PROJECT NO: FP6-017893

MEDI-VOICE

A Low Cost, Environmentally Friendly, Smart Packaging Technology to Differentiate European SME Suppliers to Service the Needs of the Blind, Illiterate and Europe's Aging Population.

Co-operative Research (Craft)

Horizontal Research Activities Involving SMEs

Final Activity Report - Reporting Period 1&2
Date of issue of this report: May 2008

Start Date: 1st September 2006 Duration: 24 Months+ 6 Months extension

Lead Contractor: Audio International Limited

Version 01

CONTENTS

PROJECT INFORMATION

PROJECT NO: FP6-017893

CONTRACT NO: COOP-CT-2004-017893

TITLE OF PROJECT: *MEDI-VOICE: A Low Cost, Environmentally Friendly, Smart Packaging Technology to Differentiate European SME Suppliers to Service the Needs of the Blind, Illiterate and Europe's Aging Population.*

COORDINATOR: Audio International Limited

SME EXPLOITATION MANAGER: Audio International Limited

***SME CONTRACTORS*:**

1 Audio International Limited
2 Faro - Pharma GmbH & CO KG
~~3 IT Mobile OY~~
4 MTC Holdings
10 AK Industries Limited

***OTHER ENTERPRISE / END USER CONTRACTORS*:**

5 Unia Farmaceutow - Wlascicieli Aptek
6 Novartis Pharma AG

RTD PERFORMER CONTRACTORS:

7 Pera Innovation Limited
8 Centre De Recerca I Investigacio Catalunya
9 Royal National Institute of Blind People

PUBLISHABLE EXECUTIVE SUMMARY

This report covers the work carried out in the second year of the project. The main body of this report is, at the request of the industrial partners, a precise overview. However more technical details can be found in the completed Deliverable Reports.

The Need

The proposed Co-operative project, 'MEDI-VOICE', aims to address the problems of miss-dosing of prescribed drugs typically by the ageing population and blind/partially sighted people, which kills over 190,000 EU citizens each year. This problem can be broken down in to various areas: a) taking wrong drugs at wrong time b) taking right drugs at wrong time c) complete missed dose. The "MEDI-VOICE" product solution addresses all these potential pitfalls.

The Benefits

In order to address these issues, the "MEDI-VOICE" project has developed a prototype product that prevents patients from taking the wrong dose of drugs at the wrong time, and only allows correct doses of correct drugs to be consumed. Furthermore the product physically prompts the patient to take the prescribed drugs in the correct quantity at the correct time through a recorded voice prompt system.

Product Features

The "MEDI-VOICE" prototype product has various built in features that collectively form the ultimate solution. Spoken instructions and a user friendly interface enable blind/partially sighted patients to use it. Embedded electronics in the tablet wallet enable dosing confirmation to be communicated to the user and also records the data for later analysis by the patient's General Practitioner.

Product Solution

The "MEDI-VOICE" project aims to take current state-of-the-art compliance monitoring, enhance it and combine it with our speech technology incorporating them into pharmaceutical blister packaging through novel manufacturing techniques such as in-mould labelling, over moulding and encapsulation. These technologies will overcome the problems associated with non-compliance and miss-dosing, specifically through the incorporation of spoken instructions.

The technical work has incorporated the tasks described in the following Work Packages:

Work Package 1 – Advancing the Scientific Understanding of In-Mould Labelling of Flexible Photovoltaics

Work Package 2 - Design of Pill Wallet
Work Package 3 - Pill Removing Monitoring
Work Package 4 - Electronics Development and Test
Work Package 5 - Encapsulation of Electronics
Work Package 6 – Integration and Validation

Suitable flexible photovoltaic cells have been identified and a method of overmoulding them has been developed, although, following detailed risk analysis associated with power failure, this technology was not selected for incorporation into the wallet. Designs and prototypes have been produced for the pill wallet, the user interface and the electrical connections to the blister pack, taking the requirements of the target user groups into account. Prototypes have been produced and subjected to user testing by the RNIB and initial discussions with companies who could bring the technology to market have been very encouraging.

For further details, contact:

Mr Brad Turkington
Audio International Limited

Tel: +44-28-867-35611
Fax: +44-793-098-4727
E-Mail: brad@audiointernational.co.uk

SECTION 1 - PROJECTIVE OBJECTIVES & MAJOR ACHIEVEMENTS DURING THE REPORTING PERIODS

1.1 Overview of General Project Objectives

The **scientific objectives** of our work are to:

- Establish scientific understanding of the effects of heat applied during the in-mould labelling process on grain growth within thin film photovoltaic laminates.
- Enhance scientific understanding of heat and pressure applied during injection moulding while encapsulating Piezo-electric speakers.

The **Technological Objectives** of our work are:

- Increased scientific understanding and development of in-mould labelling of thin film flexible photovoltaics that will enable high speed production and reduced manufacturing cost.
- The development of an encapsulation process that will enable the heterogeneous incorporation of working piezo-electric speaker technology into the medication packaging.
- The novel configuration of compliance monitoring and recording technology with conventional blister packaging.
- The development of a novel sensing system to detect when pills have been removed from blister packaging.
- The development of a software control system to allow up/down loading of medication instructions, patient specific requirements and medication compliance data.

1.2 Summary of Recommendations from Previous Reviews

It was commented that the project was far behind schedule at the end of RP1, and that high spends had been reported by Faromed and MTC. Nevertheless, the overall claim was insufficient to release a payment at that time.

1.3 Summary of Project Objectives & Major Achievements for Reporting Period 1& 2

The specific objectives for the thirty-month period of 01/09/2005 to 28/02/2008 of the project are summarised in the table below.

No.	Deliverable Title	Delivery Month	Nature	Dissemination Level	Delivery Month	Delivery Date	Reporting Deadline	Responsible	WP
D1	Specification of PV requirements	Month 3	R	CO	3	01/12/2005	15/01/06	Cric	1
D2	Prototype in-mould labelled PVs	Month 6	P	CO	6	01/03/2006	15/04/06	Pera	1
D3	Results of power production tests	Month 12	R	CO	12	01/09/2006	15/10/06	Cric	1
D4	Design for external surfaces of wallet, including user interface. Specification for the functionality of the wallet.	Month 3	R	CO	3	01/12/2005	15/01/06	Pera	2
D5	Design for interlock between wallet and blister packs providing mechanical fixture, data exchange and electrical connections.	Month 6	R	CO	6	01/03/2006	15/04/06	Cric	2
D6	Prototype model of wallet.	Month 6	P	CO	6	01/03/2006	15/04/06	Pera	2
D7*	Design of system of conductive paths. System to produce paths on blister foil and prototype paths on foil	Month 12	R	CO	12	01/09/06	15/10/06	MTC	3
D10	Prototype electronics module and evaluation results and performance specifications.	Month 18	P	CO	18	01/03/07	15/04/07	Cric	4

D11	PC based software for reading/writing data to/from the wallet	Month 18	R	CO	18	01/03/07	15/04/07	Cric	4
D13*	Speaker encapsulation and circuit board overmoulding optimal conditions and design rules	Month 27	R	CO	27	01/12/07	15/01/08	Pera	5
D15	Moulded and printed pharmaceutical packaging prototype.	Month 27	P	RE	27	01/12/07	15/01/08	AKI	6
D16*	System economic assessment. Recommendations for commercialisation and initial commercial product for development after the project.	Month 30	R	CO	30	01/03/08	15/04/08	Audio International	6
D18*	A report on potentially competitive patents and a plan for patent application(s) and a registered design application if required with exploitation agreements between the partners. A Dissemination and Use Plan (DUP). Draft at month 12 and final at month 24	Month 30	R	CO	30	01/03/08	15/04/08	Audio International	7
D19	Production of support material for transfer of the knowledge to the partners through case studies and a generic design guide.	Month 30	R	RE	30	01/03/08	15/04/08	Audio International	7
D20	Presentations at 2 conferences or major exhibitions, including IPACK-IMA and production of 4 publications per year in the form of editorials, technical papers and trade press, including Medical Device Technology.	Month 30	R	PU	30	01/03/08	15/04/08	Audio International	7
D21	Through RNIB and UFWA survey end user requirements and report feed back on prototype system usability. Contact drug companies and Pharmacist associations to promote system benefits and report findings on supply chain feed back	Month 30	R	PU	30	01/03/08	15/04/08	Audio International	7
D23	On-time and accurate cost claims with audit	Month 30	R	CO	30	01/03/08	15/04/08	Audio International	8

	certificates.								
D24	Project documentation in order and maintained.	Month 30	R	CO	30	01/03/08	15/04/08	Audio International	8

Deliverable	WP	Objective	Progress Towards Achieving Objectives
D1	1	Specification of PV requirements	Completed and Deliverable Report submitted on time.
D2	1	Prototype in-mould labelled PVs	Completed and a Deliverable Report submitted on time
D3	1	Results of power production tests	Completed and a Deliverable Report has been submitted
D4	2	Design for external surfaces of wallet, including user interface. Specification for the functionality of the wallet.	Completed and Deliverable Report submitted on time.
D5	2	Design for interlock between wallet and blister packs providing mechanical fixture, data exchange and electrical connections.	Completed and Deliverable Report has been submitted.
D6	2.C	Production of Tactile & Cosmetic Prototype	Completed and Deliverable Report has been re-submitted
D7*	3.A	Design a System of Electrical Conductors Crossing the Blisters so that removing the tablet from the blister will produce a monitorable change in resistance.	Completed and Deliverable Report has been re-submitted
D10	4	Design & develop prototype electronics, decision making, voice synthesis & RFID system. A fully integrated prototype electronic circuit has been modelled and prototyped. MicroContoller 18F4550 has been specified. The software to control all on-board wallet functions has been written and tested.	Completed and Deliverable Report has been submitted
D11	4	Produce prototype RF communication unit for reading/writing data to/from wallet.	Completed and Deliverable Report has been submitted

Deliverable	WP	Objective	Progress Towards Achieving Objectives
D13*	5	Identify the optimum thermoplastic for the packaging. Design & build prototype wallet tool suitable for the overmoulding of the electronics & the encapsulation of the speakers. Establish parameters for the successful overmoulding of electronics & piezoelectric speakers.	Completed and Deliverable Report has been submitted
D15	6	To produce a prototype pill package	Completed and Deliverable Report has been submitted
D16*	6	To validate the prototype device for all user groups and assess the commercial viability.	Completed and Deliverable Report has been submitted
18*	7	Creation and implementation of a plan to exploit the knowledge by granting of licences to future global manufacturers/distributors. To ensure that all project results are formulated and compiled into a protectable form and all necessary application are made. To transfer specific knowledge from the RTD performers to the SME participants to enable them to rapidly apply and embed the technology onto specific products. To broadcast the benefits of the developed technology and knowledge beyond the consortium to potential end user communities. To assess the socio-economic impact of the generated knowledge and technology.	Completed and Deliverable Report has been submitted
D19	7	Absorption of the project results by the consortium.	Completed and Deliverable Report has been submitted
D20	7	Dissemination of the knowledge to end users outside the SME core group.	Completed and Deliverable Report has been submitted

Deliverable	WP	Objective	Progress Towards Achieving Objectives
D21	7	Dissemination of the knowledge to end users outside the SME core group.	Completed and Deliverable Report has been submitted
D23	8	On-time and correct cost claims	In progress. Some cost documents still outstanding at time of this report.
D24	8	Effective consortium management and the production of consortium documents.	In progress. Some cost documents still outstanding at time of this report.

These specific objectives have been reported in the technical progress section and details can be found in the in the relevant Deliverable Reports.

1.4 Problems/Issues During Second Reporting Period

There have been some technical delays during the Second Reporting Period, which necessitated the 6 month extension.

SECTION 2 - WORK PACKAGE PROGRESS REVIEW FOR REPORTING PERIODS 1& 2

2.1 Work Package Objectives

The specific work package objectives for the thirty-month period of 01/09/2005 to 28/02/2008 of the project are summarised in the table below.

Work Package No	Work Package Title	Lead Contractor Short Name	Person Months	Start Month	End Month	Deliverable No
1	Work Package 1: Advancing the Scientific Understanding of In-Mould Labelling of Flexible Photovoltaics	Pera	11.4	Month 0	Month 9	1,2,3
2	Work Package 2: Design of Pill Wallet	CRIC	19.3	Month 0	Month 6	4,5,6
3	Work Package 3: Pill Removal Monitoring	MTC	9.7	Month 3	Month 9	7*
4	Work Package 4: Electronics Development and Test	CRIC	12.3	Month 9	Month 18	10,11
5	Work Package 5: Encapsulation of Electronics	PERA	17.7	Month 6	Month 22	13*
6	Work Package 6: Integration and Validation	AUDIO INTERNATIONAL	21.6	Month 18	Month 30	15, 16*
7	Work Package 7: Knowledge Transfer, Dissemination and Exploitation (Innovation Related Activities)	AUDIO INTERNATIONAL	16.6	Month 6	Month 30	18*,19,20,21
8	Work Package 8: Consortium Management	AUDIO INTERNATIONAL	4.1	Month 0	Month 30	23,24

2.2. Overview of Work Package Technical Progress

The following summarises the work carried out in the project. The objectives of each Work Package are recalled followed by the activities carried out on each Task.

Work Package 1: Advancing the Scientific Understanding of In-Mould Labelling of Flexible Photovoltaics

Work Package Objectives: To understand the effects of in-mould labelling on flexible photovoltaics and to prove that a sufficient area of the most suitable state of the art flexible photovoltaic technology can be incorporated into a thermoplastic moulding through in-mould labelling technology.

Deliverables:

- Specification of flexible photovoltaic requirements.
- Identification of up to 3 state of the art flexible photovoltaic cells suitable for the application.
- Moulding trials with up to 3 types of flexible photovoltaics to establish the effect of in-mould labelling on the efficiency of the cells and the conditions for incorporation of that area of flexible photovoltaics into the surface of a thermoplastics as an in-mould label.
- Assessment of the power production after moulding.

Task 1.A: Specification & Selection of Photovoltaic Cells
Task Leader: Pera
Partners Involved: MegaVoice, Pera, CRIC

Objectives: To specify and select suitable state of the art photovoltaic cells

Progress: The requirements for flexible solar (photovoltaic) cells were specified, and samples of various size cells obtained from the manufacturer.

Deliverable Status (D1):
This deliverable has been completed and was submitted

Task 1.B: In-Mould Labelling of Photovoltaic Cells
Task Leader: Pera
Partners Involved: AKI

Objectives: To Design & Perform a Series of Experiments to Optimise the In-Mould Labelling of Photovoltaic Cells

Progress: This work has proven that flexible PV cells can be overmoulded with a thermoplastic without destroying their power production properties. It has also been noted that there is a wide variation in the power produced by individual cells, but there is no demonstrable effect on power production of overmoulding.

Deliverable Status (D2):
This deliverable report has been submitted.

Task 1C: Power Production Assessment and Optimisation
Task Leader: Pera
Partners Involved: AKI & CRIC

Objectives: To obtain maximum power production.

Progress: A measurement system has been developed and built. Measurements have been made on flexible photovoltaic cells under controlled lighting conditions, demonstrating that in-mould labelling of photovoltaic cells does not significantly affect their power production performance.

Deliverable Status (D3):

This deliverable report has been submitted.

Work Package 2 - Design of Pill Wallet

Work Package Objectives: To design the wallet device, including the user and product interface and connection with interchangeable blister packs

Deliverables:

- Design for external surfaces of wallet, including user interface. Specification for the functionality of the wallet.
- Design for interlock between wallet and blister packs providing mechanical fixture, data exchange and electrical connections.
- Prototype model of wallet.

Task 2.A: Design of User Interface to Optimise the Information Transfer Process between the Wallet & the Patients in the Target Groups

Task Leader: Megavoice Ireland
Partners Involved: UFWA, Pera, RNIB

Objectives: To design the interface between the wallet & the patient

Progress: The requirements of the targeted user groups have been investigated, and designs for improving the accessibility of the device have been produced. Aspects including graphics, Braille, languages, fonts, colours, text size, sound quality, physical manipulation and overall shape have been considered.

Deliverable Status (D4):
This deliverable report has been submitted.

Task 2.B: Design of Electrical Connection Between the Wallet & the Interchangeable Blister Packs

Task Leader: Faro
Partners Involved: AKI, MTC, UFWA, CRIC, RNIB

Objectives: To design the connection between the wallet & interchangeable blister packs.

Progress: Connections have been designed which guarantee the electrical connection between the conductive ink tracks printed in the blister with the connectors placed in the wallet and are usable by the target populations. They also support the blister pack in the wallet, providing a physical connection.

Deliverable Status (D5):
This deliverable report has been submitted.

Task 2.C: Production of Tactile Prototype

Task Leader: Megavoice Ireland
Partners Involved: UFWA, Pera, RNIB

Objectives: Production of Tactile & Cosmetic Prototype

Progress:

Steroelithography has been used to produce a tactile prototype that can be used for consumer trials with the target user groups. An initial stereolithography prototype was used to identify some design improvements, and a further prototype has been produced to the improved design.

Deliverable Status (D6):

This work is complete and a deliverable report has been submitted.

Work Package 3 - Pill Removal Monitoring

Work Package Objectives: To design and produce a system to monitor and record the timing of pill-popping events.

Deliverables:

- Design of system of conductive paths
- System to produce paths on blister foil
- Prototype paths on foil

Work Package 3 - Pill Removing Monitoring

Task 3.A: Design of Conductive Paths
Task Leader: MTC
Partners Involved: CRIC

Objectives: To design a system of electrical conductors crossing the blisters so that removing the tablet from the blister will break the conduction path producing a monitorable change in resistance.

Progress: Designs for the printed paths and pill monitoring sensor have been produced. The results of printing trials, including track width and accuracy are required to validate the design.

Deliverable Status (D7*):
This deliverable report has been submitted, and an update has been resubmitted with this report.

Task 3.B: Track Printing System
Task Leader: MTC

Partners Involved: Pera & CRIC

Objectives: To design a method of producing the paths designed in Task 3.A & to produce a prototype.

Progress: Sources of conductive ink have been identified, and the sample size required for trials has been calculated. Printing trials using the facilities at MTC have been performed using 2 different inks and conductive tracks have now been successfully produced.

Deliverable Status (D7*):
This deliverable report has been submitted and an update has been resubmitted with this report.

Work Package 4 - Electronics Development & Test

Work Package Objectives: To develop and prove a simple and highly reliable electronic control system for power management, prescription management, prescription compliance monitoring, memory management, voice synthesis and RF communication.

Deliverables:

- Prototype electronics module and evaluation results and performance specifications.
- PC based software for reading/writing data to/from the wallet

Task 4.A: Prototype Controller
Task Leader: CRIC

Objectives: Design & develop prototype electronics, decision making, voice synthesis & RFID system.

Progress: A design has been made and prototyped incorporating the processing, button inputs, memory, power, connections, memory and speaker. Batteries and the speaker have been placed outside the PCB. 2 Battery holders are required to hold 2 AAA batteries. Mini USB was used to connect the wallet to the data transfer computer.

Deliverable Status (D10):
This deliverable is complete and a report has been submitted. An update has been resubmitted with this report.

Task: 4.B: System Integration

Task Leader: CRIC
Partners Involved: Pera

Objectives: Produce a fully integrated prototype electronic circuit for incorporation into prototype wallet

Progress: A fully integrated prototype electronic circuit has been modelled and prototyped.

Deliverable Status (D10):
This deliverable is complete and a report has been submitted. An update has been resubmitted with this report.

Task 4.C: Prototype Programming Unit
Task Leader: UFWA
Partners Involved: CRIC & Pera

Objectives: Produce prototype RF communication unit for reading/writing data to/from wallet.

Progress: The communication method has been designed as being from desktop PC to the wallet via a mini USB connection. The PC graphical user interface software to facilitate the reading and writing to and from the wallet has been designed and prototyped and distributed to members of the consortium for use with the prototype wallets.

Deliverable Status (D11):
This deliverable is complete and a report has been submitted. An update has been resubmitted with this report.

Task 4.D: Controller Software
Task Leader: Audio International
Partners Involved: UFWA, Novartis, CRIC

Objectives: Produce microcontroller software to control all on board wallet functions and communication protocols.

Progress: MicroContoller 18F4550 has been specified. The software to control all on-board wallet functions has been written and tested.

Deliverable Status (D10):

This deliverable is complete and a report has been submitted. An update has been resubmitted with this report.

Work Package 5 - Encapsulation of Electronics

Work Package Objectives: To produce a system for overmoulding a circuit board and piezoelectric speaker with thermoplastic

Deliverables:

- Selection of thermoplastic
- Speaker encapsulation conditions and design rules
- Circuit board overmoulding optimal conditions

Task 5.A: Thermoplastic Selection for Appearance, Function & Acoustic Performance

Task Leader: Audio International
Partners Involved: Pera, AKI, RNIB

Objectives: Identify the optimum thermoplastic for the packaging

Progress: The optimum thermoplastic material for the packaging has been identified as ABS as no “living hinge” function is required. A pip and hole hinge design has been incorporated. A white pigmented ABS has been used to produce the prototype mouldings.

Deliverable Status (D13*):
This deliverable is complete and a report has been submitted with this report.

Task 5.B: Tool Design & Manufacture
Task Leader: AKI
Partners Involved: Pera

Objectives: Design & build prototype wallet tool suitable for the overmoulding of the electronics & the encapsulation of the speakers.

Progress: A tool has been designed and manufactured to produce the wallet case. Tools have also been designed and produced to make the spine and clamp components. The tools have been used to produce the prototype wallets.

Deliverable Status (D13*):
This deliverable is complete and a report has been submitted with this report.

Task 5.C: Overmoulding of Electronics and Encapsulation of Speaker
Task Leader: Audio International
Partners Involved: AKI

Objectives: Establish parameters for the successful overmoulding of electronics & piezoelectric speakers.

Progress: A tool has been designed to produce a wallet and to allow the electronics to be incorporated within the wallet. This work was modified from the original proposal to ensure compliance with the WEEE directive. The electronics have been incorporated in a way that makes them easy to separate and recycle.

Deliverable Status (D13*):
This deliverable is complete and a report has been submitted with this report.

Work Package 6 – Integration and Validation

Work Package Objectives: To combine the prototype elements that have been developed and produce a single prototype device

Deliverables:
- Moulded and printed pharmaceutical packaging prototype
- System economic assessment
- Recommendations for commercialisation and initial commercial product for development after the project.

Task 6.A: Integration of Innovations
Task Leader: Audio International
Partners Involved: Faromed, AKI, MTC, Pera and CRIC

Objectives: To produce a prototype pill package

Progress: 3 prototype devices and over a hundred prototype pill packets have been made and used for exploitation and user feedback tasks.

Deliverable Status (D15):
This deliverable is complete and a report has been submitted with this report.

Task 6.B: Validation
Task Leader: Audio International

Partners Involved: Faromed, AKI, MTC, UFWA, Novartis, Pera, CRIC and RNIB

Objectives: To validate the prototype device for all user groups and assess the commercial viability.

Progress: Two prototype devices and over a hundred prototype pill packets have been used for user feedback tasks, which highlighted some interesting issues. A costing exercise has been completed, and initial exploitation discussions have confirmed the commercial validity of continuing to work to bring this device to market.

Deliverable Status (D16*):
This deliverable is complete and a report has been submitted with this report.

Work Package 7 - Knowledge Transfer, Dissemination and Exploitation

Work Package Objectives: To ensure that all project results are arranged into a legally protectable form and that all necessary attempts are made to protect them. To transfer specific knowledge from the RTD performers to the SME participants to enable them to rapidly apply and embed the technology onto specific products. To ensure all end user and interest groups associated with the consortium (including those identified in Annex 1 p22) have full access to prototypes for dissemination of the protected knowledge and designs. To broadcast the benefits of the developed technology and knowledge beyond the consortium to potential industrial and end user communities. To assess the socio-economic impact of the generated knowledge and technology.

Deliverables:

- A report on potentially competitive patents s and a plan for the patent applications and registered design applications with exploitation agreements between the partners.
- Production of support material for transfer of the knowledge to the partners through case studies and a generic design guide.
- Presentations at 2 conferences or major exhibitions, including IPACK-IMA and production of 4 publications per year in the form of editorials, technical papers and trade press including Medical Device Technology.
- Through RNIB and UFWA survey end user requirements and report feedback on prototype system usability. Contact drug companies and pharmacist associations to promote system benefits and report findings on supply chain feedback.

Task 7.A: Development of the Exploitation Strategy

Task Leader: Audio International
Partners Involved: Faromed, AKI, MTC, UFWA, Novartis, Pera, CRIC and RNIB

Objectives: Creation and implementation of a plan to exploit the knowledge by granting of licences to future global manufacturers/distributors.

Progress: An exploitation plan has been produced and initial discussions have begun with Novartis and American routes to market. A full business plan, including the concept of issuing shares in the IP owning company to consortium partners, is being drafted with the assistance of European Capital Solutions.

Deliverable Status (D18):
This deliverable is complete and a report has been submitted with this report.

Task 7.B: Protection of IPR
Task Leader: Audio International
Partners Involved: Pera and CRIC

Objectives: To ensure that all project results are formulated and compiled into a protectable form and all necessary application are made. To transfer specific knowledge from the RTD performers to the SME participants to enable them to rapidly apply and embed the technology onto specific products. To broadcast the benefits of the developed technology and knowledge beyond the consortium to potential end user communities. To assess the socio-economic impact of the generated knowledge and technology.

Progress: A patent application has been submitted via F R Kelly & Co, European Patent Attorneys. Knowledge has been transferred within the consortium and publications have been produced.

Deliverable Status (D18):
This deliverable is complete and a report has been submitted with this report.

Task 7.C: Knowledge Transfer Within the Consortium
Task Leader: Audio International
Partners Involved: Faromed, AKI, MTC, UFWA, Novartis, Pera, CRIC and RNIB

Objectives: Absorption of the project results by the consortium.

Progress: The project results have been transferred within the consortium by methods including demonstration, explanation, reports and specifications.

Deliverable Status (D19):
This deliverable is complete and a report has been submitted with this report.

Task 7.D: Dissemination Outside Consortium
Task Leader: Audio International
Partners Involved: Faromed, AKI, MTC, UFWA, Novartis, Pera, CRIC and RNIB

Objectives: Dissemination of the knowledge to end users outside the SME core group.

Progress: Publications, websites, conferences and exhibitions have been used to publicise aspects of this project to a wider audience, and face to face events have been held with key end user groups and routes to market.

Deliverable Status (D20 and D21):
These deliverables are complete and reports have been submitted with this report.

2.3 Deviation from the Plan and Corrective Actions

Work Package No	Work Package Title	Deviation	Corrective Action Taken
1	Work Package 1: Advancing the Scientific Understanding of In-Mould Labelling of Flexible Photovoltaics	None, but photovoltaics not chosen to power the wallet	Alternative power sources investigated.
2	Work Package 2: Design of Pill Wallet	First prototype identified issues with the design	Task timescale extended. Second prototype made. Task now complete.
3	Work Package 3: Pill Removal Monitoring	Initial ink was not conductive	Task timescale extended. Additional ink trials successful. Task now complete
4	Work Package 4: Electronics Development and Test	None	None
5	Work Package 5: Encapsulation of Electronics	None, but work delayed by WP2.	Project extension
6	Work Package 6: Integration and Validation	None, but work delayed by WP2	Project extension
7	Work Package 7: Knowledge Transfer, Dissemination and Exploitation (Innovation Related Activities)	None	None
8	Work Package 8: Consortium Management	Cost claims and audit certificates delayed	Available documents submitted. Others will be submitted as they become available.

2.4 Work Package Deliverables Update

No.	Deliverable Title	WP	Lead Participant	Delivery Month	Update
D1	Specification of PV requirements	1	Cric	Month 3	Submitted
D2	Prototype in-mould labelled PVs	1	Pera	Month 6	Submitted
D3	Results of power production tests	1	Cric	Month 12	Submitted
D4	Design for external surfaces of wallet, including user interface. Specification for the functionality of the wallet.	2	Pera	Month 3	Submitted
D5	Design for interlock between wallet and blister packs providing mechanical fixture, data exchange and electrical connections.	2	Cric	Month 6	Submitted
D6	Prototype model of wallet.	2	Pera	Month 6	Submitted
D7*	Design of system of conductive paths. System to produce paths on blister foil and prototype paths on foil	3	MTC	Month 12	Submitted
D10	Prototype electronics module and evaluation results and performance specifications.	4	Cric	Month 18	Submitted
D11	PC based software for reading/writing data to/from the wallet	4	Cric	Month 18	Submitted
D13*	Speaker encapsulation and circuit board overmoulding optimal conditions and design rules	5	Pera	Month 30	Submitted
D15	Moulded and printed pharmaceutical packaging prototype.	6	AKI	Month 30	Submitted
D16*	System economic assessment. Recommendations for commercialisation and initial commercial product for development after the project.	6	Audio	Month 30	Submitted
D18*	A report on potentially competitive patents and a plan for patent application(s) and a registered design application if required with exploitation agreements between the partners. A Dissemination and Use Plan (DUP). Draft at month 12 and final at month 24	7	Audio	Month 30	Submitted
D19	Production of support material for transfer of the knowledge to the partners through case studies and a generic design guide.	7	Audio	Month 30	Submitted
D20	Presentations at 2 conferences or major exhibitions, including IPACK-IMA and production of 4 publications per year in the form of editorials, technical papers and trade press, including Medical Device Technology.	7	Audio	Month 30	Submitted
D21	Through RNIB and UFWA survey end user requirements and report feed back on prototype system usability. Contact drug companies and Pharmacist associations to promote system benefits and report findings on supply chain feed back	7	Audio	Month 30	Submitted
D23	On-time and accurate cost claims with audit certificates.	8	Audio	Month 30	Progress
D24	Project documentation in order and maintained.	8	Audio	Month 30	Progress

2.5 Work Package Milestones Update

Milestone No.	Milestone Title	Completion Date	Update	Verification Level
1	Creation of new production knowledge that enables the optimised in-mould labelling of flexible photovoltaic cells.	Month 12	Complete	Report and samples
2	Creation of product design and prototype showing user interface and connection to interchangeable blister packs.	Month 12	Complete	Report and prototype
3	Proof of principle for pill monitoring system showing that a change in resistance can be produced by the removal of a pill.	Month 9	Complete	Report and samples
4	Proof of prototype electronics, decision making, voice synthesis and RFID system	Month 18	Complete	Report and demonstration
5	Proof of overmoulded electronics and speaker function.	Month 22	Complete	Report and demonstration
6	Validated prototype package	Month 30	Complete	Report
7	Provide a report on the strategy and implementation for the translation of the project results into a protectable form and provide a plan and timescales for patent and registered design protection. This will be verified by discussion and agreement of all the partners that the plan and actions will secure the knowledge for commercial use and exploitation.	Month 18	Complete	Report
7	Transfer of the project knowledge from the RTD performers to the SME participants through the successful completion of 2 technology transfer events and interactions. Report on the critical knowledge elements to be transferred for successful exploitation by the SMEs verified by discussion and agreement of all the partners.	Month 30	Complete	Report
7	Completed promotion of the benefits of the developed technology and knowledge beyond the consortium to potential pharmaceutical user communities including pharmacist companies and health care providers. This will be verified by a report detailing the activities completed and the specific companies engaged with together with their feedback and willingness to adopt the results through the partners.	Month 30	Complete	Report
8	Draft DUP written. Cost claim submitted on time and audit certificates provided. Project meetings arranged and attended.	Month 12	Complete	Report
8	Year 2 Cost claim submitted on time with audit certificates. Dissemination and Use Plan	Month 30	In Progress	Report
8	All documentation in order. Final report issued in draft and approved by EC. Final cost claim submitted with audit certificates. All payments made on time.	Month 30	In Progress	Report

SECTION 3 - CONSORTIUM MANAGEMENT

3.1 Consortium Management Tasks & Achievements

Work Package 8: Consortium Management

Task 8.A: Coordination of Knowledge Management & IRA
Task Leader: Audio International Limited

Objective: Effective coordination of knowledge and innovation-related activities.

Progress: A patent application has been made and a Dissemination & Use Plan (DUP) has been created. This can be found in Deliverable Report D18*.

Task 8.B Collation of Cost Statements & Audit Certificates
Task Leader: Audio International Limited
Partners Involved: Faro, AKI, MTC, UFWA, Novartis, Pera, CRIC, RNIB

Objective: On-time and correct cost claims.

Progress: Audio International and Pera have co-ordinated the collation of all cost statements and audit certificates. Delays have been encountered in producing Form Cs that satisfy auditors. Additional delays have been found due to auditors being involved with company year-end accounts. Some documents are submitted on time, but some are delayed and will be submitted as soon as they are available.

Task 8.C: Co-ordination of Legal, Contractual, Ethical & Financial Aspects
Task Leader: Audio International Limited
Partners Involved: Faro, AKI, MTC, UFWA, Novartis, Pera, CRIC, RNIB

Objective: Effective consortium management and the production of consortium documents.

Progress: A consortium agreement document was successfully drafted and submitted to the European Commission before the start of the project. This was updated to reflect the partner change from IT Mobile to A K Industries. Other contract amendments have been made to accommodate a 6 month extension, a change in business name and a change in legal partner to reflect the actual collaboration. Audio International and Pera have cooperated to manage the consortium, and regular meetings have been held and are always well attended by the whole consortium.

Task 8.D: Communications Between the Consortium & the EC. Organisation of Project Meetings
Task Leader: Audio International Limited

Objective: Effective two way communication between consortium and EC. Organisation of project meetings.

Progress: Brad Turkington of Audio International has been the single point of contact between the EC and the consortium, except when communications with Pera have been initiated by the EC. Audio International and Pera have cooperated to arrange regular consortium meetings. These have been hosted by a number of consortium partners and are always well attended by the whole consortium.

Task 8.E: Coordination of Gender Equality, Ethical and Societal Aspects of the Project
Task Leader: Audio International Limited

Objective: To co-ordinate the Equality, Ethical and Societal Aspects of the Project

Progress: The equality, ethical and societal aspects of this project particularly relate to the accessibility of the wallet device to a wide range of users, including those with vision, language, memory and dexterity impairments. This Medi-Voice wallet will encourage independent living.

3.2 Consortium Status Overview

The consortium is continuing to work very well together providing valuable input and direction for the research programme and progressing towards exploitation. The only change in the member companies occurred during the first months, and was the change from IT Mobile to A K Industries to perform the moulding aspects of the consortium. There have been some changes in contact details to reflect a company name change and move to the holding company for MTC.

3.3 Project Timetable & Status

3.3.1 Work Programme (Original)

	Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
	Work Package 1: Advancing the Scientific Understanding of In-Mould Labelling of Flexible Photovoltaics																								
Task 1A	Specification and selection of photovoltaic cells.																								
Task 1B	In-Mould Labelling of Photovoltaic Cells																								
Task 1C	Power production assessment and optimisation																								
	Work Package 2: Design of Pill Wallet																								
Task 2A	Design of user interface to optimise the information transfer process between the wallet and patients in the target groups.																								
Task 2B	Design of electrical connection between wallet and interchangeable blister packs																								
Task 2C	Production of Tactile Prototype																								
	Work Package 3: Pill Removal Monitoring																								
Task 3A	Design of conductive paths																								
Task 3B	Track Printing System																								
	Work Package 4: Electronics Development and Test																								
Task 4A	Prototype controller																								
Task 4B	System Integration																								
Task 4C	Prototype programming unit																								
Task 4D	Controller Software																								
	Work Package 5: Encapsulation of Electronics																								
Task 5A	Thermoplastic Selection for Appearance, Function and Acoustic Performance																								
Task 5B	Tool Design and Manufacture																								
Task 5C	Overmoulding of Electronics and Encapsulation of Speaker																								
	Work Package 6: Integration and Validation																								
Task 6A	Integration of Innovations																								
Task 6B	Validation																								
	Work Package 7: Knowledge Transfer, Dissemination and Exploitation (Innovation Related Activities)																								
Task 7A	Development of the Exploitation Strategy																								
Task 7B	Protection of IPR																								
Task 7C	Knowledge Transfer within the Consortium																								
Task 7D	Dissemination Outside Consortium																								
	Work Package 8: Consortium Management																								
Task 8A	Coordination of Knowledge Management and IRA.																								
Task 8B	Collation of Cost Statements and Audit Certificates.																								
Task 8C	Co-ordination of Legal, Contractual, Ethical and Financial Aspects																								
Task 8D	Communications between the Consortium & the EC. Organisation of Project Meetings																								
Task 8E	Co-ordination of Gender Equality, Ethical and Societal Aspects of the Project																								

3.3.2 Work Programme (As Updated)

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
WP1	**Advancing the Sci. Understanding of PVs**																														
1A	Spec and Selection of PV Cells																														
1B	In-mould Labelling of PV Cells																														
1C	Power Assessment and Optimisation																														
WP2	**Design of Pill Wallet**																														
2A	Design of User Interface																														
2B	Design of Electrical Connection																														
2C	Production of Tactile Prototype																														
WP3	**Pill Removal Monitoring**																														
3A	Design of Conductive Paths																														
3B	Track Printing System																														
WP4	**Electronics Development and Test**																														
4A	Prototype Controller																														
4B	System Integration																														
4C	Prototype Programming Unit																														
4D	Controller Software																														
WP5	**Encapsulation of Electronics**																														
5A	Thermoplastic Selection																														
5B	Tool Design and Manufacture																														
5C	Overmoulding and Encapsulation																														
WP6	**Integration and Validation**																														
6A	Integration of Innovations																														
6B	Validation																														
WP7	**Innovation Related Activities**																														
7A	Exploitation Strategy																														
7B	Protection of IPR																														
7C	Knowledge Transer Within Consortium																														
7D	Dissemination Outside Consortium																														
WP8	**Consortium Management**																														
8A	Coord. of Knowledge Management and IRA																														
8B	Collation of Cost Statements and Audits																														
8C	Coord. of Legal, Contractual and Financials																														
8D	Comms with EC. Organisation of Meetings																														
8E	Coord. Of Gender, Ethical and Societals																														

3.3.3 Clarification of Changes to Work Programme

A 6 month extension was required partly due to delays in WP2, which also delayed other aspects of the work. The extension enabled the consortium to continue to develop the conductive tracks innovation and to make a patent application based on the developed technology. This work could then be done under the rules and security of the EC contract, ensuring confidentiality and that the ownership of the intellectual property was retained by the SMEs.

3.4 Meetings & Communication

There have been seven project review meetings in RP2 of the project. These have all combined technical, management and exploitation issues, and have spanned 2 days each to encourage broad discussions of the project between the consortium members.

	Date	Type of meeting	Location
1	19/10/2005	Kick Off Meeting	Pera
2	29-30/11/2005	3 Month Technical Meeting	CRIC
3	07-08/03/2006	6 Month Technical Meeting	A K Industries
4	07-08/06/2006	9 Month Technical Meeting	MTC Polska
6	4-5/10/2006	Midterm Meeting	RNIB, London, UK
7	14-15/12/2006	15 Month Meeting	Faromed and MTC, Vienna, Austria
8	21-23/02/2007	18 Month Meeting	CRIC, Barcelona, Spain
10	23-24/5/2007	21 Month Meeting	Audio International, Belfast, Northern Ireland
12	29-30/08/2007	24 Month Meeting	Coventry, UK
13	3-4/12/2007	27 Month Meeting	Stansted, UK
14	25-26/02/2008	Final Meeting	Novartis, Basel, Switzerland

All meetings have been characterised by good attendances and open discussion, thus exploring broad views on the direction and content of the technical work. Partners have also carried out technical presentations at these meetings and have brought technical knowledge to the project consortium. This clearly illustrates the positive commitment of the partners. A

tour of facilities has followed each meeting allowing consortium members to further understand the potentials of each others businesses. Some meetings, towards the end of the period, have been held at hotels conveniently located close to airports to maximise the benefit of the time available.

Between the main technical meetings some additional working party meetings have been held to discuss specific project issues to focus the work programme.

A website has been created (www.medi-voice.pera.com) which is an on-line administrative and archiving tool for the partners. The administrative and archive elements of the website are password protected.

SECTION 4 - DISSEMINATION AND USE (EXPLOITATION)

4.1 Dissemination Activities

Exploitation was discussed at all of the project meetings. A project web portal has been established, and includes access to the ProjectCoordinator software from DesignTech. This not only allows public dissemination of selected information, but improves the administration of the project and facilitates active involvement and communication between all partners at times between the face-to-face meetings.

We have attended a number of exhibitions and conferences, in addition to website publicity and papers. The outline of the project has also been briefly mentioned in HCPC (Healthcare Compliance Packaging Council) bulletin. These dissemination activities have been fecilitated by the patent application.

SECTION 5 - CONCLUSIONS

- The in-mould labelling of photovoltaics has been successfully demonstrated, and although found not suitable for the wallet, this technology is being considered for spin-off applications.

- Prototypes demonstrating the integration of the other technologies have been produced and used for user testing and market stimulation activities.

- Commercially feasible technologies and a product concept has been developed by the consortium, and are expected to lead to further real commercial benefits for all partners after the project.