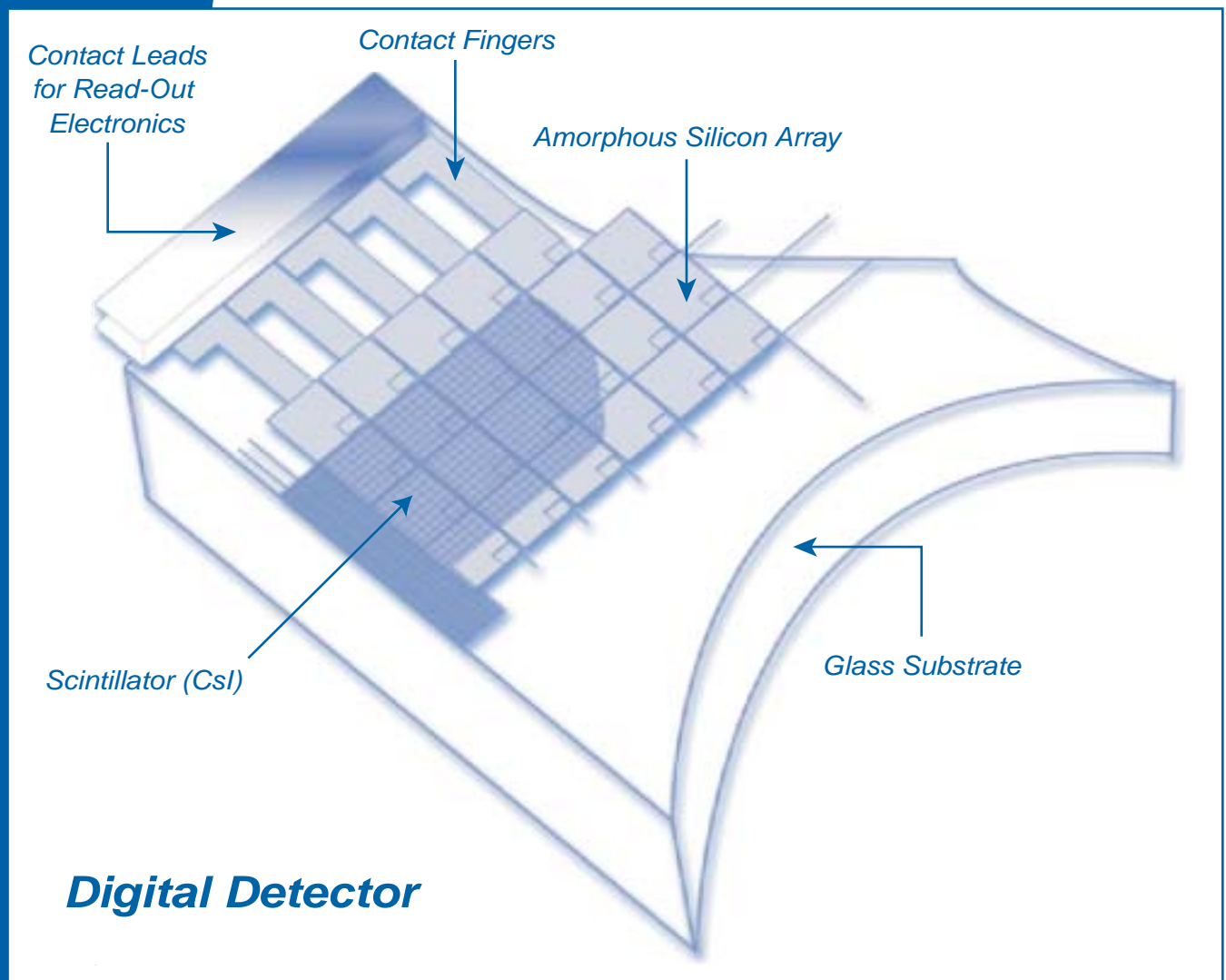




Low-Cost Manufacturing Process Technology for Amorphous Silicon Detector Panels:

*Applications in Digital
Mammography and Radiography*

Prospective Economic Case Study for an ATP-Funded Project



Digital Detector

February 2003

Low-Cost Manufacturing Process Technology for Amorphous Silicon Detector Panels: Applications in Digital Mammography and Radiography

*Prospective Economic Case Study
for an ATP-Funded Project*

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Abstract

In its 1995 General Competition, the Advanced Technology Program (ATP) co-funded a joint-venture project involving two U.S. companies, General Electric Global Research (formerly General Electric Corporate Research & Development) and PerkinElmer, Inc. (formerly EG&G Reticon), to develop a low-cost manufacturing process for fabricating amorphous silicon detector panels for digital mammography and digital radiography systems. The project was successfully completed in 2000. Following some additional investment in completing tasks needed for commercial production, implementation is expected by 2004.

Market analyses show that healthcare professionals and business managers are becoming aware of the benefits of converting to digital imaging technologies. These analyses show further that the ATP-funded low-cost manufacturing process is well positioned to directly impact digital mammography and digital radiography equipment costs, making the benefits of digital imaging available to more patients and healthcare facilities.

This case study estimates the following measures of societal economic benefit from the ATP investment in the low-cost manufacturing technology:

- Net present value of ATP investment: \$219 million to \$339 million (2002 dollars).
- Internal rate of return (public return) on ATP investment: 69 percent to 77 percent.
- Benefit-to-cost ratio of ATP investment: 125:1 to 193:1.

These measures reflect the estimated benefits to healthcare industry users and patients relative to the ATP investment. Estimated benefits to General Electric Company and PerkinElmer are excluded.

Additional qualitative and quantitative benefits are reported.

Based on primary research and analysis completed during 2001 and early 2002, the study concludes that:

- Broad-based benefits to patient populations and to the healthcare industry have a strong probability of being realized.
- ATP's industry partners would not have developed the high-risk, low-cost process technology without ATP support.
- These benefits are directly attributable to the ATP investment.

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Executive Summary

In its 1995 General Competition, the Advanced Technology Program (ATP) funded a joint-venture project involving General Electric Global Research (formerly General Electric Corporate Research & Development) and PerkinElmer, Inc. (formerly EG&G Reticon), to develop a low-cost manufacturing (LCM) process for fabricating amorphous silicon (a-Si) detector panels for digital mammography and digital radiography systems. The project was successfully completed in 2000 and implementation is expected by 2004.

The new low-cost process will be less complex than current panel fabrication, and will reduce detector costs by 25 percent, increase the affordability and clinical availability of digital mammography and radiography systems, and provide more Americans access to the medical and economic benefits of digital imaging.

This Executive Summary describes the results of a case study of the ATP-funded LCM project, the history of the project, an assessment of medical and other applications, and an analysis of economic impact. Case study research, analysis, and conclusions were completed during 2001 and early 2002.

DEVELOPMENT OF THE LOW-COST PROCESS

Thirty-three million mammography procedures are conducted every year to screen American women for asymptomatic breast cancer. Sixty-eight million chest X-rays, or radiography, are performed each year to diagnose a variety of medical conditions.

Conventional X-ray screening mammography and radiography capture images of the breast and chest area on photographic film. While conventional X-ray is generally effective, it has diagnostic limitations and only limited potential for improved productivity. The new digital mammography and radiography systems are innovative technologies to address the diagnostic and productivity limitations of conventional X-ray.

Digital imaging provides a range of benefits to patients and healthcare facilities, including higher patient throughput, improved diagnostic capability, less patient exposure to radiation, near real-time connectivity for remote expert consultation, and lower operating cost. At the same time, digital mammography and radiography systems are expensive, and equipment cost is an important barrier to widespread clinical availability.

General Electric Company (GE) was an early pioneer of digital imaging for medical applications and has developed an FDA-approved digital mammography system (Senographe 2000D) and an FDA-approved digital radiography system (Revolution XR/d). A key component in both systems is a full-field photosensitive detector plate large enough to capture the entire breast or chest area in a single image. Detector plates are fabricated as integrated circuits, utilizing thin-film a-Si semiconductor layers. Fabrication involves a complex photolithographic deposition, patterning, and etching process. Fabrication complexity contributes to the high cost of detector plates and the limited clinical availability of Senographe 2000D and Revolution XR/d units.

To reduce process complexity and equipment cost and to increase clinical availability, GE Global Research (GEGR) proposed the development of an innovative LCM process for internal GE funding. LCM would be a breakthrough technology involving dual use layers for interleaved fabrication of the photosensitive diode and the thin-film transistor element, without compromising either diode or transistor performance.

The proposal was viewed by GEGR management as an unfundable, high-risk proposition associated with the following technical uncertainties:

- Could processing be developed to substantially reduce the number of process steps without compromising detector performance?
- Could the photodiode device be deposited at the same temperature as the transistor without degrading detector performance?
- Could data lines be properly insulated to facilitate low noise readout?

GE Global Research, together with PerkinElmer (PKI), its strategic manufacturing partner for detector fabrication, submitted a proposal to the ATP to cost share the development of the high-risk LCM technology.

In its 1995 General Competition, the ATP selected the GEGR/PKI joint-venture proposal for an award to develop an improved LCM process for full-field a-Si devices to be used in medical imaging systems and other applications. The ATP agreed to cost share \$1.575 million of the \$3.438 million project. GEGR and PKI committed to fund the balance.

The ATP-funded project was successfully completed in 2000, setting the framework for less complex fabrication with fewer mask steps (seven versus eleven) and fewer

total process steps (200 versus 300). Reduced complexity would increase production yields and reduce manufacturing cycle times. It was estimated that LCM would provide manufacturing cost savings in excess of 25 percent.

While the low-cost process was demonstrated to be technically feasible, all risks have not been fully retired. Some additional GE and PKI investment will be required to complete remaining technical tasks, and GE and PKI have yet to finalize their decision to implement the process. Critical decision factors are expected to be:

- Demonstrated technical feasibility.
- Growing market demand for digital imaging.
- Competitive pressures to reduce component (detector) costs.

These factors are currently evolving to support a business decision to complete technical development and implementation.

MARKET ANALYSIS

As part of this case study, an analysis of digital mammography and digital radiography market opportunities was completed to provide a basis for estimating the prospective economic impact of the low-cost process technology. Market analysis used extensive fact finding in the medical equipment, medical imaging services, and private medical insurance industries as well as government laboratories and social service agencies.

Healthcare professionals and business managers are generally becoming aware of the benefits of converting to digital imaging technologies. These benefits include increased patient throughput, enhanced diagnostic capabilities, reduced radiation dosage, reduced operating and patient costs, and near real-time consultation with remote radiologists. At the same time, medical professionals and managers are apprehensive about the complexity of new digital technologies, learning curves, high equipment costs, and the current lack of price competition.

Given these market dynamics, the ATP-funded LCM process is well positioned to directly impact digital mammography and digital radiography equipment costs, facilitate the deployment of additional digital systems, and make available the benefits of digital imaging to more patients and healthcare facilities.

ECONOMIC IMPACT

The case study identifies medical benefits for patient populations and broad-based economic benefits to the U.S. economy from an ATP-funded LCM process technology. The study examines the effects of improved productivity, reduced false-positive findings (showing abnormal results when cancer is not present), avoided patient costs, improved diagnostic capabilities, opportunities for remote teleradiology

applications, and cross-industry knowledge diffusion from ATP-funded innovations. Benefits are estimated for a conservative base case and an alternative step-out scenario.

To assess economic impact, the case study estimates the number of additional Senographe 2000D and Revolution XR/d units that would be deployed given the availability and use of the ATP-funded low-cost process technology, as compared to a counterfactual case without the ATP-funded technology. Under the base case, the study projects the cumulative deployment of 159 Senographe 2000D units and 175 Revolution XR/d units beyond the counterfactual case during the 2005–2014 period. Under a more optimistic "step-out" scenario, the case study projects the deployment of 17 percent additional units (27 additional Senographe 2000D units and 29 additional Revolution XR/d units) beyond the base case. These projections for the base-case and step-out scenarios were based on discussions with equipment vendors and healthcare industry participants and serve as key assumptions in the analytical framework for quantifying economic benefits.

For the two scenarios, the case studies quantify the economic benefits of these additional Senographe 2000D units and Revolution SR/d units deployed as a result of the ATP-funded low-cost process. Quantified economic benefits of additional Senographe 2000D units include:

- Cost savings to healthcare facilities from the reduction in the number of unnecessary medical procedures, the doubling of the rate of patient throughput, and the reduction in costs for retrieving and managing digital mammograms and attendant medical records.
- Cost savings to patients from fewer lost work hours, attendant lost wages, and travel costs.

Quantified economic benefits from additional Revolution XR/d units include cost savings to healthcare facilities from the increased rate of patient throughput and the reduction in records management costs for retrieving and managing digital chest X-rays and attendant medical records.

Using these cost savings from the deployment of additional Senographe 2000D and Revolution XR/d units, the case study estimates prospective cash flow benefits measured in 2002 dollars and projects several measures of the public return on ATP's investment: net present value, internal rate of return, and benefit-to-cost ratio. These measures reflect the benefits to healthcare industry users and patients relative to the ATP investment. For the base-case scenario, the study estimates a benefit-to-cost ratio of 125:1; that is a return of \$125 for every dollar of ATP investment. The internal rate of return (public return) on the ATP investment is 69 percent, and the net present value of ATP investment is \$219 million. For the step-out scenario, the study estimates a benefit-to-cost ratio of 193:1, an internal rate of return of 77 percent, and a net present value of \$339 million.

Net present value is calculated by subtracting the present value of ATP investment from the present value of incremental cash flows resulting from the ATP investment (experienced by the general public but not including cash flows to GE and PKI) attributable to increased productivity and reduced patient costs. All cash flows are normalized to 2002 dollars and discounted at the 7 percent Office of Management and Budget designated rate. This measure describes the net total benefit to the nation in 2002 dollars.

Internal rate of return (public return) is calculated by iterative solution for a rate at which the discounted value of ATP's investment would equal the discounted value of incremental cash flows experienced by the general public. This measure describes the rate of return to the nation on ATP's investment.

Benefit-to-cost ratio is computed by dividing the present value of incremental cash flows resulting from the ATP investment (experienced by the general public but not including cash flows to GE and PKI) by the present value of ATP's investment. This measure shows the benefit to the nation for every dollar of ATP investment.

In addition to substantial public benefits to the U.S. economy, the case study estimates private benefits to GE and PKI from implementing the LCM process technology and generating additional Senographe 2000D and Revolution XR/d unit sales. The magnitude of these private benefits, as reflected in additional revenues for GE and PKI, is expected to provide the necessary motivation to complete remaining technical development and to implement the LCM process technology.

Besides quantitative returns, the LCM technology will also provide qualitative benefits to those American women and chest X-ray patients who would not have access to these benefits without the ATP-funded project. Qualitative benefits include:

- Decreased medical risk to patients and reduced patient anxiety by avoiding unnecessary medical procedures.
- Reduced patient exposure to radiation.
- Improved analytical continuity (from rapid retrieval of prior mammograms and the elimination of lost mammograms) and facilitation of computer-aided detection (CAD).
- Facilitation of regional telemammography and teleradiology networks, expanding access to quality mammography and radiology services by underserved rural populations.
- Knowledge diffusion through GEGR's transfer of the digital detector technology to PKI and potentially to other sub-licensees for the future development of non-medical applications.

CONCLUSIONS

The case study concludes that the new low-cost process technology has made significant progress toward meeting the conditions for commercial implementation. Indicators of this progress include:

- Successful completion of the ATP-funded joint-venture project demonstrating the technical feasibility of the low-cost process.
- Initial sales momentum for GE Senographe 2000D and Revolution XR/d units along with independent market studies pointing to longer term demand growth.
- Technological advantages that can be translated into business advantages. In the context of increasing competition and downward pricing pressures, the 25 percent cost reduction will be an attractive incentive for industry partners to implement the low-cost process technology.

Based on the above elements of progress toward commercial implementation, the study concludes that anticipated public returns from ATP's investment in the low-cost process technology and the broad-based medical and economic benefits to patient populations and to the healthcare industry have a strong probability of being realized.

Research performed for this study leads to the further conclusion that ATP's industry partners would not have developed the high-risk, low-cost process technology without ATP support. As a result, estimated benefits are directly attributable to the ATP investment. These benefits are summarized in Table 1.

Table 1. Benefits from ATP’s Investment in the Low-Cost Manufacturing Process Through Additional Digital Mammography and Radiography Units

Measures of Public Benefit: Improved Productivity and Avoided Patient Costs

Net Present Value of ATP investment: \$219 million to \$339 million.

Internal rate of return on ATP investment: 69 percent to 77 percent.

Benefit-to-cost ratio for ATP investment: 125:1 to 193:1.

Qualitative Benefits: Digital Mammography

Avoidance of unnecessary medical procedures and patient anxiety as a result of lower false-positive rates.

Improved breast cancer detection by facilitating the use of CAD technologies and the availability of baseline mammograms.

Reduced patient exposure to radiation.

Reduced examination time, counteracting the growing shortage of mammographers, and reduced patient waiting times, encouraging more regular screening.

Reduced health disparities across population groups by facilitating the development of telemammography networks for the delivery of high-quality cancer screening programs to remote populations and to medically underserved ethnic, racial, and economically disadvantaged populations.

Qualitative Benefits: Digital Radiography

Reduced patient radiation dosage.

Reduced examination time, counteracting the growing shortage of radiologists, and reduced patient waiting times.

Reduced health disparities across population groups by facilitating the development of teleradiology networks for the delivery of high-quality chest X-ray services to remote populations and to medically underserved ethnic, racial, and economically disadvantaged populations.

Cross-Industry Knowledge Diffusion

Transfer of the digital detector technology from industry partners to sub-licensees for the potential development of nonmedical applications, such as industrial machine vision.

Contents

| | |
|--|------------|
| Abstract | .ii |
| Acknowledgments | .iv |
| Executive Summary | .v |
| DEVELOPMENT OF THE LOW-COST PROCESS | .v |
| MARKET ANALYSIS | .vii |
| ECONOMIC IMPACT | .vii |
| CONCLUSIONS | .x |
| 1. Introduction | .1 |
| CASE STUDY OBJECTIVES AND SCOPE | .1 |
| 2. Development of Low-Cost Process Technology | .3 |
| HOW DOES IT WORK? | .3 |
| ATP PROJECT HISTORY | .5 |
| MAJOR INNOVATIONS | .6 |
| LOW-COST PROCESS IMPLEMENTATION | .8 |
| 3. Digital Mammography | .9 |
| BREAST CANCER AND EARLY DETECTION | .9 |
| BREAST CANCER TRENDS | .10 |
| CONVENTIONAL MAMMOGRAPHY | .11 |
| COMPLEMENTARY BREAST SCREENING MODALITIES | .12 |
| SCREENING MAMMOGRAPHY TRENDS | .12 |
| LIMITATIONS OF SCREENING MAMMOGRAPHY | .13 |
| DIGITAL MAMMOGRAPHY | .15 |
| CLINICAL TRIALS: DIGITAL MAMMOGRAPHY | .16 |
| COMPUTER-AIDED DETECTION | .17 |
| POTENTIAL BENEFITS FROM DIGITAL MAMMOGRAPHY | .17 |
| 4. Digital Chest Radiography and Other Applications | .19 |
| DIGITAL CHEST RADIOGRAPHY | .19 |

| | |
|---|-----------|
| DIGITAL RADIOLOGY | 20 |
| DIGITAL IMAGING FOR INDUSTRY AND HOMELAND SECURITY | 20 |
| 5. Market Analysis | 23 |
| MAMMOGRAPHY EQUIPMENT MARKET | 23 |
| DIGITAL MAMMOGRAPHY MARKET | 24 |
| CHEST RADIOGRAPHY MARKET | 27 |
| MARKET SUMMARY | 28 |
| 6. Economic Analysis | 29 |
| METHODOLOGICAL APPROACH | 29 |
| ATP AND INDUSTRIAL PARTNER INVESTMENTS | 31 |
| BASE-CASE ECONOMIC ANALYSIS | 32 |
| STEP-OUT SCENARIO ECONOMIC ANALYSIS | 35 |
| ESTIMATED PRIVATE BENEFITS TO ATP INDUSTRIAL PARTNERS | 37 |
| QUALITATIVE BENEFITS | 38 |
| 7. Conclusions | 41 |
| Glossary | 43 |
| References | 47 |
| Related Reading | 53 |
| AMORPHOUS SILICON PANEL FABRICATION | 53 |
| MEDICAL IMAGING | 53 |
| MEDICAL IMAGING APPLICATIONS | 54 |
| TELEMEDICINE | 55 |
| NONMEDICAL IMAGING | 56 |
| Appendix A. Low-Cost Manufacturing Technology for the Fabrication of Amorphous Silicon Detectors | 57 |
| MANUFACTURING PROCESS | 58 |
| ACCOMPLISHMENTS OF ATP-FUNDED PROJECT | 60 |
| COST REDUCTION FROM LOW-COST PROCESS | 60 |
| REMAINING TECHNICAL ISSUES | 61 |
| Appendix B. Base-Case Calculations | 63 |
| Appendix C. Step-Out Scenario Calculations | 71 |

TABLES

| | |
|--|-----------|
| Table 1. Benefits from ATP's Investment in the Low-Cost Manufacturing Process Through Additional Digital Mammography and Radiography Units |xi |
| Table 2. Incidence of Breast Cancer for American Women |10 |
| Table 3. Projected U.S. Sales of FFDM and Senographe 2000D Units Without ATP-Funded Low-Cost Process: Counterfactual Case |26 |
| Table 4. Projected U.S. Sales of Revolution XR/d Units Without ATP-Funded Low-Cost Process: Counterfactual Case |28 |

| | | |
|----------|--|----|
| Table 5. | Projected Unit Sales Enabled by ATP-Funded Low-Cost Process | 31 |
| Table 6. | Cash Flows from Additional Unit Sales, Assuming Implementation of ATP-Funded Low-Cost Process in 2004 (\$ Millions, in 2002 Dollars): Base Case | 33 |
| Table 7. | Cash Flows from Additional Unit Sales, Assuming Implementation of ATP-Funded Low-Cost Process in 2004 (\$ Millions, in 2002 Dollars): Step-Out Scenario | 36 |
| Table 8. | Estimated Revenues to ATP Partners from Future Implementation of ATP-Funded Low-Cost Process (\$ Million, in 2002 Dollars) | 38 |
| Table 9. | Percentage of Cancer Victims Diagnosed at Various Stages, Screened Versus Unscreened Populations | 39 |

APPENDICES TABLES

| | | |
|-----------|---|----|
| Table A1. | Projected Equipment Utilization for a-Si Detector Fabrication | 61 |
| Table B1. | Projected Additional Senographe 2000D Unit Sales: Base Case | 63 |
| Table B2. | Projected Additional Revolution XR/d Unit Sales: Base Case | 64 |
| Table B3. | Productivity Gains from Senographe 2000D: Base Case | 65 |
| Table B4. | Productivity Gains from Revolution XR/d Unit Sales: Base Case | 66 |
| Table B5. | Savings from Avoided False Positives with Senographe 2000D: Base Case | 67 |
| Table B6. | Patient Savings from Avoided Time Off and Travel with Senographe 2000D: Base Case | 68 |
| Table B7. | Summary Cash Flow Benefits with Senographe 2000D and Revolution XR/d: Base Case | 69 |
| Table C1. | Projected Additional Senographe 2000D Unit Sales: Step-Out Scenario | 71 |
| Table C2. | Projected Additional Revolution XR/d Unit Sales: Step-Out Scenario | 72 |
| Table C3. | Productivity Gains from Senographe 2000D Units: Step Out Scenario | 73 |
| Table C4. | Productivity Gains from Revolution XR/d Units: Step-Out Scenario | 74 |
| Table C5. | Savings from Avoided False Positives with Senographe 2000D: Step-Out Scenario | 75 |
| Table C6. | Patient Savings from Avoided Time Off and Travel with Senographe 2000D: Step-Out Scenario | 76 |
| Table C7. | Summary Cash Flow Benefits with Senographe 2000D and Revolution XR/d: Step-Out Scenario | 77 |

FIGURES

| | | |
|-----------|--|----|
| Figure 1. | Principles of Amorphous Silicon Detector | 4 |
| Figure 2. | Percentage of Women (Aged 40+) Who Had Mammograms Within Past 2 Years, by Race and Ethnicity | 13 |
| Figure 3. | Direct Digital Mammography | 15 |

Figure 4. Flow of Benefits from the ATP-Funded Low-Cost Process30
Figure 5. Net Present Value Component Analysis: Base Case35

APPENDICES FIGURES

Figure A1. Principles of Amorphous Silicon Detector57
Figure A2. Thin Film Processing: Depositing, Patterning, and Etching of Multiple
Layers59

1. Introduction

The Advanced Technology Program (ATP), National Institute of Standards and Technology (NIST), fosters partnerships among government, industry, and academia by co-funding innovative, high-risk research to develop enabling technologies that promise broad economic benefits for the nation.

In 1995, ATP co-funded a joint-venture project with General Electric Global Research (formerly General Electric Corporate Research & Development) and PerkinElmer, Inc. (formerly EG&G Reticon) to develop an innovative low-cost manufacturing (LCM) process for thin-film amorphous silicon (a-Si) detectors with primary applications in medical imaging, as well as potential future applications in industrial machine vision and nondestructive testing. If successful, the LCM process would enhance the affordability of digital imaging for screening mammography and chest radiography and deliver the medical and productivity benefits of digital technologies to patient populations and healthcare facilities that would not have otherwise enjoyed these benefits.

The ATP conducts economic analyses to assess the short- and long-term benefits of ATP-funded projects to the nation. It evaluates impacts on project participants, their customers, patient populations, and other recipients of technologies developed with ATP assistance.

CASE STUDY OBJECTIVES AND SCOPE

The objectives of this case study are to summarize the key technical features of the enabling LCM process technology developed with ATP-funding, to describe application opportunities, and to identify, characterize, and quantify the medical and economic benefits of the LCM process technology. The case study is aimed at evaluating:

- Broad-based medical, economic, and social benefits for various patient populations and the healthcare industry.

- Public returns from ATP's investment.
- Knowledge diffusion concerning ATP-funded technical innovation.
- Private benefits for ATP industry partners.

Analysis focuses on the estimation of quantifiable public returns for the U.S. economy, as measured against ATP's investment during the 1996–2000 period. The analysis also identifies medical, economic, and social benefits that cannot be quantified at this time.

2. Development of Low-Cost Process Technology

HOW DOES IT WORK?

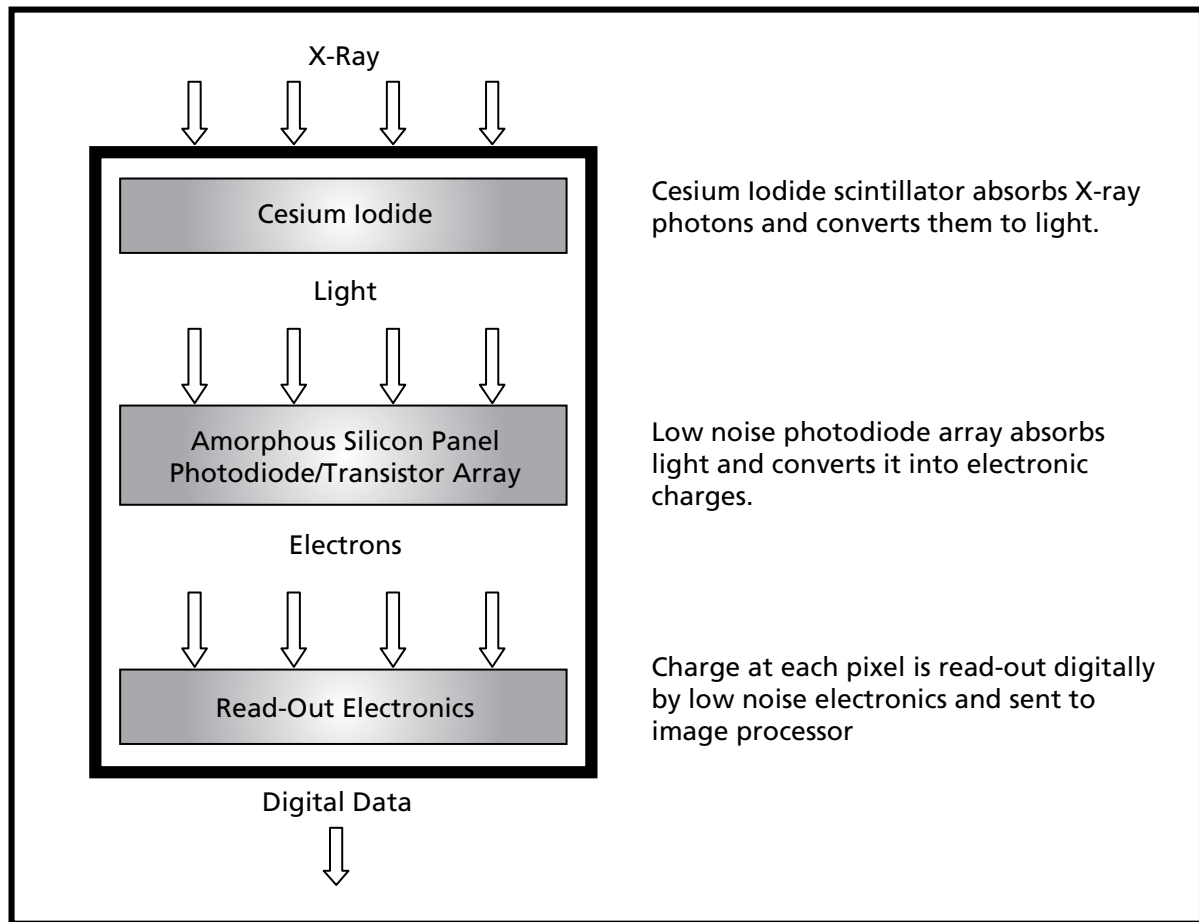
In medical X-ray imaging, photosensitive detectors are a functional alternative to photographic film. Detector integrated circuits are fabricated with amorphous silicon (a-Si) semiconductor layers for full-field imaging of the entire breast or chest. Unlike single crystal silicon, a-Si layers can cover large areas for full-field imaging.

As indicated in Figure 1, the a-Si detector consists of a scintillator layer that converts incident X-ray energy to light and a photosensitive array that converts light into electrical charges. The photosensitive array is made up of picture elements (pixels) sized at 100–200 microns. Each pixel contains a photodiode that absorbs light from the scintillator and generates electrical charges and a field-effect transistor (FET) that serves to isolate each pixel element and acts as a switch to convey electrical charges to external electronics for read-out and image processing. The entire array of more than a million pixels can be read and converted to a composite digital representation in less than a second.

GE was an early pioneer of digital imaging for medical applications and has developed an FDA-approved digital mammography system (Senographe 2000D) and an FDA-approved digital radiography system (Revolution XR/d). A key component in both systems is a full-field photosensitive detector plate large enough to capture the entire breast or chest area in a single image. To fabricate photosensitive a-Si detectors for GE Senographe digital mammography units and GE Revolution digital chest radiography units, GE and PKI currently use a manufacturing process that GE developed prior to ATP funding. This original manufacturing process has come to be known as the baseline process and provides a point of reference for ATP-funded process improvements.

In the baseline process, multiple layers of a-Si thin film are deposited on a glass plate and photolithography is used for pattern formation. The design approach (order and thickness of successive layers) starts with the buildup of FET layers, followed by the

Figure 1. Principles of Amorphous Silicon Detector



Source: <<http://gemedicalsystems.com/>>.

buildup of diode layers, and completed with the deposition of the scintillator layer. The baseline process consists of approximately 300 process steps and 11 photolithographic masks. The complexity of this process contributes to the high manufacturing cost of digital imaging devices and limits the widespread clinical utilization of digital mammography and radiography.

In response to GEGR's proposal for federal funding to reduce process complexity and the high cost of photosensitive detectors and thereby enable increased clinical utilization of digital imaging, ATP cost shared the development of an LCM process for the fabrication of thin-film a-Si detectors.

LCM is an advanced manufacturing process with only seven photolithography masks and significantly reduced fabrication complexity. LCM reverses fabrication process order with the deposition of the diode island preceding the deposition of the FET. Several a-Si fabrication steps, originally kept separate to optimize different aspects of photodiode and FET performance, are combined into dual-use process layers.

ATP PROJECT HISTORY

Beginning in the early 1970s, medical imaging has been moving toward replacing film-based technologies with digital imaging technologies. Computed tomography (CT) and magnetic resonance imaging (MRI) were originally developed as digital technologies tied to computers. Ultrasound and nuclear medicine transitioned to a digital format, and doctors and radiologists became increasingly familiar and experienced with computerized medical image processing.

Digital mammography, chest radiography, and cardiac imaging represent a more recent initiative. Starting in 1990, GEGR led the development of thin-film a-Si digital detectors. The Defense Advanced Research Project Agency (DARPA) participated in funding early demonstration projects for detector fabrication. GE's initial target market for utilizing a-Si digital detectors was cardiac imaging, a field not particularly sensitive to the higher equipment costs of digital technology.

In the early 1990s, GE developed digital detectors for the more cost-sensitive mammography and chest radiography applications. During this second phase, GE obtained federal support from the U.S. Army Medical Research and Materiel Command, the U.S. Navy, Department of Radiology and Nuclear Medicine, and the Office of Women's Health in the Department of Health and Human Services to develop and field test detectors for the GE Senographe 2000D digital mammography and Revolution XR/d digital radiography units.

Looking for ways to increase Senographe 2000D and Revolution XR/d market penetration, GE research scientists and engineers actively pursued ways to reduce the fabrication costs of digital detectors. GEGR proposed an innovative technical approach, the LCM process, for internal funding. LCM would reduce process complexity and eliminate several photolithographic masks. However, "getting internal support for the LCM proposal was hard. At the time, it was difficult for some executives to see the advantages of taking digital imaging beyond cardiac applications. Also, combining process steps in the fabrication of a-Si integrated circuits was considered to be a high-risk proposition" (Edelheit, 2001), including the following uncertainties:

- Could processing be developed to substantially reduce the number of process steps without compromising detector performance?
- Could the photodiode device be deposited at the same temperature as the FET without degrading detector performance?
- Could data lines be properly insulated to facilitate low noise readout?

Business risks were also significant. The President's Task Force on National Healthcare Reform had recently been appointed. The task force was perceived by GE as advocating major reform for the healthcare industry, creating widespread market uncertainties. As a result of the technical risks and market uncertainties, GE was

reluctant to approve the LCM process proposal for internal funding. Subsequently, GE Global Research, together with PKI, its strategic manufacturing partner for digital detector fabrication, approached the ATP for a grant to cost share the development of this high-risk, enabling process technology. “Given technical and other risks, had the ATP turned down the GEGR/PKI proposal, the promising low-cost manufacturing process initiative would have been shelved” (Edelheit, 2001).

ATP Joint-Venture Project Partners

General Electric Global Research, formerly General Electric Corporate Research & Development, is the corporate research unit of General Electric Company, a diversified manufacturer of medical diagnostic imaging, industrial automation, aircraft engine, and electrical power generation and distribution equipment. GE is headquartered in Stamford, Connecticut, and employs more than 300,000 people worldwide. General Electric Global Research is located in Niskayuna, NY.

PerkinElmer Inc., formerly EG&G Reticon, is a leader and innovator in semiconductors, optoelectronics, and life sciences and is headquartered in Wellesley, Massachusetts.

In its 1995 General Competition, the ATP selected the proposed joint-venture project for a three-year award to develop an LCM process for large-area a-Si devices to be used in medical imaging systems and other applications. The award was later extended to five years. The core challenge was to combine manufacturing steps, which originally were kept separate to optimize different aspects of device performance without sacrificing any aspect. The ATP agreed to cost share \$1.575 million of the \$3.438 million project and GEGR and PKI committed to fund the balance.

The GEGR/PKI joint venture used a well-defined project structure to assign complementary roles to each strategic partner. At project inception, GEGR provided PKI access to its proprietary a-Si technology. Throughout the project, GEGR provided technology development, product specification, device testing, and evaluation for both 21 cm and 41 cm detector units. GEGR conducted additional process development for 21 cm detectors, and PKI provided process technology development and pilot production runs for 41 cm detectors. Once in full-scale production, GE and PKI fabrication departments will provide digital detectors to their “customer,” GE Medical Systems (GEMS), for use in Senographe digital mammography and Revolution digital radiography units.

MAJOR INNOVATIONS

The original GEGR baseline fabrication process was developed with the intent of optimizing the performance of each device (diode and FET). Given its complexity, the

process is characterized by a large number of steps, long manufacturing cycle times, and high cost.

The goal of the ATP-funded low-cost process was a technology breakthrough in processing simplicity and lower cost. The project was successfully completed in 2000 and resulted in less complex fabrication with fewer masks (seven versus eleven) and fewer total process steps (200 versus 300). Fewer process steps increased production yield and reduced manufacturing cycle times. “Detailed modeling has verified that reductions in mask count closely scales with reduced process cost,” pointing to 25 percent cost reduction from low-cost process implementation (General Electric Global Research staff, 2001).

The major innovation of the low-cost process is the “interleaved fabrication of the light sensitive diode and the thin film transistor switching (FET) element without compromising either diode or FET performance” (Giambattista, 2001). Interleaved fabrication included the following dual and multiuse layers:

- Gate metal layer for scan line, FET gate, and bottom contact.
- FET dielectric layer for FET gate, diode sidewall passivation, and common electrode insulation.
- Barrier dielectric layer for FET sidewall passivation and protection barrier.
- Indium tin oxide (ITO) layer for diode and contact pads to drive electronics.

Additional innovations included:

- Elimination of labor-intensive test and repair steps for fabrication throughput advantage and improved data line repair capability intrinsic in device structure.
- Electronic noise reduction in data lines without additional process complexity.

Related technical accomplishments included:

- Reaching an acceptable compromise in FET and diode deposition temperatures.
- Identifying gate metals with acceptable sidewall slope after the etch.
- Optimizing FET island etch for selectivity to gate dielectric removal.
- Contact finger design for electronic bonding.

Technical accomplishments are reflected in patents issued to General Electric Company: US5838054 for Contact Pads for Radiation Imagers, US5648296 for Post Fabrication Repair Method for Thin Film Imager Device, and a patent filed for Gated Diodes for a Reduced Mask Imager Process.

While the low-cost process was demonstrated to be technically feasible for producing medical quality X-ray imagers up to 41 cm², the process is still considered to be developmental and “all risks have not been fully retired” (Giambattista, 2001). The need for additional effort beyond the ATP project was anticipated in the 1995

GEGR/PKI proposal to ATP: “Commercialization of program results will be accomplished by further, independent design and development to assure that ATP-funded R&D leads to a manufacturable low-cost process” (Giambattista, 2001). Additional work is required to eliminate particle contamination that limits the yield impact of mask count reductions in fully optimizing the etch profile of bimetallic gate structures and to block light hitting the FET causing leakage in the data lines (Giambattista, 2001). Appendix A provides a more in-depth description of the LCM process technology and the technical accomplishments of the ATP-funded project.

LOW-COST PROCESS IMPLEMENTATION

The decision to implement the low-cost process, the timing of that decision, and the resolution of remaining technical issues will be made by GE and by PKI management. It is expected that this business decision will be shaped by the following three factors:

- Demonstrated technical feasibility.
- Growing market demand for direct digital imaging in medical applications.
- Competitive pressures to reduce component (a-Si detector) costs.

These three factors are currently evolving and should effectively support a business decision to complete development and to implement the LCM process.

- Technical feasibility has been demonstrated and economic analysis indicates a 25 percent cost reduction.
- Independent market research points to long-term market demand for digital screening mammography and radiography.
- The FDA has approved GE digital mammography and digital radiography systems. As other equipment vendors obtain FDA approval, there will be substantial downward pressure on equipment pricing. Even now, GE management is “very interested in component price reduction in the 5 to 10 percent range” (Giambattista, 2001).

A senior GE executive offered the following observation concerning the prospects of LCM implementation:

In the end, competition will drive down digital mammography equipment costs and we will all look back and feel very happy that GE has available technology (the ATP-funded low-cost manufacturing process) at its disposal to control costs, to compete effectively, and to keep the technology in the United States. General Electric Company will also be happy to be associated with the many qualitative social benefits of digital mammography and radiography, as they are more widely adopted over time (Edelheit, 2001).

3. Digital Mammography

Cancer is a group of diseases characterized by uncontrolled growth and spread of abnormal cells. It is caused by genetic and environmental factors. Ten or more years may pass between the occurrence of mutations or exposure to environmental factors and detectable cancers.

Breast cancer is a devastating disease and is the second most common cause of cancer-related death in the United States. In 2002, approximately 205,000 new cases of invasive breast cancer will be diagnosed, and about 40,000 women are expected to die from the disease (American Cancer Society, 2002a).

Conventional film-based mammography is a screening technology for the early detection of breast cancers. Early detection is vital to facilitating more effective treatment. The new technology of digital mammography was recently developed to go beyond the clinical capabilities of conventional film mammography and to address its productivity limitations.

BREAST CANCER AND EARLY DETECTION

Breast cancer is a complex of more than twenty distinct types of breast disease (Thompson, 2002). It progresses in stages. The first, in situ stage is limited to small areas and confined to the cells in which the cancer began, without invasion of surrounding tissues. The second, localized stage is invasive cancer into surrounding mammary tissue, but not invasive outside the breast tissue. In the third, regional stage, cancer spreads to the chest wall, muscles, and immediately upstream lymph nodes. In the fourth or distant stage, cancerous tumor cells have metastasized or spread to other parts of the body.

Early detection, prior to cancer spreading from initial cells to adjacent breast tissue and other regions of the body, is widely believed to save lives by facilitating early intervention, when treatment is most likely to be effective. If detected “when small and local, treatment options may be less dangerous, intrusive, and costly and more

likely to lead to a cure” (Institute of Medicine, 2001). At the same time, in clinical practice there is an exception to every rule and early detection of some slow-growing cancers could lead to overly aggressive treatment causing unnecessary medical risks and treatment expenses. But because medicine is an applied science of probabilities rather than certainties, for the majority of cases early detection is widely considered to be a desirable outcome.

BREAST CANCER TRENDS

Breast cancer primarily affects female populations and is relatively uncommon in men. The National Cancer Institute estimates that about one in eight, or 13 percent, of women in the United States will develop breast cancer during their lifetime.

The risk of developing breast cancer increases with age (Table 2). More than 80 percent of breast cancers occur in women aged fifty years or older. It is uncommon under the age of forty.

Age-related incidence rates do not properly characterize high-risk populations. Five to seven percent of breast cancer is hereditary, linked to BRCA1, BRCA2, and other genes. These mutations carry lifetime risks on the order of 56 to 85 percent, compared to 13 percent average lifetime risk. Additional groups of high-risk populations include women with a family history of breast cancer, personal cancer history, and possibly higher breast density (Jardines, 2001). Obesity and urban residence also correlate with higher risk (Miller, 1996).

Incidence patterns vary by race and ethnicity, “revealing that white, Hawaiian, and black women have the highest age adjusted rates. Lowest U.S. rates occur among Korean, American Indian, and Vietnamese women” (Miller, 1996). Mortality patterns by race and ethnicity differ from incidence patterns. “The highest age adjusted mortality occurs among black women, followed by white and Hawaiian women. Higher mortality among black women is thought to be related to a larger percentage of breast cancers being diagnosed at a later, less treatable stage” (Miller, 1996).

During the 1987–1999 period there was an increase in the incidence of breast cancer. This trend is expected to continue as “the U.S. population grows older and cancer is largely a disease of older people.” At the same time, “breast cancer death rates are

Table 2. Incidence of Breast Cancer for American Women

| Age Group | Women Diagnosed with Breast Cancer |
|-----------|------------------------------------|
| 30–39 | 1 of 257 |
| 40–49 | 1 of 67 |
| 50–59 | 1 of 36 |
| 60–69 | 1 of 28 |

Source: National Cancer Institute (2001a).

down, due to screening mammography, which catches cancers earlier when they are more treatable, and to improved treatment modalities” (American Cancer Society, 2002b).

CONVENTIONAL MAMMOGRAPHY

Mammography is a medical imaging procedure for breast cancer screening and diagnosis. Screening mammography is the X-ray imaging of the breasts of women with no complaints or symptoms of breast cancer. The goal is to detect asymptomatic cancer when it is still too small to be felt by a woman or a physician. Diagnostic mammography is an X-ray examination of the breasts of women who either have a breast complaint (for example, a breast lump or nipple discharge) or when an abnormality has been found during previous screening mammography. Eighty percent of U.S. mammography procedures are used for cancer screening.

Conventional screen film mammography (SFM) uses a low-dose X-ray system and high-contrast, high-resolution film to create detailed images of the breasts. To take a mammogram, the X-ray source is turned on and low dose X-rays are radiated through the compressed breast and onto a film cassette positioned under the breast. SFM procedures consist of X-ray production, differential X-ray absorption by breast tissues, recording of transmitted X-rays on photographic film, film development, and image display for reading or interpretation by a specialized radiologist (mammographer).

Breast abnormalities or lesions that may be detected through mammography include calcification and lumpy masses. The goal of the mammographer is to detect those abnormalities that can be suggestive of malignancy.

- Calcifications are tiny mineral deposits within the breast tissue that appear as small white spots on films. *Macrocalcifications* are coarse (larger) mineral deposits that most likely represent degenerative changes in the breast, such as aging of arteries, injuries, or inflammations. These deposits are usually associated with benign (non-cancerous) conditions and do not require a subsequent biopsy. Macrocalcifications are found in about 50 percent of women over the age of fifty. *Microcalcifications* are tiny specs of calcium in the breasts, may appear singly or in clusters, and may be indicative of cancer. The shape and arrangement of microcalcifications help the radiologist judge the likelihood of cancer being present and the need to prescribe a biopsy (American Cancer Society, 2002c).
- Masses are abnormal breast tissue that may be benign or cancerous. Some masses are fluid-filled spaces called cysts. To evaluate cysts, the radiologist may prescribe a breast ultrasound procedure. Sometimes radiologists will decide to aspirate the cyst, that is, remove a fluid sample from the cyst using a needle. The fluid is then examined by a pathologist to determine if the cells are cancerous. For masses other than cysts, the size, shape, and edges of the mass may be indicative of cancer and the radiologist could prescribe a biopsy.

For the most effective interpretation of mammograms and the detection of calcifications and lumpy masses, it is important to have prior mammograms available for comparison. If prior mammograms indicate that calcifications and mass patterns have not changed, benign condition may be indicated and unnecessary diagnostic procedures avoided.

COMPLEMENTARY BREAST SCREENING MODALITIES

Other breast screening modalities (technologies) that complement mammography include:

- **Ultrasound.** High-frequency sound waves are bounced off breast tissues. The echoes produce a picture called a sonogram. Ultrasound imaging can be used to distinguish between solid tumors and fluid-filled cysts and evaluate lumps that are hard to see on mammograms. Ultrasound is not used for routine breast cancer screening as it does not consistently detect early signs of cancer such as microcalcifications.
- **Magnetic Resonance Imaging.** A magnet linked to a computer creates a series of detailed cross-sectional pictures of the breast without the use of radiation. Like ultrasound, MRI cannot detect microcalcifications and is generally not used for cancer screening except in special cases, such as screening high-risk women with a strong family history of breast cancer, where “MRI may be a superior screening modality” (Stoutjesdijk, 2001).
- **Computed Tomography.** A pencil-thin beam of high-energy radiation is used to create a series of breast images, taken from different angles. The images are fed into a computer and combined into a single image of the breast.

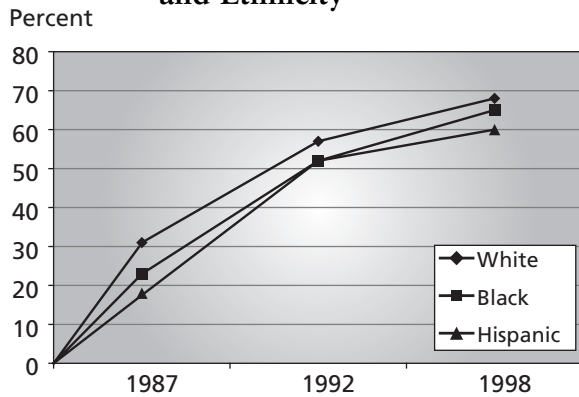
In general, the above technologies are used to complement and not displace mammography as the primary modality for breast cancer screening. “Though imperfect, mammography remains the best screening tool as well as the gold standard for breast cancer diagnosis” (Institute of Medicine, 2001).

SCREENING MAMMOGRAPHY TRENDS

The use of screening mammography for detecting breast cancer has increased dramatically. In 1987, 29 percent of women over forty years of age had a mammogram in the past two years. In 1998, more than 60 percent had a mammogram. As Figure 2 indicates, expanded mammography use has reached most racial and ethnic groups, with only Hispanic women lagging average use rates by 6 percent. In 2000, more than 32.5 million mammograms were performed in the United States. Further increases in screening mammography use are expected to encounter substantial barriers, including:

- High volume workloads coupled with a growing shortage of radiologists.
- High mammography costs coupled with lack of medical insurance.

Figure 2. Percentage of Women (Aged 40+) Who Had Mammograms Within Past 2 Years, by Race and Ethnicity



Source: Centers for Disease Control and Prevention, National Center for Health Statistics.

- Poor accessibility in some isolated, rural, or inner city neighborhoods, and for the growing population of older women (Lichtman, 1996).

LIMITATIONS OF SCREENING MAMMOGRAPHY

Since the 1960s, eight clinical trials of screening mammography have been conducted in the United States, Sweden, the United Kingdom, and Canada. The results of these clinical trials indicated substantial reductions (more than 30 percent) in breast cancer mortality and were extensively used to justify national screening mammography programs.

In 2001, the Nordic Cochrane Centre commissioned a meta-analysis of the results of these clinical trials. The authors of the meta-analysis argued that the clinical trials were not properly randomized and concluded “that there is no reliable evidence that screening mammography reduces breast cancer mortality and breast cancer screening may not be worth the physical and financial toll it exerts.” Radiation exposure was also a concern (Gotzsche and Olsen, 2001).

A subsequent, February 2002, “fresh look” at the original data of the Swedish clinical trials concluded that mammography does save lives, but at a somewhat lesser rate than claimed in the original clinical studies (Nystrom et al., 2002). The predominant U.S. and international medical opinion largely accepts the Nystrom rebuttal of the Cochrane meta-analysis concerning the value of screening mammography.

- According to the American Cancer Society, “the overwhelming weight of evidence shows that mammography saves lives” (Norton, 2002).
- According to the International Agency for Research on Cancer, “a woman who is screened regularly can expect about 35 percent reduction in her risk of death from breast cancer” (Reaney, 2002).
- According to the American College of Radiology, “there is sufficient data that clearly demonstrates that screening mammograms are saving lives” (AuntMinnie, 2002).

While medical opinion is generally supportive of screening mammography, there is a parallel tendency to recognize its limitations. These limitations revolve around the subjectivity of image interpretation.

Mammographers (specialized radiologists) use imaging procedures to detect breast abnormalities that can be suggestive of malignancy. “Unfortunately, [a] great deal of overlap exists between imaging patterns produced by benign and malignant breast lesions, creating the possibility of both false positives and false negative results” (Kornguth and Bentley, 2001). “Most cancers become visible on mammograms only after they have been present for several years and about 20 percent of detectable cancers are overlooked or misdiagnosed on first inspection (Lawrence Livermore Laboratories, 1995).

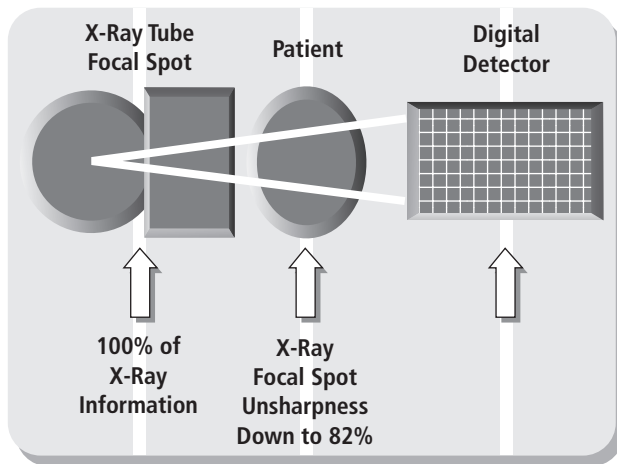
In particular, screening mammography results are currently characterized by:

- Twenty-percent rate of false negatives where mammography fails to detect cancerous conditions (National Cancer Institute, 2002).
- Inadequate screening of high-risk women, necessitating more frequent examinations (beyond annual) and other screening modalities such as MRIs (Stoutjesdijk et al., 2001).
- Missing rapidly proliferating, high-grade tumors or detecting these too late (Porter, 1999).
- Tendency to miss cancers in women with dense breast tissue. The breasts of younger women contain many glands and ligaments that appear dense on a mammogram making it difficult to spot tumors. High-quality mammograms detect approximately 90 percent of cancers in women over fifty but only 60 percent of breast cancers in women under fifty (National Cancer Institute, 2002).
- Up to 12 percent false-positive rate where incorrect interpretation identifies cancer where none is present. False-positive readings result in unnecessary recalls for diagnostic mammography and biopsies, unnecessary medical and transportation expenses, and unnecessary anxiety and physical discomfort (Alexander, 1999).
- Concern about radiation exposure.

Longitudinal comparison of mammograms can alleviate some of the above limitations and is frequently used by radiologists to distinguish microcalcifications and breast lumps that are likely to be malignant (Medscape, 2001).

However, at typical U.S. imaging centers, 20 percent of archived film is lost or otherwise unavailable for clinical comparison, impeding the analytical continuity of mammogram interpretation.

Figure 3. Direct Digital Mammography



“Though imperfect, screen film mammography remains the best screening tool for breast cancer detection” (Institute of Medicine, 2001). The new technology of digital mammography was recently developed to go beyond the clinical capabilities of conventional film mammography and to effectively address its limitations.

DIGITAL MAMMOGRAPHY

In digital mammography, a digital detector is added to replace the film

cassette of the conventional system (Figure 3). Due to the detector’s high detective efficiency, or detective quantum efficiency (DQE), it has the potential to capture up to 82 percent of the original signal or breast image information. Digital mammography also operates at significantly higher speeds, facilitates the independent interpretation of mammograms by two radiologists (double reading), and supports the development of regional tele mammography networks, designed to reach isolated and underserved populations.

Digital mammography uses electronic detector panels for capturing the X-ray images of the breast as a collection of discrete electrical charges. After the X-ray passes through the tissue undergoing imaging, it encounters the scintillator layer of the detector that converts X-rays to light. Next, light signals encounter the detector’s photodiode layer where signals are converted into electrical charges. Electrical charges are converted to voltage signals and transferred to a monitor for image display and to a computer for image analysis and storage.

GE uses a-Si for the fabrication of the detector photodiode layer. A-Si makes it possible to fabricate large panels of one continuous piece for capturing a full breast in one high-resolution image. This capability is referred to as full-field digital mammography (FFDM) and is deemed to be desirable for optimal mammogram reading and interpretation. A-Si appears to be the most promising design for dose-efficient FFDM, as well as for other high performance medical applications (Granfors and Aufrichtig, 2000). Alternative design approaches may be appropriate for less demanding imaging tasks.

Alternative Digital Designs for Less Demanding Applications

Slot Scan:

This approach involves acquiring several lines of information as detectors are swept over the anatomy of interest. Although it can potentially yield relatively high resolution, slot scan requires very precise synchronization of electronics and mechanics to avoid blurring. It may also result in slow acquisition speeds and higher X-ray dosage.

Tiled Charge-Coupled Device (CCD) Arrays:

This transitional technology employs multiple CCDs. The potential disadvantages include stitching artifacts, associated lost spaces, and longer image-processing time to form the digital image.

Selenium Panels (Direct Conversion without Scintillator):

This technique employs flat-panel Selenium detectors that absorb X-rays directly and convert them into electrical charges. The charges are read by read-out electronics and converted to digital data. Selenium detectors are associated with potentially lower DQEs.

CLINICAL TRIALS: DIGITAL MAMMOGRAPHY

A recently completed clinical trial funded by the U.S. Army Medical Research and Material Command and conducted through the University of Colorado and University of Massachusetts Medical Centers compared the screening accuracy of FFDM and conventional film mammography on 5,000 subjects. The study identified no statistically significant difference in cancer detection. However, digital mammography had a 20 percent lower recall rate from false positive readings (Lewin et al., 2000).

The Army clinical trial used a relatively small sample size, and “used prototype digital systems with lower resolution, lower luminance monitors, and inferior image processing capabilities” compared to the Senographe 2000D, the current FDA-approved GE FFDM (Schubert, 2002).

Given the limitations of the U.S. Army study as well as technical advances since the prototype stage, the radiological community generally anticipates improved results from the new FDA-approved fully commercial FFDM system. Per the National Cancer Institute, “digital mammography has the potential to provide better detection of early breast cancer, but a large study is needed to really determine whether it is better than conventional mammography and how large the difference” (RSNA, 2002). To identify whether the anticipated performance improvements are being realized and to generate results with higher statistical validity, the National Cancer Institute and the American College of Radiology Imaging Network (ACRIN) have

initiated a large, multi-center clinical trial using various digital mammography devices made by four different manufacturers (GE, Fuji Medical Systems, Fischer Imaging, and LORAD). The \$26.3 million clinical trial with a screening population of 49,500 women is currently underway in the United States and Canada (Pisano, 2001).

COMPUTER-AIDED DETECTION

FFDM facilitates the use of computer-aided detection (CAD), a process in which radiologists use computers and specialized software to read mammograms and identify breast abnormalities. “Currently, mammograms are visually examined in search of subtle and complicated indicators of breast cancer. This can be a difficult, tedious, and time-consuming task as only one in a thousand mammograms may show an abnormality of concern. Computers can assist mammographers by consistently scanning every part of every mammogram and reporting suspicious areas. This allows the human expert to make the most efficient use of his/her time and focus on those cases generating the greatest concern” (Lawrence Livermore, 1995).

A 12-month study of 12,900 women, screened with mammography plus CAD, identified a 19.5 percent increase in the number of cancers detected relative to mammography without CAD (Freer, 2001). Another smaller 2002 study identified a more than 50 percent increase (Jong et al., 2002). Other studies pointed to the benefits of CAD in reducing variability in radiologist interpretations (Yulei et al., 2001) and the greater sensitivity of CAD for breast masses as opposed to calcifications (Markey et al., 2002).

POTENTIAL BENEFITS FROM DIGITAL MAMMOGRAPHY

The ongoing ACRIN clinical trials may find superior cancer detection performance over conventional film mammography. However, even in the absence of findings indicating improved cancer detection, digital mammography can be associated with the following medical, economic, and social benefits that make it an attractive screening tool for diagnostic imaging centers.

Medical Benefits

- Lower false positive rates, and therefore fewer unnecessary biopsies.
- Lower call-back rates for mammogram over- and under-exposure, and therefore avoidance of unnecessary procedures.
- Reduced radiation exposure for women with dense breast tissue.
- Simplified retrieval, and elimination of loss, of prior mammograms, facilitating analytical continuity and improved cancer detection.
- Facilitation of use of CAD for improved cancer detection.
- Enhanced real-time sharing of mammograms in clinical settings for double reading, associated with improved cancer detection.

Productivity and Economic Benefits

- Increased throughput (counteracting the growing shortage of radiologists), reduced patient examination time, and reduced waiting time.
- Reduced lost wages and travel time for patients by avoiding unnecessary recalls.
- Reduced medical diagnostic costs from avoided recalls and biopsies.
- Reduced operating costs by eliminating film and film development.
- Reduced record-keeping costs by eliminating film archiving.

Social Benefits

- Facilitation of regional tele mammography networks, thus expanding access to quality mammography services at underserved rural locations (for example, at military bases and field hospitals) and by underserved minority populations.

Key component costs, such as for digital detectors, must be reduced, and digital mammography equipment must become more affordable, for more American women and healthcare providers to experience the above medical, economic, and social benefits. These are the goals of the ATP-funded low-cost manufacturing process technology.

4. Digital Chest Radiography and Other Applications

DIGITAL CHEST RADIOGRAPHY

In the United States, 68 million chest X-rays are performed each year with conventional photographic film. Chest X-rays are performed for the evaluation of lungs, heart, and surrounding anatomy. Pneumonia, heart failure, pleurisy, and lung cancer can be diagnosed or suspected on the basis of chest X-ray examination, along with other less common conditions. Traditionally, chest X-rays have been taken prior to employment, prior to surgery, or during immigration proceedings.

Digital radiography uses full-field a-Si detectors and electronic display monitors for routine chest X-rays. It is designed to work with Picture Archiving and Communications Systems (PACS) so that doctors at different locations can simultaneously view X-rays for double reading and remote consultation.

Medical and Productivity Benefits

- Reduced radiation dosage. A recent study indicates that digital radiography achieved comparable image quality with conventional film radiography with 50 percent to 70 percent radiation dosage reduction (Rong et al., 2001).
- Increased equipment throughput, thereby reducing the cost of operations and improving radiologist productivity (Fratt, 2002).
- Facilitation of the development of teleradiology networks for delivering high-quality chest radiography services to medically underserved populations.

Less expensive digital detectors from the ATP-funded LCM process are expected to deliver these benefits to healthcare facilities and patients that would not have received these benefits otherwise.

DIGITAL CARDIOLOGY

The objective of cardiac imaging is to take real-time pictures of the beating heart using fluoroscopic procedures. X-rays are pulsed at 30 frames per second, at which speed images are continuous to the human eye.

GE's Innova 2000 Cardiovascular Imaging System uses a-Si detectors to view coronary artery blockages that could cause heart attacks or other serious health risks. With digital imaging capabilities, cardiologists can also view hard-to-see blood vessels, as well as devices used during cardiac catheterization procedures: stents, guide wires, and catheters. More than 4.5 million cardiac catheterization procedures are performed in the United States every year (General Electric, 2001a). GE claims the following potential benefits for digital cardiology with a-Si detectors:

- Faster procedures.
- Significantly lower radiation dosage.
- Greater ability to see cardiovascular details.
- Improved imaging for larger, more overweight patients.
- Improved pediatric imaging at lower dosages (babies' hearts beat faster and children have a greater adverse sensitivity to radiation than adults).

The market for cardiac suites is less cost sensitive than the markets for mammography and radiography systems. One reason is that cardiac suites are priced well over a million dollars and the detector is a relatively small component that does not significantly impact the overall system price. As a result, a 25 percent cost reduction for the digital detector component is not likely to result in additional equipment sales that would deliver the benefits of digital cardiology to patients who would not have had access to these benefits otherwise.

DIGITAL IMAGING FOR INDUSTRY AND HOMELAND SECURITY

Potential industrial and security applications for a-Si detector panels include:

- Aircraft structural inspection.
- Industrial nondestructive testing.
- Airport and customs cargo inspection for homeland security.
- Pipeline weld inspection.
- Machine vision.

These industrial and security applications have lower performance requirements than medical imaging systems and are more price sensitive. At this time, it is not expected that a 20 to 30 percent detector panel cost reduction (tied to the ATP-funded LCM process) will result in additional industrial sales (Gilblom, 2001).

However, different device structures and additional fabrication experience, perhaps resulting from licensing the LCM process or from other ATP-funded projects, could lead to price reductions sufficiently deep to enable an increase in detector unit sales for industrial applications. Thus there is potential for diffusion of the benefits of digital detectors to industrial customers as well as for contributing to homeland security through improved airport and customs cargo inspection.

5. Market Analysis

U.S. medical imaging services are provided through 2,300 large hospitals and 3,300 free-standing diagnostic imaging centers and chains (DICs). Free-standing DICs are owned by professional radiologist groups, partnerships with hospitals, and for-profit corporations. Thirty-seven percent of the DICs are located in four states: New York, Florida, Texas, and California. All states have at least one operational DIC, except Vermont (SMG Marketing Group, 2000).

Hospital and DIC imaging centers employ more than 14,000 radiologists (Firstmark, 2001). “Procedure growth and the aging of the population are increasing demand for radiologists at 4 to 5 percent per year and the supply of radiologists is projected to fall short of growing demand levels. The American College of Radiology projects continued acute shortages until 2018 and is actively promoting new technologies and procedures to increase radiologists’ productivity to offset projected shortages” (Wagner, 2001).

In addition to rapid growth, the medical imaging sector is subject to cost pressures, as well as increased competition from nonradiologists performing imaging procedures. Cardiologists are performing vascular diagnostic procedures, obstetricians are running their own ultrasounds and sonograms, and orthopedists are X-raying patients’ bones. Cost pressures and competition from other medical specialties are forcing consolidation of radiologist practices. In 2000, 37 percent of DICs consolidated their operations (SMG Marketing Group, 2000).

MAMMOGRAPHY EQUIPMENT MARKET

As of 2000, the installed U.S. base of mammography units (including conventional film and full-field digital systems) was 15,300. Worldwide installed base was approximately 30,000 units, with 10,270 units in Europe (Garcia, 2001).

The 2002 global market for mammography equipment sales is projected to be \$339 million. The North American market leads with 51 percent of total market sales, and this market is expected to grow at a compound annual rate of more than eight percent during the 2002–2007 period. Europe has 38 percent of the market, and the European market is expected to grow at a compound annual rate of more than 10 percent. The rest of the world represents less than 11 percent of the global market, and is expected to grow at more than 20 percent per year. North American and European market shares can be attributed to national breast screening programs in operation or in various stages of planning. Japan is also expected to implement a breast screening program within the 2002–2005 timeframe (Garcia, 2001).

Projected growth rates of U.S. and worldwide mammography equipment sales reflect several market drivers: the need to replace aging inventory of SFM systems operating beyond design economic lives, FDA-mandated quality enhancements, and the desire of leading hospital-affiliated and DIC imaging centers to acquire state-of-the-art FFDM units (Garcia, 2001).

DIGITAL MAMMOGRAPHY MARKET

During the last four decades, the medical imaging industry has been gradually replacing film-based imaging technologies with digital technologies. CT scanners became available in the early 1970s. They generate digital signals for computer processing. MRI followed in the early 1980s, also tied to digital signals and computers. Based on decades of experience with digital data acquisition and computers, doctors and radiologists have become increasingly familiar and experienced with computer-based medical imaging.

The recent commercial introduction of GE's FDA-approved Senographe 2000D FFDM system, and a high level of activity among GE competitors with their own digital mammography products, indicate that the long expected digital revolution in mammography has arrived. "The array of full-field digital mammography products at this year's Radiological Society of North America meeting ranges from systems on the cusp of commercialization to those that are currently undergoing clinical trials" (RSNA, 2001).

"The vendors of imaging equipment are committed to digital X-ray. They have little choice. The practice of medicine is growing increasingly dependent on computers and networking" (Freiherr, 1999). To be cost effective, healthcare facilities must maximize their installed local area networks by moving all X-ray imaging modalities—mammography, cardiac imaging, and chest/body radiography—to digital technology.

The digital mammography market is evolving into a three-tiered structure.

- FFDM units with a-Si and selenium detector panels represent the premium quality market segment.
- Tiled CCD units using crystalline detectors represent the less expensive, middle tier of the FFDM market. “Most places going with CCDs are small radiology clinics who want to get some of the benefits of DM but do not have the high volume and productivity requirements to purchase a premium a-Si FFDM unit” (Schubert, 2002).
- Small-field digital mammography (SFDM) using single CCD crystal detectors for partial imaging of the breast represents the third tier. The target application for SFDM units is diagnostic rather than screening mammography.

GE is the market leader for the high-end digital mammography tier with the FDA-approved Senographe 2000D unit. Other significant market participants include:

- Fischer Imaging: Recently received FDA approval for SenoScan CCD system using slot scanning technique (Fischer Imaging, 2001).
- Hologic and Siemens: Agreed to form a FFDM alliance. Hologic will supply amorphous selenium flat panel detectors for incorporation in Siemens mammography units.
- Hologic’s LORAD division: Filed for FDA approval for a separate CCD system.
- PlanMed: Finnish mammography equipment firm, working on a slot scanning CCD system.
- Fuji: Showcased its FCR 5000MA system, currently available in Europe and Asia, using a dual-side reading feature allowing X-ray information to be simultaneously recorded on both sides of the plate.
- Sectra: Swedish firm MicroDose Mammography system is in clinical tests in Stockholm. Sectra claims that the system can achieve same image quality as conventional film systems, but at one-fifth the radiation exposure.
- Internazionale Medico Scientifica (IMS): Giotto FFDM system in clinical trials.

European competition is expected to be an important factor in shaping industry market dynamics and challenging GE dominance of the U.S. FFDM market (Katz, 2001).

In the context of the above market dynamics and tiering structure, Table 3 provides U.S. unit sales projections for the GE Senographe 2000D. Sales projections through 2007 are excerpted from a recent Frost and Sullivan market study that indicates a dramatic 600 percent increase in FFDM sales during the 2004–2007 period. Beyond 2007, we extrapolate unit sales at 10 percent per annum through 2010 and at five

Table 3. Projected U.S. Sales of FFDM and Senographe 2000D Units Without ATP-Funded Low-Cost Process: Counterfactual Case

| Year | Projected FFDM Unit Sales | GE Senographe 2000D Market Share | GE Senographe 2000D Unit Sales |
|------|------------------------------|-------------------------------------|-----------------------------------|
| 2002 | 57 | 100% | 57 |
| 2003 | 63 | 90% | 57 |
| 2004 | 74 | 90% | 67 |
| 2005 | 111 | 80% | 89 |
| 2006 | 200 | 80% | 160 |
| 2007 | 440 | 70% | 308 |
| 2008 | 484 | 70% | 339 |
| 2009 | 532 | 65% | 346 |
| 2010 | 559 | 65% | 363 |
| 2011 | 587 | 63% | 370 |
| 2012 | 616 | 60% | 370 |
| 2013 | 647 | 60% | 388 |
| 2014 | 679 | 60% | 407 |

Source: 2001–2007 FFDM unit sales, in the first column, are from Frost and Sullivan (2001). Beyond 2007, FFDM unit sales are independently estimated.

percent per annum through 2014. GE’s U.S. market share is estimated on the basis of expert industry input, reflecting the expectation that competitive trends will reduce GE’s market share to 60 percent by 2012.

The FFDM sales projections in Table 3 constitute the counterfactual case of expected sales levels without the ATP-funded LCM process. These counterfactual projections reflect significant near-term barriers to the rapid adoption of FFDM systems. According to Frost and Sullivan (Garcia, 2001), these barriers include:

- Limited U.S. customers for new mammography installations. Unit sales will be replacement driven with minimal growth in new installments.
- Consolidation, leading to facility closings and service reductions in less attractive locations, further reducing customer base and increasing competition.
- High first cost of installed FFDM systems, reflecting substantial research and development (R&D) investments, greater system complexity, and minimal price competition initially. As R&D investment is recovered and competition is energized, significant reductions in first-installed costs are expected.
- Financial success of mammography vendors depends on the financial health of their customers, reflecting available Medicare and private insurance reimbursement patterns.

Changing Financial Barriers for Digital Mammography

Low reimbursement rates make it difficult for healthcare providers to recover the high initial cost of FFDM units. Recent increases in reimbursement rates, including a 50 percent higher reimbursement rate for digital mammography, are expected to help.

Medicare Reimbursements: Health and Human Services' Centers for Medicare and Medicaid Services recently issued final rules for 2002 mammography reimbursements for conventional film and digital mammography. Medicaid reimbursements tend to follow Medicare.

| Plain Film | Digital Mammography | Approved Increment for CAD | Digital Mammography Plus CAD |
|------------|---------------------|----------------------------|------------------------------|
| \$90.50 | \$133.58 | \$17.74 | \$151.32 |

Source: Centers for Medicare and Medicaid Services (2002).

HMO and PPO systems: Member benefits typically include screening mammography services with little or no co-payment. However, cost pressures may mitigate against buying premium FFDM systems.

Private Health Insurance (Blue Cross/Blue Shield): "All states except Utah enacted legislation for screening mammography coverage, either mandating coverage or mandating that coverage be made available" (National Cancer Institute, 2001b). There is substantial interstate variability on implementation.

CHEST RADIOGRAPHY MARKET

In the United States, 68 million chest X-rays are performed each year with conventional photographic film technology. Table 4 presents U.S. sales projections for digital chest radiography and GE Revolution XR/d units under the counterfactual situation, where the ATP-funded low-cost process has not been deployed.

The reduced dosage and productivity benefits of digital radiography are becoming increasingly recognized by medical professionals and business managers. However, the high equipment cost of digital technology relative to conventional radiography is a significant barrier to widespread clinical use. The 25 percent reduction in the cost of a-Si detector panels due to the ATP-funded LCM process is likely to enable additional sales in the extremely price sensitive radiography system market and

Table 4. Projected U.S. Sales of Revolution XR/d Units Without ATP-Funded Low-Cost Process: Counterfactual Case

| Year | Projected Digital Radiography Unit Sales | GE Revolution XR/d Market Share | Projected GE Revolution XR/d Unit Sales |
|------|--|---------------------------------|---|
| 2002 | 158 | 50% | 79 |
| 2003 | 183 | 50% | 92 |
| 2004 | 222 | 50% | 111 |
| 2005 | 299 | 50% | 150 |
| 2006 | 438 | 50% | 219 |
| 2007 | 689 | 50% | 345 |
| 2008 | 758 | 50% | 379 |
| 2009 | 834 | 50% | 417 |
| 2010 | 917 | 50% | 459 |
| 2011 | 1000 | 50% | 500 |
| 2012 | 1000 | 50% | 500 |
| 2013 | 1000 | 50% | 500 |
| 2014 | 1000 | 50% | 500 |

Source: 2002–2007 Digital Radiography unit sales, in the first column, are from Frost and Sullivan (2002). Beyond 2007, unit sales are independently estimated.

therefore have a significant impact in providing patients and healthcare facilities access to the dosage and productivity benefits of digital technology.

MARKET SUMMARY

The market analysis was based on extensive fact finding in the medical equipment, medical imaging services, and private medical insurance industries as well as government laboratories and social service agencies.

The market analysis indicates that the deployment of digital imaging technologies at leading U.S. medical institutions and free-standing diagnostic imaging centers will be subject to:

- Limited demand for new X-ray installations. Most equipment sales will be replacement driven.
- High equipment cost of new digital mammography and radiography systems.
- Financial health of the healthcare industry, subject to Medicare and private insurance reimbursement patterns.

Given these market dynamics, the ATP-funded LCM process is expected to have a substantial impact on lowering equipment costs, facilitating accelerated deployment of digital systems and making the benefits of these systems available to patient populations that would not otherwise have access to those benefits.

6. Economic Analysis

Digital mammography and chest radiography are advanced technologies that provide medical benefits to patients, as well as economic benefits to patients and healthcare providers.

However, only some healthcare facilities and only some patients will have access to these benefits. The first cost of digital imaging equipment is substantially higher than the cost of conventional film-based X-ray units, and high cost is expected to limit the number of digital imaging systems placed in service.

The ATP-funded low-cost process will reduce the equipment cost of digital imaging, facilitate the deployment of additional units, and make it possible for many more Americans to participate in the above benefits. Figure 4 summarizes the flow of these benefits and distinguishes those that can be quantified from those where only a qualitative analysis is feasible.

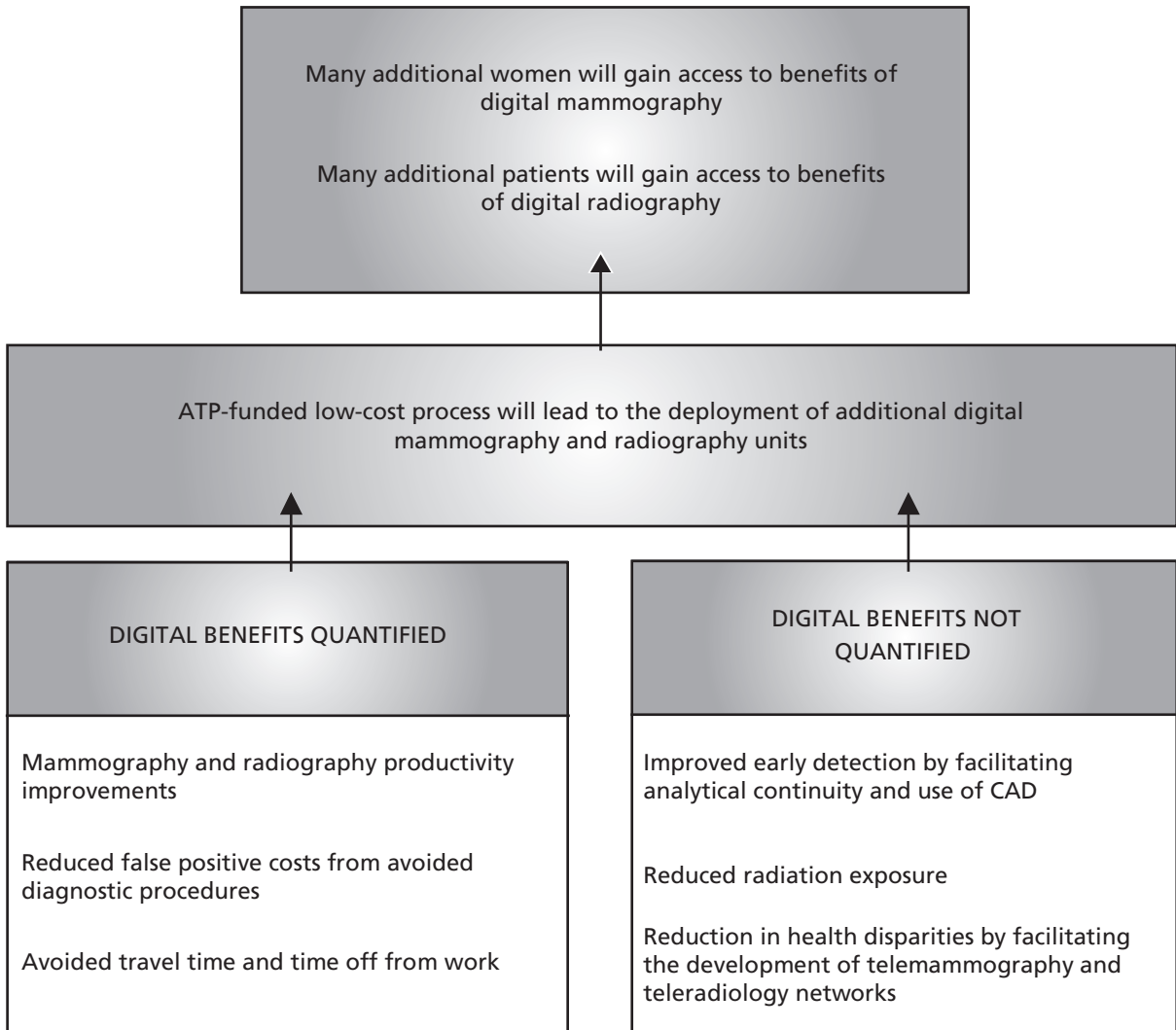
METHODOLOGICAL APPROACH

The chief mechanism for delivering the healthcare and economic benefits of the LCM process is expected to be additional sales of Senographe 2000D and Revolution XR/d units beyond the unit sales that would occur without the LCM process.

Discussions with ATP's industry partners, a review of independent market estimates, and broad-ranging discussions with healthcare industry participants, including healthcare and imaging center administrators, provided the basis for estimating additional unit sales that would occur following deployment of the ATP-funded LCM process. The following assumptions were developed following these discussions:

- **Base Case:** A projected year-to-year increase in sales 50 percent above the counterfactual case. This is equivalent to a six months' increase in sales, over the counterfactual case.

Figure 4. Flow of Benefits from the ATP-Funded Low-Cost Process



- **Step-Out Scenario:** A projected year-to-year increase in sales 7/12 higher than for the counterfactual case. This is equivalent to an increase by seven months over the counterfactual case, or by one month over the base case.

Table 5 shows the projected number of additional units expected to be deployed as a result of the ATP-funded low-cost process based on these assumptions. Columns A and D present the counterfactual case, i.e., unit sales without the impact of the ATP-funded LCM process. Columns B and E present base-case estimates of additional unit sales associated with LCM cost reductions, and columns C and F present step-out scenario estimates of additional unit sales.

Additional sales will be contingent on GE Medical Systems (GEMS) completing the remaining technical development tasks, implementing the low-cost process, and

Table 5. Projected Unit Sales Enabled by ATP-Funded Low-Cost Process

| Years | Senographe 2000D Units Sales | | | Revolution XR/d Unit Sales | | |
|-------|--|--|---|--|--|---|
| | (A) Counterfactual Case Without ATP-Funded Low-Cost Process (Unit Sales) | (B) Base-Case Scenario (Additional Unit Sales) | (C) Step-Out Scenario (Additional Unit Sales) | (D) Counterfactual Case Without ATP-Funded Low-Cost Process (Unit Sales) | (E) Base-Case Scenario (Additional Unit Sales) | (F) Step-Out Scenario (Additional Unit Sales) |
| 2003 | 57 | | | 92 | | |
| 2004 | 67 | | | 111 | | |
| 2005 | 89 | 36 | 42 | 150 | 35 | 41 |
| 2006 | 160 | 74 | 86 | 219 | 63 | 73 |
| 2007 | 308 | 15 | 18 | 345 | 17 | 20 |
| 2008 | 339 | 4 | 4 | 379 | 19 | 22 |
| 2009 | 346 | 9 | 10 | 417 | 21 | 24 |
| 2010 | 363 | 3 | 4 | 459 | 21 | 24 |
| 2011 | 370 | 0 | 0 | 500 | 0 | 0 |
| 2012 | 370 | 9 | 11 | 500 | 0 | 0 |
| 2013 | 388 | 10 | 11 | 500 | 0 | 0 |
| 2014 | 407 | 0 | 0 | 500 | 0 | 0 |

Source: 2003–2007 unit sales in columns A and D are from Frost and Sullivan (2001, 2002). Beyond 2007, unit sales are independently extrapolated.

instituting price reductions to reflect decreased detector costs. Given intense competitive pressures in the medical equipment industry, there is a strong probability that GEMS will implement the low-cost process during the next two years, but not a 100 percent certainty. As a result, a 70 percent probability factor is used to adjust the expected value of combined cash flow benefits. The 70 percent probability estimate is based on three component factors expected to drive a potential business decision to implement the LCM process:

- Technical feasibility of the low-cost process.
- Growing market demand for digital imaging.
- Increasing competitive pressures to reduce component costs.

ATP AND INDUSTRIAL PARTNER INVESTMENTS

During the 1996–2000 period, ATP invested \$1.575 million, and its industry partners, GE Global Research and PerkinElmer, invested \$1.863 million in the LCM process. The ATP investment was approximately equivalent to the project’s direct costs. For purposes of the cash flow analyses, the ATP investment was normalized to 2002 dollars (using an average annual inflation rate of three percent) and assumed to occur in 1998, the midpoint of the four-year investment period.

The normalized ATP investment, expressed in 2002 dollars, was \$1.773 million, and the normalized industry investment was \$2.097 million. Before the low-cost process can be deployed for high volume detector fabrication, some additional GE and PKI investment will be required to complete the remaining technical tasks.

BASE-CASE ECONOMIC ANALYSIS

Additional unit sales of the Senographe 2000D and Revolution XR/d associated with the prospective implementation of the low-cost process will deliver substantial benefits to many Americans who would not otherwise be able to enjoy these benefits. Of these benefits, only the following can be meaningfully quantified at this time:

- Higher productivity and reduced operating costs for healthcare providers.
- Avoided diagnostic costs from fewer mammography false-positive results.
- Avoided patient time and travel expenses resulting from fewer mammography false-positive results and fewer call backs for retakes.

Table 6 presents the estimated cash flow impact for the base case of these quantifiable benefits to healthcare providers and patients that will result from additional unit sales following deployment of the ATP-funded low-cost process. The cash flow estimates reflect the following assumptions:

Senographe Productivity Assumption: GE’s product financial pro formas specify that the Senographe 2000D has an operating capacity of 9,600 procedures per year, twice the procedure volume for one conventional mammography unit (General Electric, 2002).

GE’s Senographe 2000D financial pro formas further specify a retake rate (due to inadequate initial image quality) of 0.5 percent for the Senographe 2000D as compared to 2.5 percent for conventional units. While equipment costs for the Senographe 2000D are 2.5 times the cost of conventional units, operating costs for personnel and material are only 44 percent of the operating costs for conventional units. Combining these productivity/cost differences, the net cash flow advantage from deploying one additional Senographe 2000D unit instead of two conventional units is indicated below. At year one, the annual cash flow variance is \$116,000 per unit. Beyond five years, the annual cash flow variance stabilizes at \$169,000 per unit.

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|--------|--------|--------|--------|--------|
| Net Cash Flow Variance Per Unit (\$000) | 116 | 128 | 140 | 154 | 169 |

Table 6. Cash Flows from Additional Unit Sales, Assuming Implementation of ATP-Funded Low-Cost Process in 2004 (\$ Millions, in 2002 Dollars): Base Case

| | From Improved Productivity of Senographe 2000D | From Avoided False Positives with Senographe 2000D | From Avoided Time Off and Travel Expenses with Senographe 2000D | From Improved Productivity of Revolution XR/d | Summation of Cash Flow Benefits | Expected Value of Cash Flows |
|--|--|--|---|---|---------------------------------|------------------------------|
| 1996 | | | | | | |
| 1997 | | | | | | |
| 1998 | Base Year of ATP Investment (at Midpoint of Investment Period) | | | | | -1.773 |
| 1999 | | | | | | |
| 2000 | | | | | | |
| 2001 | | | | | | |
| 2002 | | | | | | |
| 2003 | | | | | | |
| 2004 | | | | | | |
| 2005 | 4.176 | 2.281 | 0.540 | 5.215 | 12.212 | 8.548 |
| 2006 | 14.080 | 6.969 | 1.650 | 19.404 | 42.104 | 29.473 |
| 2007 | 17.500 | 7.920 | 1.875 | 28.865 | 56.160 | 39.312 |
| 2008 | 19.866 | 8.173 | 1.935 | 41.808 | 71.783 | 50.248 |
| 2009 | 23.153 | 8.680 | 2.055 | 51.054 | 84.943 | 59.460 |
| 2010 | 23.829 | 8.934 | 2.115 | 59.055 | 93.933 | 65.753 |
| 2011 | 23.660 | 8.870 | 2.100 | 66.675 | 101.306 | 70.914 |
| 2012 | 25.350 | 9.504 | 2.250 | 66.675 | 103.779 | 72.646 |
| 2013 | 26.871 | 10.074 | 2.385 | 66.675 | 106.006 | 74.204 |
| 2014 | 26.871 | 10.074 | 2.385 | 66.675 | 106.006 | 74.204 |
| Net Present Value of ATP Investment (7% Discount Rate) | | | | | 219 | |
| Internal Rate of Return on ATP Investment | | | | | 69% | |
| Benefit-to-Cost Ratio for ATP Investment | | | | | 125:1 | |

Note: Appendix B provides a more detailed analysis.

Assumption About Fewer False Positive Results: Senographe 2000D systems provide fewer false positive results and therefore require fewer patient recalls than conventional systems, by approximately 20 percent (Lewin et al., 2000). Based on 9,600 screening procedures per year, 10 percent, or 960 women, can expect to receive false-positive results from a conventional mammography unit (FDA, 1997). The Senographe 2000D reduces this number by 20 percent, or by 192 women, who will be able to avoid the medical risks, expenses, and anxiety associated with unnecessary follow-up procedures. The average medical cost of unnecessary procedures was conservatively estimated at \$330 per woman, and the deployment of each additional unit is then associated with \$63,360 of medical savings on behalf of 192 women.

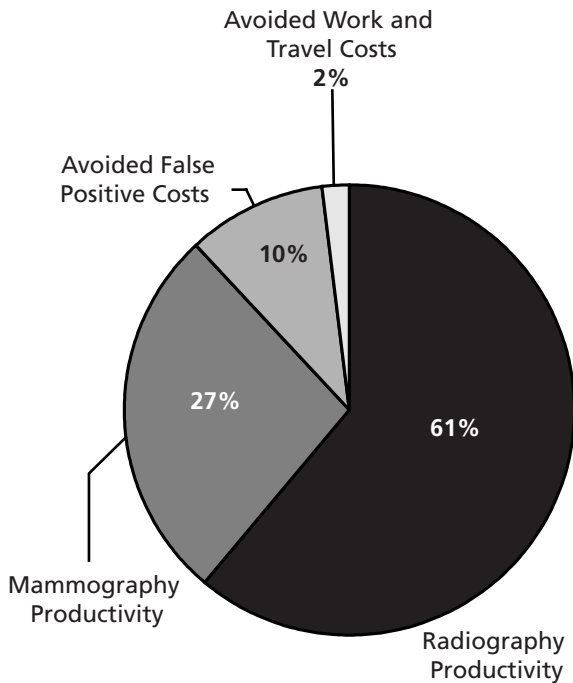
Assumptions About Avoided Time Loss and Travel Expenses: Patient recalls and retakes involve loss of work time and travel costs. For every Senographe unit in use, 192 women avoid being recalled for unnecessary diagnostic procedures. In addition, 2 percent (of the 9,600 women screened), or 193 women, avoid being called back for retakes due to poor image quality. In total, 385 women will avoid unnecessary loss of work time and travel expenses. Assuming that 70 percent of 385 women work full time, earn \$16.66 per hour (U.S. Department of Labor, 2001), and lose 3 hours of work to comply with recall and retake notices, and that travel expenses average \$4.00 per incident, annual avoided expenses for 385 women are estimated at \$15,003. Cash flow benefits from avoided time loss and travel expenses are calculated by multiplying the \$15,003 savings by the cumulative number of additional Senographe units that are deployed as a result of the low-cost process.

Revolution XR/d Productivity Assumption: GE's product financial pro formas specify that the system capacity of the Revolution XR/d is 24,000 X-ray procedures per year, twice the annual volume of a screen film unit (General Electric, 2002a). The retake rate (due to inadequate initial image quality) for the Revolution XR/d is specified at 0.5 percent, as compared to 4 percent for screen film units. While Revolution XR/d equipment costs were 1.7 times the cost of conventional units, operating costs for personnel and material are only 23 percent. The net cash flow advantage of deploying one additional Revolution XR/d unit instead of two conventional units is indicated below. Beyond five years, the annual cash flow variance stabilizes at \$381,000 per unit.

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|--------|--------|--------|--------|--------|
| Net Cash Flow Variance Per Unit (\$000) | 149 | 198 | 251 | 312 | 381 |

Public returns on ATP's investment in the low-cost process for the base case are summarized at the bottom of Table 6. The deployment of additional Senographe 2000D and Revolution XR/d units resulting from the implementation of the ATP-funded low-cost process is associated with a net present value of \$219 million, an internal rate of return (public return) of 69 percent, and a benefit cost ratio of 125:1. These measures of return reflect benefits to the healthcare industry and to patients resulting from the ATP investment.

Figure 5 Net Present Value Component Analysis: Base Case



Given clear GE representations that the high-risk LCM process would not have been undertaken without ATP funding, the analysis summarized in Table 6 attributes 100 percent of net cash flows to the ATP investment. To allow for uncertainties in predicting the future, net cash flows were adjusted by a 70 percent probability factor (based on technical and commercial discussions with GE, PKI, and other industry participants) as to the future deployment of the low-cost process (see Methodological Approach above). This adjustment is applied in the last column of Table 6.

A component analysis of the net present value (Figure 5) points to the substantial impact of

productivity gains from Revolution XR/d and Senographe 2000D technologies, accounting for 61 and 27 percent of net present value, respectively. Avoided treatment costs from reduced false-positive results account for 10 percent of the net present value, and avoided patient time and travel costs account for less than two percent.

STEP-OUT SCENARIO ECONOMIC ANALYSIS

Table 7 presents the estimated cash flow impact for the step-out scenario of quantifiable benefits resulting from additional unit sales and the ATP-funded low-cost process. Cash flow estimates reflect the following assumptions.

Senographe Productivity Assumptions: For the step-out scenario, the GE Senographe 2000D operating capacity was specified at 10,560 procedures per year, a 10 percent increase in the 9,600 procedures per year used in the base case and by the Senographe 2000D financial pro formas. The net cash flow productivity advantage of deploying one additional Senographe unit instead of two conventional units is indicated below. Beyond five years, the annual cash flow variance stabilizes at \$275,000.

Table 7. Cash Flows from Additional Unit Sales, Assuming Implementation of ATP-Funded Low-Cost Process in 2004 (\$ Millions, in 2002 Dollars): Step-Out Scenario

| | From Improved Productivity of Senographe 2000D | From Avoided False Positives with Senographe 2000D | From Avoided Time Off and Travel Expenses with Senographe 2000D | From Improved Productivity of Revolution XR/d | Summation of Cash Flow Benefits | Expected Value of Cash Flows |
|--|--|--|---|---|---------------------------------|------------------------------|
| 1996 | | | | | | |
| 1997 | | | | | | |
| 1998 | Base Year of ATP Investment (at Midpoint of Investment Period) | | | | | -1.773 |
| 1999 | | | | | | |
| 2000 | | | | | | |
| 2001 | | | | | | |
| 2002 | | | | | | |
| 2003 | | | | | | |
| 2004 | | | | | | |
| 2005 | 8.526 | 3.190 | 0.977 | 7.626 | 20.319 | 14.223 |
| 2006 | 28.032 | 9.723 | 2.977 | 27.132 | 67.864 | 47.505 |
| 2007 | 34.456 | 11.090 | 3.396 | 39.664 | 88.606 | 62.024 |
| 2008 | 38.250 | 11.394 | 3.489 | 56.316 | 109.449 | 76.614 |
| 2009 | 44.000 | 12.154 | 3.721 | 78.480 | 138.355 | 96.848 |
| 2010 | 45.100 | 12.457 | 3.814 | 88.944 | 150.316 | 105.221 |
| 2011 | 45.100 | 12.457 | 3.814 | 88.944 | 150.316 | 105.221 |
| 2012 | 48.125 | 13.293 | 4.070 | 88.944 | 154.432 | 108.102 |
| 2013 | 51.150 | 14.128 | 4.326 | 88.944 | 158.548 | 110.984 |
| 2014 | 51.150 | 14.129 | 4.326 | 88.944 | 158.548 | 110.984 |
| Net Present Value of ATP Investment (7% Discount Rate) | | | | | 339 | |
| Internal Rate of Return on ATP Investment | | | | | 77% | |
| Benefit-to-Cost Ratio for ATP Investment | | | | | 193:1 | |

Note: Appendix C provides a more detailed analysis.

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|--------|--------|--------|--------|--------|
| Net Cash Flow Variance Per Unit (\$000) | 203 | 219 | 236 | 255 | 275 |

Assumptions About Fewer False-Positive Results: Assuming 10,560 screening procedures per unit each year, 1,056 women can be expected to receive false-positive results with conventional equipment. The Senographe 2000D reduces that number by 20 percent, or 211 women. Further assuming for the step-out scenario that the per capita medical cost of unnecessary follow-up procedures increases by 9 percent over the base case to \$360, the deployment of every additional Senographe unit deployed as a

result of the ATP-funded LCM process can be associated with \$75,960 of medical savings on behalf of 211 women.

Assumptions About Avoided Time Loss and Travel Expenses: For every Senographe 2000D unit, in addition to the 211 women who will avoid being recalled for unnecessary diagnostic procedures because of false-positive results, 2 percent (of the 10,560 women screened), or 212 women, will avoid being called back for retakes due to poor image quality. In total, 423 women will avoid unnecessary loss of time from work and travel expenses. In the step-out scenario, travel expenses per each incident were increased to \$5.00 from the \$4.00 assumed in the base case.

Revolution XR/d Productivity Assumption: Annual system capacity was assumed to be 5 percent higher than for the base case, or 25,200 procedures per year. The net cash flow advantage of deploying one additional Revolution unit is indicated below for the first five years of operation. Beyond five years, the annual cash flow variance stabilizes at \$436,000 per unit.

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|--------|--------|--------|--------|--------|
| Net Cash Flow Variance Per Unit (\$000) | 186 | 238 | 296 | 361 | 436 |

Public returns on ATP’s investment in the high-risk, low-cost process for the step-out scenario are summarized at the bottom of Table 7. The deployment of additional Senographe 2000D and Revolution XR/d units resulting from the implementation of the ATP-funded low-cost process is associated with a net present value of \$339 million, an internal rate of return (public return) of 77 percent, and a benefit cost ratio of 193:1. Again, these measures of return reflect benefits to healthcare industry users and to patients resulting from the ATP investment.

ESTIMATED PRIVATE BENEFITS TO ATP INDUSTRIAL PARTNERS

Continued motivation to commercialize the ATP-funded technology on the part of General Electric Company and PerkinElmer is a necessary precondition for completing the remaining technical tasks and for implementing the low-cost process. Only then will the general public come to enjoy the associated medical and economic benefits from improved productivity, reduced false-positive rates, and avoided patient expenses.

Table 8. Estimated Revenues to ATP Industry Partners from Future Implementation of ATP-Funded Low-Cost Process (\$ Million, in 2002 Dollars)

| | Additional Revenues from LCM Process | |
|------|--------------------------------------|-------------------|
| | Base-Case Scenario | Step-Out Scenario |
| 2000 | | |
| 2001 | | |
| 2002 | | |
| 2003 | | |
| 2004 | | |
| 2005 | 39.14 | 45.66 |
| 2006 | 73.61 | 85.87 |
| 2007 | 12.85 | 14.99 |
| 2008 | 14.70 | 17.15 |
| 2009 | 10.35 | 12.07 |
| 2010 | 8.95 | 10.44 |
| 2011 | 8.12 | 9.47 |
| 2012 | 12.05 | 14.05 |
| 2013 | 12.64 | 14.74 |
| 2014 | 0.00 | 0.00 |

Source: Data from Table 5, expanded to include European sales and combined with informed assumptions about GE market shares.

To characterize the motivation of ATP’s industrial partners to implement the low-cost process, we estimated prospective worldwide sales revenues from additional Senographe 2000D and Revolution XR/d unit sales, expressed in 2002 dollars. Estimated sales revenues are shown in Table 8. Because GE operating cost projections were not available, future profit contributions from Senographe 2000D and Revolution XR/d units could not be estimated.

The magnitude of benefits, as reflected in additional revenues for GE and PKI from the low-cost process, appears to be consistent with ongoing motivation of the ATP industry partners to complete remaining technical tasks and to implement the ATP-funded low-cost process.

QUALITATIVE BENEFITS

In addition to the benefits quantified, many important qualitative benefits will be experienced by Americans who gain access to Senographe 2000D and Revolution XR/d equipment through additional units sold as a result of the ATP-funded LCM process technology.

Early Detection Benefits Associated with Analytical Continuity and Computer-Aided Detection

According to a 1997 FDA Report, breast cancers detected early (for example, through screening mammography) tend to be at significantly less advanced stages than cancers diagnosed for unscreened women. As Table 9 indicates, 73 percent of screened populations were diagnosed with in situ or stage 1 cancers, while only 54 percent of unscreened populations had similar outcomes, showing a substantial early detection advantage from periodic screening. Differential treatment costs for in situ and early stage breast cancers versus later stage cancers also point to significant economic benefits from early detection to be facilitated by Senographe 2000D technology and the ATP-funded low-cost process. “The average cost of treating early stage breast cancer is \$11,000 and for late-stage lesions, \$140,000” (Evans, 1999).

Table 9. Percentage of Cancer Victims Diagnosed at Various Stages, Screened Versus Unscreened Populations

| | In Situ | Stage 1 | Stage 2 | Stage 3 | Stage 4 | |
|---------------------------|--|---------|--|---------|---------|------|
| Screened Populations | 17% | 56% | 20% | 3% | 4% | 100% |
| Unscreened Populations | 15% | 39% | 34% | 8% | 4% | 100% |
| Early Detection Advantage | 73% screened versus 54% unscreened women | | 27% screened versus 46% unscreened women | | | |

Source: U.S. Food and Drug Administration (1997).

Screening with the Senographe 2000D, instead of conventional X-ray units, can be expected to facilitate early detection of breast cancer by eliminating the loss of prior mammograms and by feeding digital data to CAD systems efficiently.

Eliminating the loss of mammograms ensures the availability of prior mammograms for continuity of interpretation. Continuity is considered to be an important analytical factor for accurate interpretation and early detection.

The Senographe 2000D generates direct digital images for CAD and facilitates the effective utilization of CAD systems. Studies indicate that CAD systems may improve breast cancer early detection rates by 20 percent compared to conventional mammography without CAD (*Oncology News*, 2001). While film mammograms can be digitized and fed into CAD systems, Senographe units will provide more efficient and timely digital input to optimize CAD system effectiveness.

Radiation Exposure Reduction

Conventional X-ray units generally use a higher radiation dosage than digital mammography units to obtain an adequate image for dense breast tissue. Digital mammography is a more effective screening modality for dense breast tissue at lower dosage levels. The 20 percent reduction in false-positive results and associated avoidance of diagnostic procedures as well as the 80 percent reduction in retakes for unacceptable image quality further contribute to the reduction in radiation exposure from the use of the Senographe 2000D rather than conventional equipment.

Counteract Growing Shortage of Radiologists

Increased productivity and throughput from Senographe 2000D and Revolution XR/d will counteract the growing shortage of radiologists and mammography specialists in the United States. Increased throughput will also reduce patient waiting times, and potentially encourage more regular screening.

Facilitating Telemammography and Teleradiology

U.S. health disparities by income, race, and ethnicity have been well documented (NIH, 2000). More than 20 million women lack adequate access to high quality screening mammography services and probably twice that number of people (men,

women, and children) lack adequate access to high-quality chest, throat, and other radiography services. Lack of adequate access results in underutilization of screening and other X-ray modalities and may be related, at least in part, to the higher percentages of advanced breast cancers among some minority populations (Lawson et al., 2000).

Telemammography and teleradiology represent evolving clusters of advanced network technologies, offering the promise of higher quality screening and imaging services for currently underserved populations.

Many diverse factors will have to line up to complete the development of viable telemammography and teleradiology networks without reliance on government subsidies. Such factors include additional technology advances, regulatory changes, novel institutional relationships, cost containment measures, market, and financial issues (Shtern, 1999). One important technical and economic requirement is direct digital image acquisition through inexpensive full-field digital imaging systems. The ATP-funded low-cost process addresses that requirement directly and could significantly contribute to telemammography and teleradiology reaching their full potential and delivering improved and cost-effective medical services to currently underserved populations.

Cardiac Imaging

Conventional cardiac imaging units are priced around \$1 million, and the incremental costs of digital over conventional technology are only 10 to 20 percent. Because digital detector components represent a smaller part of the overall system price of digital cardiac systems, detector cost reductions are less likely to impact digital unit sales than is the case for mammography or radiography systems.

Nevertheless, digital detector cost improvements may have some beneficial impact. When this occurs, the ATP-funded low-cost process will be instrumental in delivering the spectrum of benefits of digital technology to cardiac patients who may not have otherwise had access to these benefits, including lower radiation dosage as well as improved fluoroscopic performance in imaging the higher heart beat rates of infants.

Knowledge Diffusion

As part of the GEGR/PKI joint-venture structure, proprietary GE detector technology, including the ATP-funded low-cost process, was transferred to PKI and may, in the future, be further transferred to sub-licensees for the potential development of non-medical imaging applications, such as in industrial machine vision, nondestructive testing, and cargo inspection for airport security. Additional knowledge diffusion may result from two patents issued to General Electric Company: US5838054 for Contact Pads for Radiation Imagers, US5648296 for Post Fabrication Repair Method for Thin Film Imager Device, and a patent filed for Gated Diodes for Reduced Mask Imager Process. These patents and patent filings resulted from work on the ATP-funded low-cost process technology.

7. Conclusions

In 1995, the ATP funded a joint-venture project involving General Electric Global Research (formerly General Electric Corporate Research & Development) and PerkinElmer (formerly EG&G Reticon) to develop dramatic improvements in manufacturing technology for fabricating thin-film amorphous silicon detector panels for medical and industrial imaging systems.

In 2000, the joint-venture project was successfully completed and process improvements resulting from this project have laid the groundwork for replacing an expensive 11-mask process with a 7-mask low-cost manufacturing process. Given competitive market pressures, it is expected that General Electric Company and PerkinElmer, Inc. will complete the remaining technical development tasks and implement the low-cost process by 2004. Implementation is expected to result in 25 percent cost savings.

For medical imaging applications, the low-cost process will significantly impact the affordability of new digital mammography and digital radiography systems and make the benefits of these innovative technologies more widely available to healthcare facilities and patient populations that would not otherwise have access to these benefits. These benefits include:

- Decreased medical risk to patients and reduced patient anxiety by avoiding unnecessary medical procedures.
- Reduction in patient radiation exposure.
- Improved analytical continuity (from rapid retrieval of prior mammograms and the elimination of lost mammograms)
- Facilitation of the use of CAD software
- Facilitation of regional telemammography and teleradiology networks, expanding access to quality mammography and radiology services by medically underserved rural, ethnic, and economically disadvantaged populations.
- Substantial productivity improvements for healthcare facilities, counteracting the growing shortage of radiologists.
- Reduced record retrieval and record management costs.

Based on primary research and analysis completed during 2001 and early 2002, the case study projects a substantial public return on ATP's investment in the high-risk, low-cost process technology:

- Net present value of ATP investment: \$219 million to \$339 million (base-case versus step-out scenarios in 2002 dollars).
- Internal rate of return (public return) on ATP investment: 69 percent to 77 percent.
- Benefit-to-cost ratio of ATP investment: 125:1 to 193:1.

These measures reflect the benefits to the healthcare industry and to patients resulting from the ATP investment. Benefits and costs to General Electric Company and PerkinElmer, Inc. are not included.

Beyond medical applications, the low-cost process may also reduce thin-film a-Si detector fabrication costs for industrial machine vision, nondestructive testing, and airport cargo inspection applications. These benefits from non-medical applications are associated with greater uncertainty and are expected to occur only in the longer term.

This case study concludes that the new low-cost process technology has made significant progress toward meeting the necessary conditions for commercial implementation. These conditions are:

- Successful completion of the ATP-funded joint-venture project, demonstrating the technical feasibility of the low-cost process.
- Initial sales momentum for Senographe digital mammography units and Revolution digital radiography units, as well as independent market studies pointing to longer-term demand growth.
- Technological advantages that can be translated into business advantages. In the context of increasing competition and downward pricing pressures, the 25 percent cost reduction from the ATP-funded low-cost manufacturing process will be an attractive incentive for industry partners to implement the technology.

Based on the above elements of progress toward commercial implementation, this study concludes that the projected public returns from ATP's investment and the broad-based medical and economic benefits to patient populations and the healthcare industry have a strong probability of being realized.

Research performed for this study leads to the further conclusion that ATP's industry partners would not have developed a high-risk, low-cost process technology without ATP support. As a result, estimated benefits are directly attributable to the ATP investment.

Glossary

| | |
|-----------------------|--|
| ACRIN | American College of Radiology Imaging Network |
| a-Si | Amorphous or non-crystalline silicon semiconductor used in the fabrication of thin film digital detector plates. |
| ATP | Advanced Technology Program |
| CAD | Computer-aided detection involves the use of computers to bring suspicious areas on a mammogram to the radiologist's attention. CAD uses complex algorithms. |
| CCD | Charge-coupled device |
| CsI | Cesium iodide used for digital detector scintillator layer. |
| CT | Computed tomography, in which a thin beam of high energy radiation is used to create a series of breast images taken from different angles that are fed into a computer and combined into a single image. |
| DARPA | Defense Advanced Research Project Agency |
| Detector Panel | Photosensor array deposited on a glass substrate, a scintillator layer, and a sealed protective cover. |
| DIC | Diagnostic Imaging Center |
| DQE | Detective Quantum Efficiency, the measure of the combined effect of noise (random variations of signal) and contrast performance of an imaging system, expressed as a function of object detail. Summary measure of digital imaging system physical performance. |

| | |
|--------------------------|---|
| False Negative | Mammogram fails to detect a present cancer. |
| False Positive | Mammogram is read as abnormal, but cancer is not present. |
| FDA | Food and Drug Administration |
| FET | Field-effect transistor that acts as a switch to convey electrical charges from the diode array to external read-out electronics. |
| FFDM | Full-field digital mammography uses detector plates large enough to capture entire breast in a single image. |
| Film Digitization | Video camera or laser scanner to digitize conventional X-ray film. |
| Fluoroscopy | Recording real-time video image of the beating heart. |
| GEGR | General Electric Global Research (formerly General Electric Corporate Research & Development), the corporate research unit of General Electric Company. |
| GEMS | General Electric Medical Systems unit of General Electric Company |
| ITO | Indium Tin Oxide |
| Large Area | Dimensions of the detector panel's active area of at least 250 cm ² . |
| LCM | Low-cost a-Si manufacturing process funded by ATP. |
| Machine Vision | Digital imaging technology for machine automation. |
| Mammography | Use of X-ray to create a picture of the breast. |
| Masks | Tool for photolithographic pattern formation. |
| Meta-Analysis | Methodology that combines the results of previous studies to arrive at a summary conclusion about a body of research. |
| Metastasize | Spread of cancer. Cancer cells break away from a primary tumor and travel through the blood stream or lymphatic system to other parts of the body. |

| | |
|-------------------------|--|
| MRI | Magnetic resonance imaging creates detailed pictures of areas inside the body without the use of radiation. |
| NDT | Nondestructive Testing |
| PACS | Picture Archiving and Communications System |
| Passivation | Protective oxide film layer in photolithographic pattern formation to protect or passivate junctions. |
| Photodiode | Device that absorbs light and converts it into electrical charges. |
| Photolithography | Technique in the semiconductor industry using ultraviolet light for integrated circuit pattern formation. |
| Pixel | Discreet microelements that collectively constitute a digital image. |
| PKI | PerkinElmer, Inc. |
| PPO | Preferred Provider Organization |
| Radiography | Use of radiology techniques for X-ray imaging and interpretation of the chest and other large anatomical regions. |
| Radiology | Branch of medicine concerned with the use of X-rays in the diagnosis and treatment of disease. |
| Revolution XR/d | FDA-approved GE digital radiography system. |
| Scintillator | Device for converting X-ray energy to light. |
| Screening | Checking for disease when there are no symptoms. |
| Selenium | Semiconductor material (alternative to a-Si) that can operate without a scintillator, absorbing X-rays directly and converting them to electrical charges. |
| Senographe 2000D | FDA-approved GE digital mammography system. |
| SFM | Screen film mammography denoting conventional X-ray film mammography. |

- Tissue Equalization** FFDM processing method that improves visibility of breast tissue out to the skin line.
- Ultrasound** High-frequency sound waves used to produce an image.
- X-ray** High-energy radiation used in low doses to diagnose disease.

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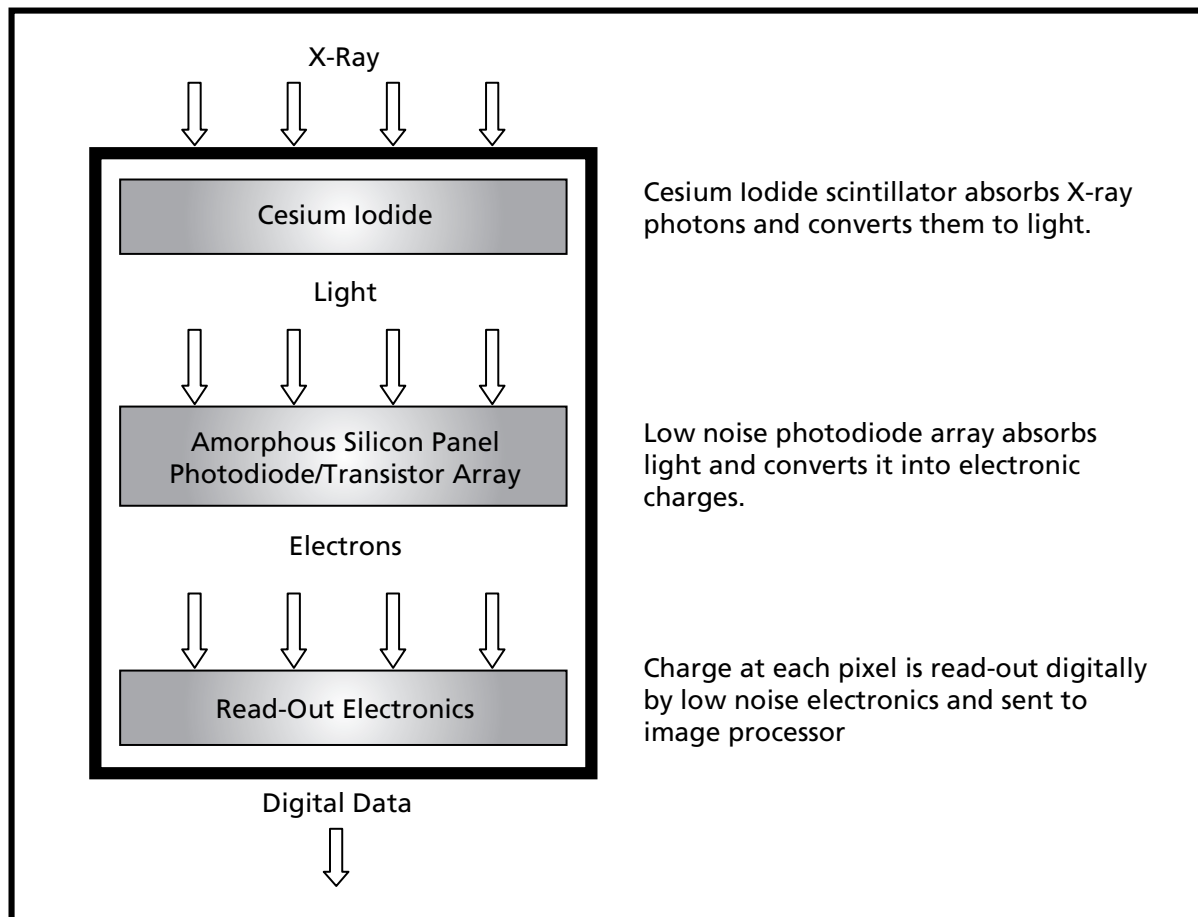
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Appendix A. Low-Cost Manufacturing Technology for the Fabrication of Amorphous Silicon Detectors

Digital detector integrated circuits are fabricated with amorphous silicon (a-Si) semiconductor layers for full-field imaging of large areas. Unlike single crystal silicon, a-Si layers can cover large areas without the need for stitching artifacts associated with lost spaces.

Figure A1. Principles of Amorphous Silicon Detector



As indicated in Figure A1, the a-Si detector consists of a scintillator layer that converts incident X-ray energy to light and a photosensitive array that converts light into electrical charges. The photosensitive array is made up of picture elements (pixels) sized at 100–200 microns. Each pixel contains a photodiode that absorbs light from the scintillator and generates and stores electrical charges and a field-effect transistor (FET) that serves to isolate each pixel element and acts as a switch to convey electrical charges to external electronics for readout. Read-out electronics circuitry converts charges from each pixel to voltage signals for image processing and display. The entire array of more than a million pixels can be read and converted to a composite digital representation in less than a second.

MANUFACTURING PROCESS

Photosensitive panels are fabricated as multiple layers of thin film deposited on a glass substrate. Photolithography is used for pattern formation. As indicated in Figure A2, each layer is built up via successive process steps:

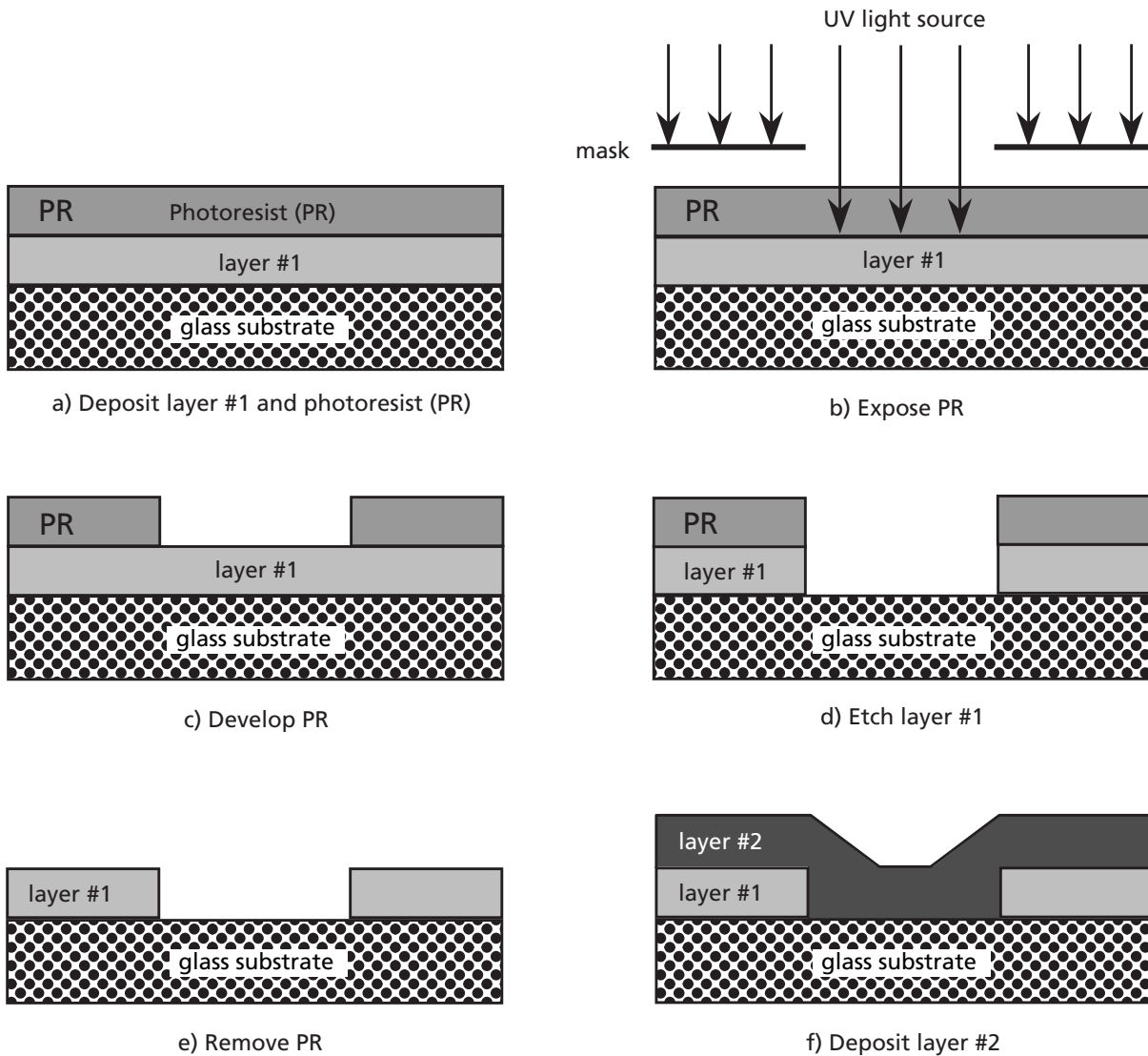
- Deposition of a-Si thin film and insulating and conducting layers and coating with photoresist.
- Exposure to UV or ultraviolet light around masks.
- Development or removal of photoresist impacted by UV.
- Etching to remove layers around masks.
- Removal of the remaining photoresist.
- Deposition of the next layer.

The original GE process, prior to ATP funding, uses approximately 300 process steps and 11-mask photolithography to fabricate large area a-Si panels for medical applications. It starts with the deposition of the FET layer, followed by the deposition of the diode layer, and is completed with the deposition of the scintillator layer.

- Mask 1: Process begins with metal deposition for FET gates and scan lines.
- Mask 2: a-Si layer is deposited by plasma enhanced chemical vapor deposition.
- Mask 3: FET openings (vias) are cut through dielectric layer.
- Mask 4: Metal layers are deposited, patterned, and etched.
- Mask 5: Protective or passivation layer is deposited and patterned.
- Masks 6 and 7: a-Si layers are deposited and diode island is masked and etched.
- Mask 8: Diode passivant is deposited.
- Mask 9: Insulating layer applied to provide isolation from underlying structures.
- Mask 10: Common biasing contacts are deposited and patterned.
- Mask 11: Third passivating layer is deposited and removed in contact region.

The final step during baseline fabrication is a vapor phase deposition of cesium iodide (CsI) scintillator layer to convert X-ray energy to light. CsI is deposited to form microscopic columns or needles with their long axis normal to the substrate

Figure A2. Thin Film Processing: Depositing, Patterning, and Etching of Multiple Layers



resulting in anisotropic properties (highly scattering to light propagating parallel to the substrate and transmissive to light normal to the substrate). CsI columns form miniature light traps that conduct light to the underlying a-Si imager with a minimum of lateral spreading.

The ATP-funded LCM process uses a different design than the baseline process. First, there is a reversal in process order whereby the deposition of the diode island precedes the deposition of the FET. Second, several fabrication steps, originally kept separate to optimize different aspects of device performance, are combined into dual or multiuse layers.

- Mask 1: Process begins with metal deposition for FET gates and scan lines.
- Mask 2: Diode fabrication begins with deposition of a-Si and indium tin oxide (ITO) layers.
- Mask 3: a-Si diode island is masked and etched.
- Mask 4: FET a-Si island is deposited, patterned, and the silicon layers are etched.
- Mask 5: Openings (vias) are cut to the bottom electrode.
- Mask 6: Metal layers are deposited, patterned, and etched.
- Mask 7: Protective barrier is deposited and removed in the contact regions.

Device fabrication is completed with the deposition of a CsI scintillator layer, using the identical process for baseline fabrication.

ACCOMPLISHMENTS OF ATP-FUNDED PROJECT

The ATP-funded process innovation resulted in fewer mask steps (seven versus eleven) and fewer total process steps (200 versus 300). This was accomplished through interleaved fabrication of the following dual or multiuse layers:

- Gate metal layer for scan line, FET gate, and bottom contact.
- FET dielectric layer for FET gate, diode sidewall passivation, and common electrode insulation.
- Barrier dielectric layer for FET sidewall passivation and protection barrier.
- ITO layer for diode and contact pads to drive electronics.

Additional innovations included:

- Elimination of labor intensive test and repair steps for fabrication throughput advantage and improved data line repair capability intrinsic in device structure.
- Electronic noise reduction in data lines without additional process complexity.

The following technical accomplishments contributed to realizing the above process innovations:

- Reaching an acceptable compromise in FET and diode deposition temperatures.
- Identifying gate metals with acceptable sidewall slope after the etch.
- Optimizing FET island etch for selectivity to gate dielectric removal.
- Contact finger design for electronic bonding.

COST REDUCTION FROM LOW-COST PROCESS

The defect-free yield from the LCM process is equivalent to the original GE process prior to ATP funding. However, the production yield from LCM will be higher as fewer process step and lower mask count reduce processing time and cost. An equipment utilization model (see Table A1) was used to estimate LCM cost reduction relative to the original process. The model simulated six equipment clusters and

verified that reduction in mask count very closely scales with reduced process cost at about 25 to 30 percent.

As an additional advantage from the ATP-funded LCM process, reduced processing times on specific equipment clusters are expected to eliminate four of six future bottlenecked processes. Removing production bottlenecks from the fabrication process will:

- Eliminate or delay need for capacity expansion (\$10 million avoided cost).
- Eliminate or delay physical disruptions associated with capacity expansion.

Table A1. Projected Equipment Utilization for a-Si Detector Fabrication

| Equipment Cluster | Reduced Processing Time with LCM | Process Bottlenecks | |
|--|----------------------------------|---------------------|-------------|
| | | Original Process | LCM Process |
| Lithography: UV Exposure and Development | 27% | X | X |
| Microscope Inspection | 33% | X | |
| Defect Tester To Detect "Shorts and Opens" | 52% | X | |
| Reactive Dry Etch/Plasma Etch | 13% | X | X |
| PECVD—Plasma Chemical Vapor Deposition | 45% | X | |
| E-Tester | 40% | | |

REMAINING TECHNICAL ISSUES

While the LCM process has been demonstrated as technically feasible, it is still considered developmental and “all risks have not been fully retired” (Giambattista 2001). The following areas require additional work:

- Particle contamination can limit yield impact of mask count reductions.
- Gate metal etch profile for the bimetallic gate structure is difficult to optimize and control.
- Too much light hitting the FET can causes leakage in the data lines. There is a need to install a light block to protect the FET.

Order of magnitude resource requirements to resolve the remaining technical issues were estimated at several FTE’s (full time equivalent positions) of engineering effort and requiring access to some production capacity to conduct engineering runs for a period of up to 24 months.

Appendix B. Base-Case Calculations

Table B1. Projected Additional Senographe 2000D Unit Sales: Base Case

| | Without ATP-Funded LCM Process: Counterfactual Case | | | With LCM Process | |
|------|---|-------------------------------------|-----------------------------------|--|--|
| | U.S. Full-Field Digital Mammography Unit Sales | General Electric Market Share | Senographe 2000D Unit Sales | Number of Additional Senographe 2000D Units | Cumulative Number of Additional Senographe 2000D Units |
| 1996 | | | | | |
| 1997 | | | | | |
| 1998 | | | | | |
| 1999 | | | | | |
| 2000 | | | | | |
| 2001 | 52 | 100% | 52 | | |
| 2002 | 57 | 100% | 57 | | |
| 2003 | 63 | 90% | 57 | | |
| 2004 | 74 | 90% | 67 | | |
| 2005 | 111 | 80% | 89 | 36 | 36 |
| 2006 | 200 | 80% | 160 | 74 | 110 |
| 2007 | 440 | 70% | 308 | 15 | 125 |
| 2008 | 484 | 70% | 339 | 4 | 129 |
| 2009 | 532 | 65% | 346 | 9 | 137 |
| 2010 | 559 | 65% | 363 | 3 | 141 |
| 2011 | 587 | 63% | 370 | 0 | 140 |
| 2012 | 616 | 60% | 370 | 9 | 150 |
| 2013 | 647 | 60% | 388 | 10 | 159 |
| 2014 | 679 | 60% | 407 | 0 | 159 |

Table B2. Projected Additional Revolution XR/d Unit Sales: Base Case

| | Without ATP-Funded LCM Process: Counterfactual Case | | | With LCM Process | |
|------|---|-------------------------------------|----------------------------------|---|---|
| | U.S. Full-Field Digital Radiography Unit Sales | General Electric Market Share | Revolution XR/d Unit Sales | Number of Additional Revolution XR/d Units | Cumulative Number of Additional Revolution XR/d Units |
| 1996 | | | | | |
| 1997 | | | | | |
| 1998 | | | | | |
| 1999 | | | | | |
| 2000 | | | | | |
| 2001 | 138 | 50% | 69 | | |
| 2002 | 158 | 50% | 79 | | |
| 2003 | 183 | 50% | 92 | | |
| 2004 | 222 | 50% | 111 | | |
| 2005 | 299 | 50% | 150 | 35 | 35 |
| 2006 | 438 | 50% | 219 | 63 | 98 |
| 2007 | 689 | 50% | 345 | 17 | 115 |
| 2008 | 758 | 50% | 379 | 19 | 134 |
| 2009 | 834 | 50% | 417 | 21 | 155 |
| 2010 | 917 | 50% | 459 | 21 | 175 |
| 2011 | 1000 | 50% | 500 | 0 | 175 |
| 2012 | 1000 | 50% | 500 | 0 | 175 |
| 2013 | 1000 | 50% | 500 | 0 | 175 |
| 2014 | 1000 | 50% | 500 | 0 | 175 |

Table B3. Productivity Gains from Senographe 2000D: Base Case

| | Cumulative Number of Additional Senographe 2000D Units | Net Operating Cash Flow Variance of Digital Unit over Conventional Unit | Cash Flow Benefit from Higher Digital Productivity |
|------|---|--|--|
| 1996 | | | |
| 1997 | | | |
| 1998 | | | |
| 1999 | | | |
| 2000 | | | |
| 2001 | | | |
| 2002 | | | |
| 2003 | | | |
| 2004 | | | |
| 2005 | 36 | 116,000 | 4,176,000 |
| 2006 | 110 | 128,000 | 14,080,000 |
| 2007 | 125 | 140,000 | 17,500,000 |
| 2008 | 129 | 154,000 | 19,866,000 |
| 2009 | 137 | 169,000 | 23,153,000 |
| 2010 | 141 | 169,000 | 23,829,000 |
| 2011 | 140 | 169,000 | 23,660,000 |
| 2012 | 150 | 169,000 | 25,350,000 |
| 2013 | 159 | 169,000 | 26,871,000 |
| 2014 | 159 | 169,000 | 26,871,000 |

Table B4. Productivity Gains from Revolution XR/d Unit Sales: Base Case

| | Cumulative Number of Additional Revolution XR/d Units | Net Operating Cash Flow Variance of Digital Unit over Conventional Unit | Cash Flow Benefit from Higher Productivity |
|------|--|--|---|
| 1996 | | | |
| 1997 | | | |
| 1998 | | | |
| 1999 | | | |
| 2000 | | | |
| 2001 | | | |
| 2002 | | | |
| 2003 | | | |
| 2004 | | | |
| 2005 | 35 | 149,000 | 5,215,000 |
| 2006 | 98 | 198,000 | 19,404,000 |
| 2007 | 115 | 251,000 | 28,865,000 |
| 2008 | 134 | 312,000 | 41,808,000 |
| 2009 | 155 | 381,000 | 51,054,000 |
| 2010 | 175 | 381,000 | 59,055,000 |
| 2011 | 175 | 381,000 | 66,675,000 |
| 2012 | 175 | 381,000 | 66,675,000 |
| 2013 | 175 | 381,000 | 66,675,000 |
| 2014 | 175 | 381,000 | 66,675,000 |

Table B5. Savings from Avoided False Positives with Senographe 2000D: Base Case

| | Cumulative Number of Additional Senographe 2000D Units | Cash Flow Benefits from Avoided False Positives per Senographe 2000D Unit | Total Cash Flow Benefits |
|------|---|--|-------------------------------------|
| 1996 | | | |
| 1997 | | | |
| 1998 | | | |
| 1999 | | | |
| 2000 | | | |
| 2001 | | | |
| 2002 | | | |
| 2003 | | | |
| 2004 | | | |
| 2005 | 36 | 63,360 | 2,280,960 |
| 2006 | 110 | 63,360 | 6,969,600 |
| 2007 | 125 | 63,360 | 7,920,000 |
| 2008 | 129 | 63,360 | 8,173,440 |
| 2009 | 137 | 63,360 | 8,680,320 |
| 2010 | 141 | 63,360 | 8,933,760 |
| 2011 | 140 | 63,360 | 8,870,400 |
| 2012 | 150 | 63,360 | 9,504,000 |
| 2013 | 159 | 63,360 | 10,074,240 |
| 2014 | 159 | 63,360 | 10,074,240 |

Table B6. Patient Savings from Avoided Time Off and Travel with Senographe 2000D: Base Case

| | Cumulative Number of Additional Senographe 2000D Units | Annual Savings from Avoided Time Off per Senographe 2000D Units | Annual Savings from Avoided Travel per Senographe 2000D Units | Cash Flow Benefits |
|------|--|---|---|-----------------------|
| 1996 | | | | |
| 1997 | | | | |
| 1998 | | | | |
| 1999 | | | | |
| 2000 | | | | |
| 2001 | | | | |
| 2002 | | | | |
| 2003 | | | | |
| 2004 | | | | |
| 2005 | 36 | 13,467 | 1,536 | 540,108 |
| 2006 | 110 | 13,467 | 1,536 | 1,650,330 |
| 2007 | 125 | 13,467 | 1,536 | 1,875,375 |
| 2008 | 129 | 13,467 | 1,536 | 1,935,387 |
| 2009 | 137 | 13,467 | 1,536 | 2,055,411 |
| 2010 | 141 | 13,467 | 1,536 | 2,115,423 |
| 2011 | 140 | 13,467 | 1,536 | 2,100,420 |
| 2012 | 150 | 13,467 | 1,536 | 2,250,450 |
| 2013 | 159 | 13,467 | 1,536 | 2,385,477 |
| 2014 | 159 | 13,467 | 1,536 | 2,385,477 |

Table B7. Summary Cash Flow Benefits with Senographe 2000D and Revolution XR/d: Base Case

| | Productivity Gain with Senographe 2000D | Savings from Avoided False Positives with Senographe 2000D | Savings from Avoided Time Off and Travel with Senographe 2000D | Productivity Gain with Revolution XR/d | Expected Value of Total Cash Flow Benefits |
|------|---|--|--|--|--|
| 1996 | | | | | |
| 1997 | | | | | |
| 1998 | | | | | -1,773,000 |
| 1999 | | | | | |
| 2000 | | | | | |
| 2001 | | | | | |
| 2002 | | | | | |
| 2003 | | | | | |
| 2004 | | | | | |
| 2005 | 4,176,000 | 2,280,960 | 540,108 | 5,215,000 | 8,548,448 |
| 2006 | 14,080,000 | 6,969,600 | 1,650,330 | 19,404,000 | 29,472,751 |
| 2007 | 17,500,000 | 7,920,000 | 1,875,375 | 28,865,000 | 39,312,263 |
| 2008 | 19,866,000 | 8,173,440 | 1,935,387 | 41,808,000 | 50,247,979 |
| 2009 | 23,153,000 | 8,680,320 | 2,055,411 | 51,054,000 | 59,459,912 |
| 2010 | 23,829,000 | 8,933,760 | 2,115,423 | 59,055,000 | 65,753,228 |
| 2011 | 23,660,000 | 8,870,400 | 2,100,420 | 66,675,000 | 70,914,074 |
| 2012 | 25,350,000 | 9,504,000 | 2,250,450 | 66,675,000 | 72,645,615 |
| 2013 | 26,871,000 | 10,074,240 | 2,385,477 | 66,675,000 | 74,204,002 |
| 2014 | 26,871,000 | 10,074,240 | 2,385,477 | 66,675,000 | 74,204,002 |
| | Net present value of ATP investment | | | \$219.4 million | |
| | Internal rate of return on ATP investment | | | 69 percent | |
| | Benefit-to-cost ratio for ATP investment | | | 125:1 | |

Appendix C. Step-Out Scenario Calculations

Table C1. Projected Additional Senographe 2000D Unit Sales: Step-Out Scenario

| | Without ATP-Funded LCM Process: Counterfactual Case | | | With LCM Process | |
|------|---|----------------------------------|-----------------------------------|--|--|
| | U.S. Full-Field Digital Mammography Unit Sales | General Electric Market Share | Senographe 2000D Unit Sales | Number of Additional Senographe 2000D Units | Cumulative Number of Additional Senographe 2000D Units |
| 1996 | | | | | |
| 1997 | | | | | |
| 1998 | | | | | |
| 1999 | | | | | |
| 2000 | | | | | |
| 2001 | 52 | 100% | 52 | | |
| 2002 | 57 | 100% | 57 | | |
| 2003 | 63 | 90% | 57 | | |
| 2004 | 74 | 90% | 67 | | |
| 2005 | 111 | 80% | 89 | 42 | 42 |
| 2006 | 200 | 80% | 160 | 86 | 128 |
| 2007 | 440 | 70% | 308 | 18 | 146 |
| 2008 | 484 | 70% | 339 | 4 | 150 |
| 2009 | 532 | 65% | 346 | 10 | 160 |
| 2010 | 559 | 65% | 363 | 4 | 164 |
| 2011 | 587 | 63% | 370 | 0 | 164 |
| 2012 | 616 | 60% | 370 | 11 | 175 |
| 2013 | 647 | 60% | 388 | 11 | 186 |
| 2014 | 679 | 60% | 407 | 0 | 186 |

Table C2. Projected Additional Revolution XR/d Unit Sales: Step-Out Scenario

| | Without ATP-Funded LCM Process: Counterfactual Case | | | With LCM Process | |
|------|---|----------------------------------|-------------------------------|---|---|
| | U.S. Full-Field Digital Radiography Unit Sales | General Electric Market Share | Revolution XR/d Unit Sales | Number of Additional Revolution XR/d Units | Cumulative Number of Additional Revolution XR/d Units |
| 1996 | | | | | |
| 1997 | | | | | |
| 1998 | | | | | |
| 1999 | | | | | |
| 2000 | | | | | |
| 2001 | 138 | 50% | 69 | | |
| 2002 | 158 | 50% | 79 | | |
| 2003 | 183 | 50% | 92 | | |
| 2004 | 222 | 50% | 111 | | |
| 2005 | 299 | 50% | 150 | 41 | 41 |
| 2006 | 438 | 50% | 219 | 73 | 114 |
| 2007 | 689 | 50% | 345 | 20 | 134 |
| 2008 | 758 | 50% | 379 | 22 | 156 |
| 2009 | 834 | 50% | 417 | 24 | 180 |
| 2010 | 917 | 50% | 459 | 24 | 204 |
| 2011 | 1000 | 50% | 500 | 0 | 204 |
| 2012 | 1000 | 50% | 500 | 0 | 204 |
| 2013 | 1000 | 50% | 500 | 0 | 204 |
| 2014 | 1000 | 50% | 500 | 0 | 204 |

Table C3. Productivity Gains from Senographe 2000D Units: Step Out Scenario

| | Cumulative Number of Additional Senographe 2000D Units | Net Operating Cash Flow Variance of Digital Unit over Conventional Unit | Cash Flow Benefit from Higher Digital Productivity |
|------|--|--|--|
| 1996 | | | |
| 1997 | | | |
| 1998 | | | |
| 1999 | | | |
| 2000 | | | |
| 2001 | | | |
| 2002 | | | |
| 2003 | | | |
| 2004 | | | |
| 2005 | 42 | 203,000 | 8,526,000 |
| 2006 | 128 | 219,000 | 28,032,000 |
| 2007 | 146 | 236,000 | 34,456,000 |
| 2008 | 150 | 255,000 | 38,250,000 |
| 2009 | 160 | 275,000 | 44,000,000 |
| 2010 | 164 | 275,000 | 45,100,000 |
| 2011 | 164 | 275,000 | 45,100,000 |
| 2012 | 175 | 275,000 | 48,125,000 |
| 2013 | 186 | 275,000 | 51,150,000 |
| 2014 | 186 | 275,000 | 51,150,000 |

Table C4. Productivity Gains from Revolution XR/d Units: Step-Out Scenario

| | Cumulative Number of Additional Revolution XR/d Units | Net Operating Cash Flow Variance of Digital Unit over Conventional Unit | Cash Flow Benefit from Higher Productivity |
|------|--|--|---|
| 1996 | | | |
| 1997 | | | |
| 1998 | | | |
| 1999 | | | |
| 2000 | | | |
| 2001 | | | |
| 2002 | | | |
| 2003 | | | |
| 2004 | | | |
| 2005 | 41 | 186,000 | 7,626,000 |
| 2006 | 114 | 238,000 | 27,132,000 |
| 2007 | 134 | 296,000 | 39,664,000 |
| 2008 | 156 | 361,000 | 56,316,000 |
| 2009 | 180 | 436,000 | 78,480,000 |
| 2010 | 204 | 436,000 | 88,944,000 |
| 2011 | 204 | 436,000 | 88,944,000 |
| 2012 | 204 | 436,000 | 88,944,000 |
| 2013 | 204 | 436,000 | 88,944,000 |
| 2014 | 204 | 436,000 | 88,944,000 |

Table C5. Savings from Avoided False Positives with Senographe 2000D: Step-Out Scenario

| | Cumulative Number of Additional Senographe 2000D Units | Cash Flow Benefits from Avoided False Positives per Senographe 2000D Unit | Total Cash Flow Benefits |
|------|---|--|-----------------------------|
| 1996 | | | |
| 1997 | | | |
| 1998 | | | |
| 1999 | | | |
| 2000 | | | |
| 2001 | | | |
| 2002 | | | |
| 2003 | | | |
| 2004 | | | |
| 2005 | 42 | 75,960 | 3,190,320 |
| 2006 | 128 | 75,960 | 9,722,880 |
| 2007 | 146 | 75,960 | 11,090,160 |
| 2008 | 150 | 75,960 | 11,394,000 |
| 2009 | 160 | 75,960 | 12,153,600 |
| 2010 | 164 | 75,960 | 12,457,440 |
| 2011 | 164 | 75,960 | 12,457,440 |
| 2012 | 175 | 75,960 | 13,293,000 |
| 2013 | 186 | 75,960 | 14,128,560 |
| 2014 | 186 | 75,960 | 14,128,560 |

Table C6. Patient Savings from Avoided Time Off and Travel with Senographe 2000D: Step-Out Scenario

| | Cumulative Number of Additional Senographe 2000D Units | Annual Savings from Avoided Time Off per Senographe 2000D Unit | Annual Savings from Avoided Travel per Senographe 2000D Unit | Cash Flow Benefits |
|------|--|--|--|--------------------|
| 1996 | | | | |
| 1997 | | | | |
| 1998 | | | | |
| 1999 | | | | |
| 2000 | | | | |
| 2001 | | | | |
| 2002 | | | | |
| 2003 | | | | |
| 2004 | | | | |
| 2005 | 42 | 13,467 | 1,536 | 976,794 |
| 2006 | 128 | 13,467 | 1,536 | 2,976,896 |
| 2007 | 146 | 13,467 | 1,536 | 3,395,522 |
| 2008 | 150 | 13,467 | 1,536 | 3,488,550 |
| 2009 | 160 | 13,467 | 1,536 | 3,721,120 |
| 2010 | 164 | 13,467 | 1,536 | 3,814,148 |
| 2011 | 164 | 13,467 | 1,536 | 3,814,148 |
| 2012 | 175 | 13,467 | 1,536 | 4,069,975 |
| 2013 | 186 | 13,467 | 1,536 | 4,325,802 |
| 2014 | 186 | 13,467 | 1,536 | 4,325,802 |

Table C7. Summary Cash Flow Benefits with Senographe 2000D and Revolution XR/d: Step-Out Scenario

| | Productivity Gain with Senographe 2000D | Savings from Avoided False Positives with Senographe 2000D | Savings from Avoided Time Off and Travel with Senographe 2000D | Productivity Gain with Revolution XR/d | Expected Value of Total Cash Flow Benefits |
|------|---|--|--|--|--|
| 1996 | | | | | |
| 1997 | | | | | |
| 1998 | | | | | -1,773,000 |
| 1999 | | | | | |
| 2000 | | | | | |
| 2001 | | | | | |
| 2002 | | | | | |
| 2003 | | | | | |
| 2004 | | | | | |
| 2005 | 8,526,000 | 3,190,320 | 976,794 | 7,626,000 | 14,223,380 |
| 2006 | 28,032,000 | 9,722,880 | 2,976,896 | 27,132,000 | 47,504,643 |
| 2007 | 34,456,000 | 11,090,160 | 3,395,522 | 39,664,000 | 62,023,977 |
| 2008 | 38,250,000 | 11,394,000 | 3,488,550 | 56,316,000 | 76,613,985 |
| 2009 | 44,000,000 | 12,153,600 | 3,721,120 | 78,480,000 | 96,848,304 |
| 2010 | 45,100,000 | 12,457,440 | 3,814,148 | 88,944,000 | 105,220,912 |
| 2011 | 45,100,000 | 12,457,440 | 3,814,148 | 88,944,000 | 105,220,912 |
| 2012 | 48,125,000 | 13,293,000 | 4,069,975 | 88,944,000 | 108,102,382 |
| 2013 | 51,150,000 | 14,128,560 | 4,325,802 | 88,944,000 | 110,983,853 |
| 2014 | 51,150,000 | 14,128,560 | 4,325,802 | 88,944,000 | 110,983,853 |
| | Net present value of ATP investment | | \$339.8 million | | |
| | Internal rate of return on ATP investment | | 77 percent | | |
| | Benefit-to-cost ratio for ATP investment | | 193:1 | | |

About the Advanced Technology Program

The Advanced Technology Program (ATP) is a partnership between government and private industry to conduct high-risk research to develop enabling technologies that promise significant commercial payoffs and widespread benefits for the economy. The ATP provides a mechanism for industry to extend its technological reach and push the envelope beyond what it otherwise would attempt.

Promising future technologies are the domain of ATP:

- Enabling technologies that are essential to the development of future new and substantially improved projects, processes, and services across diverse application areas;
- Technologies for which there are challenging technical issues standing in the way of success;
- Technologies whose development often involves complex "systems" problems requiring a collaborative effort by multiple organizations;
- Technologies which will go undeveloped and/or proceed too slowly to be competitive in global markets without ATP.

The ATP funds technical research, but it does not fund product development—that is the domain of the company partners. The ATP is industry driven, and that keeps it grounded in real-world needs. For-profit companies conceive, propose, co-fund, and execute all of the projects cost-shared by ATP.

Smaller firms working on single-company projects pay a minimum of all the indirect costs associated with the project. Large, "Fortune 500" companies participating as a single company pay at least 60% of total project costs. Joint ventures pay at least half of total project costs. Single-company projects can last up to three years; joint ventures can last as long as five years. Companies of all sizes participate in ATP-funded projects. To date, more than half of ATP awards have gone to individual small businesses or to joint ventures led by a small business.

Each project has specific goals, funding allocations, and completion dates established at the outset. Projects are monitored and can be terminated for cause before completion. All projects are selected in rigorous, competitions, which use peer review to identify those that score highest against technical and economic criteria.

Contact ATP for more information:

- On the Internet: <http://www.atp.nist.gov>
- By e-mail: atp@nist.gov
- By phone: 1-800-ATP-FUND (1-800-287-3863)
- By writing: Advanced Technology Program, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 4701, Gaithersburg, MD 20899-4701

About the Author

Dr. Thomas Pelsoci is the managing director of Delta Research Co., specializing in the economic assessment of new technologies and manufacturing processes, including prospective economic impact studies during the early stage 'proof of concept' and demonstration phases. Along these lines, he recently completed an economic case study of an ATP-funded Close Cycle Air Refrigeration Technology. His industrial experience includes positions as R&D engineer at TRW and management consultant in the high technology practice of Bearing Point (KPMG Peat Marwick). Subsequently, Dr. Pelsoci held senior banking positions at First National Bank of Chicago and at Sanwa Bank, specializing in financing information systems and technology projects. He received a degree in Mechanical Engineering from Case Western Reserve University and a Ph.D. in Public Policy and Administration from the University of Minnesota.