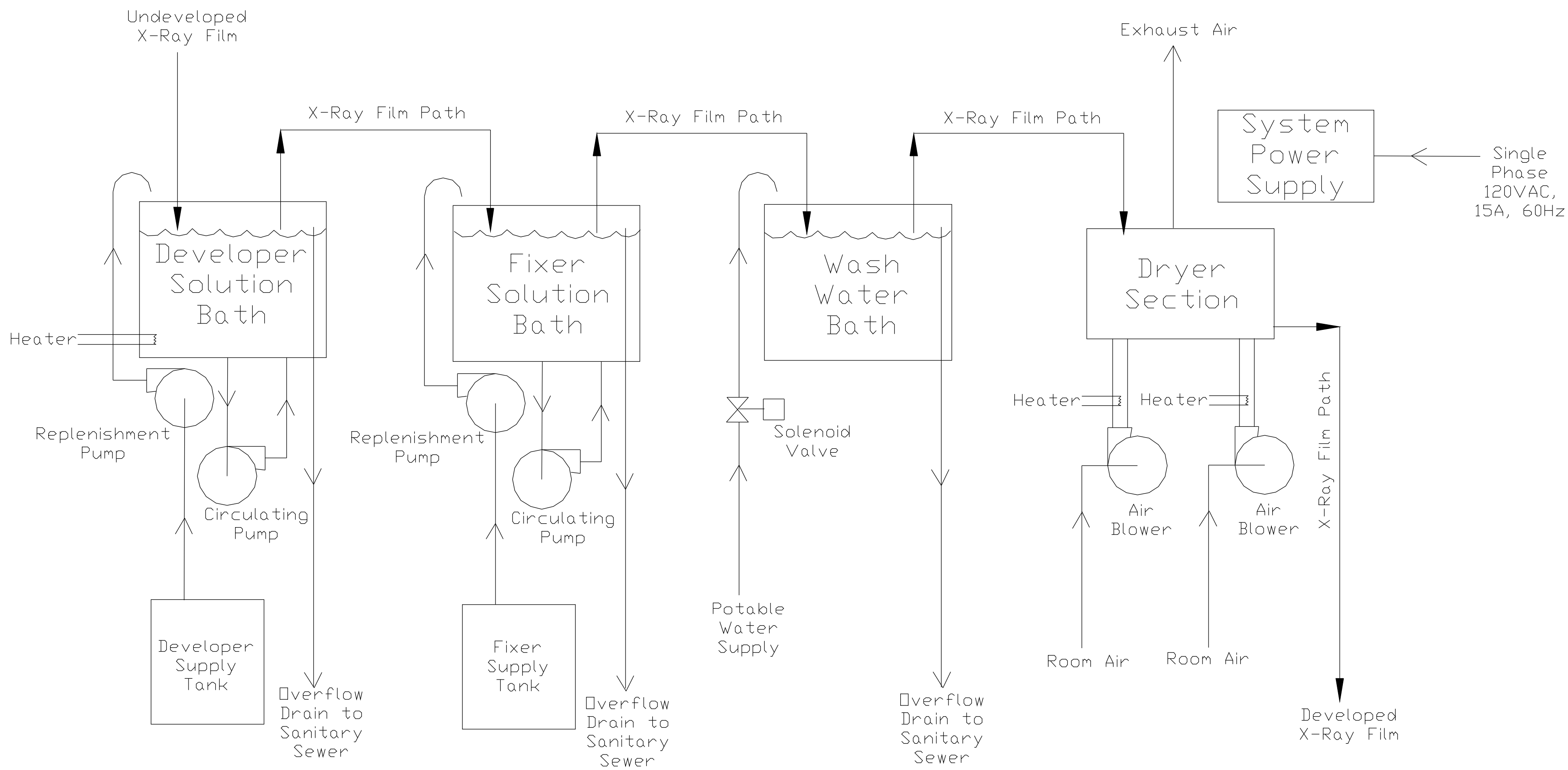

Figure 2A – Fischer Industries “Classic E” Film Processor Process Diagram

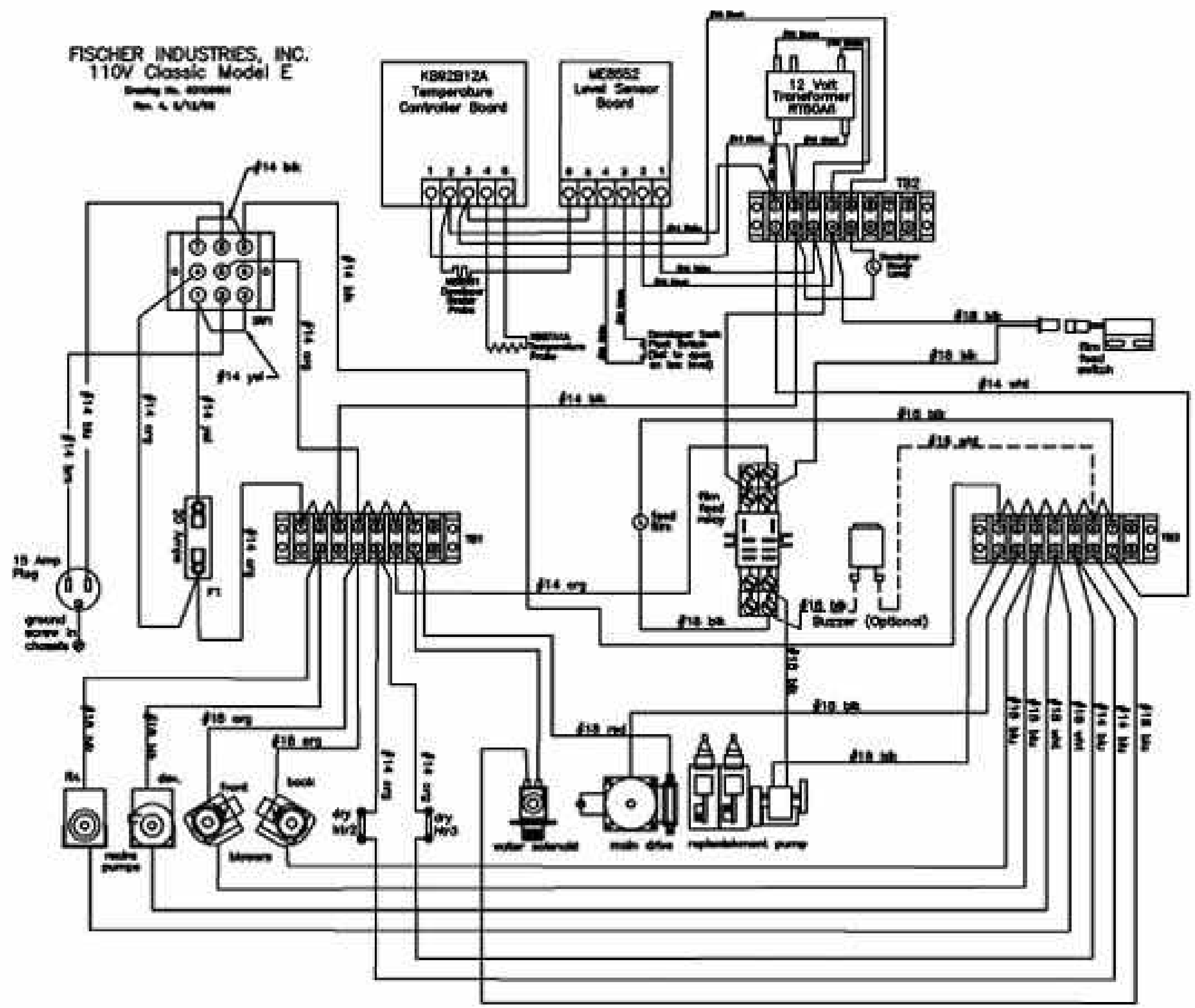

Figure 3A – Fischer Industries Classic E Film Processor Wiring Diagram

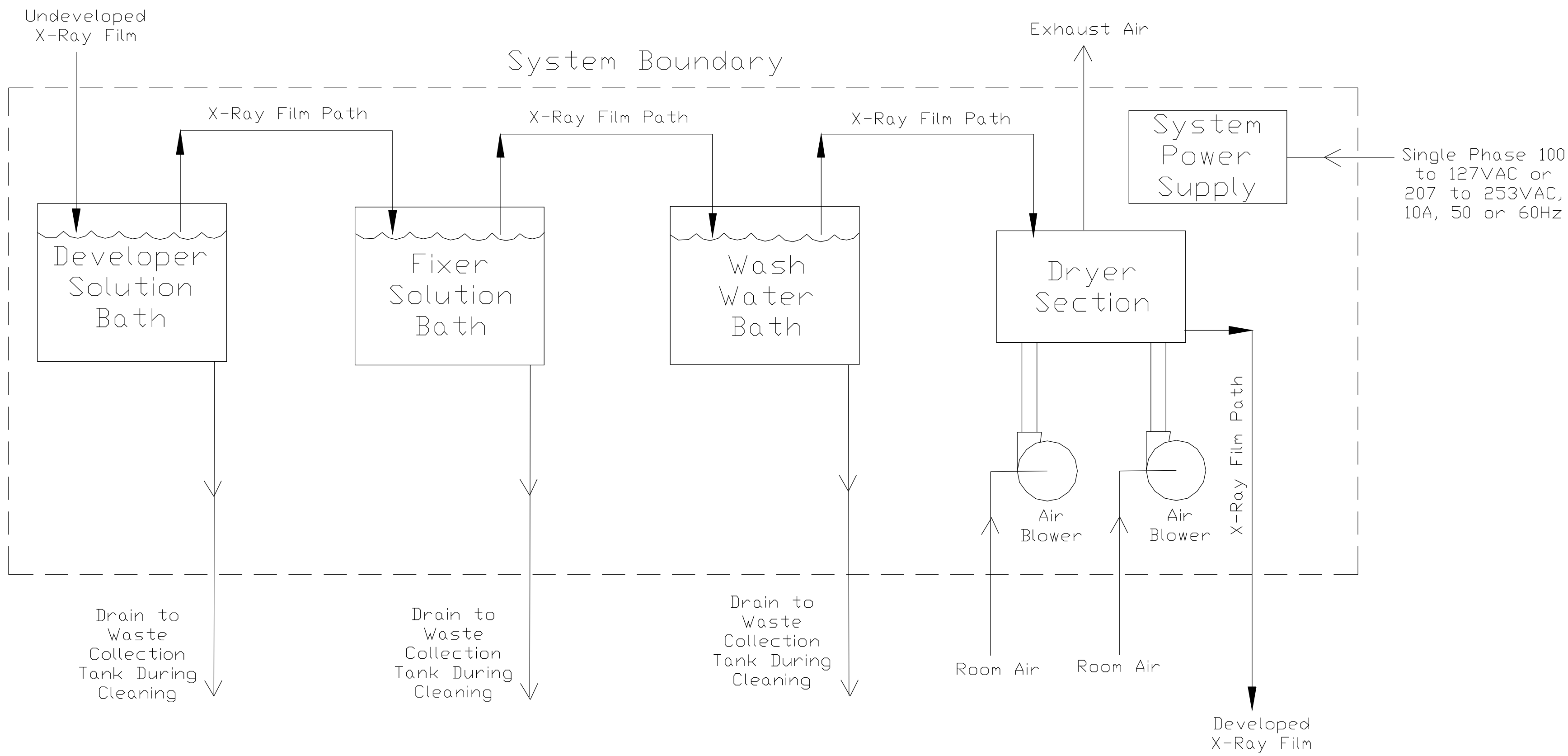

Figure 4A - AutoTank™ Concept Film Processor Process Diagram