INFORMATION SOCIETY TECHNOLOGIES PROGRAMME (IST)

DIAFOOT

IST-2001-33281

Best Practice Action

REMOTE MONITORING OF DIABETIC FOOT

SUMMARY:

- ✓ Project partners
- ✓ Diabetic foot – Plantar pressure
- ✓ State of the art
- ✓ DIAFOOT system
- ✓ Data transmission
- ✓ Clinical evaluation protocols
- ✓ Orthopaedic insole materials
- ✓ Dissemination activities
- ✓ Calendar of activities
- ✓ Deliverables
- ✓ Conclusions

Partners

Proyección Europlan XXI, S.L.

Universidad Miguel Hernández

Aziende Osppedalaria Pisana

INESCOP
INSTITUTO TECNOLÓGICO
DEL CALZADO Y CONEXAS

RED 21
Proyectos Informáticos

Red XXI, S.L.

C.G.S di Coluccia & C. Sas

Clínica Virgen del Consuelo

U.P.D
Unidad Pie Diabético

Diabetic foot

- In 2000: 150 millions diabetics
- Lack of sensitiveness in foot: neuropathy
- 15% of diabetics: problems with diabetic foot
- High risk of amputation
- High sanitary costs (10 millions of European diabetics represent 29 000 millions €)

Measurement of plantar pressure

- Give functional information from foot-ankle when walking or making physical activities.
- Indicator of
  - Muscle-skeleton changes.
  - Neurological changes
- Pressure Data for:
  - Checking patient
  - Treatment implementation.
  - Education
  - Investigation: Pressure-plantar morphology

Utilities

- Evaluate the effect of plantar orthesis
- Evaluate footwear modifications
- Analyse different materials or therapeutic footwear
- Evaluate cost-effectiveness of a treatment

State of the art

Diagnosis systems

- Platform issues
  - EMED SF
  - MUSGRAVE
  - Footscan plate
- In Shoe issues
  - Footscan Insole
  - F-Scan
  - EMED Pedar
  - Biofoot

Monitoring systems

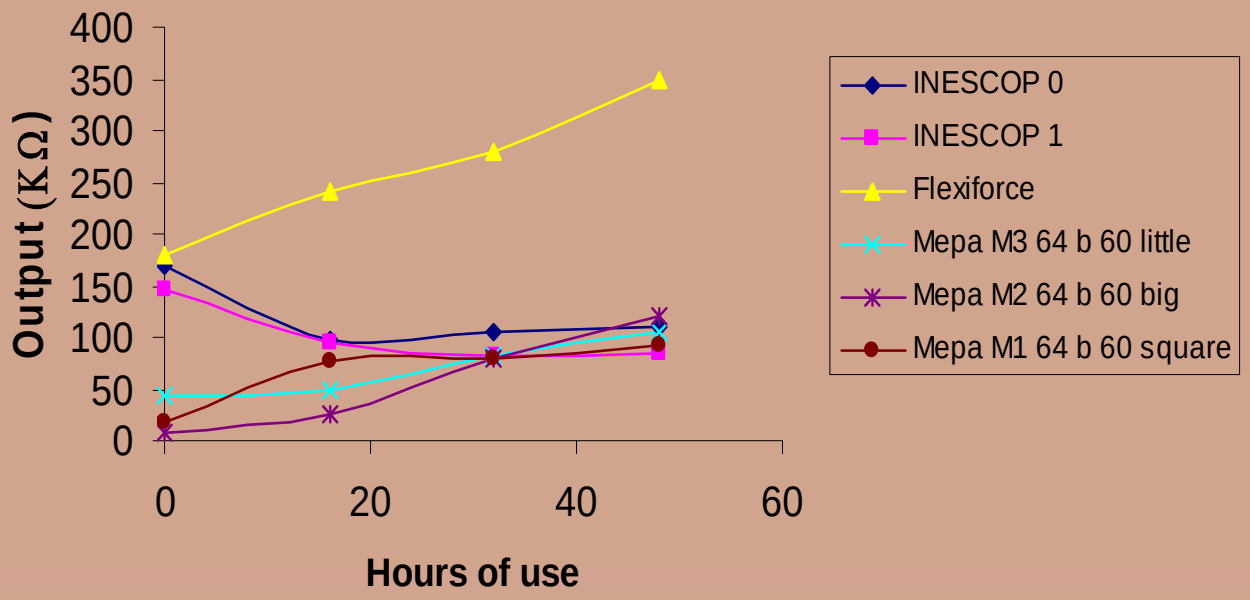
DIAFOOT

State of the art

- Platform issues
  - ✓ *Advantages:* wireless, not sensitive to temperature.
  - ✓ *Disadvantages:*big dimensions, patient walks barefoot, path lenght limited, targeting.
- In Shoe issues
  - ✓ *Advantages:*inside the shoe, design of insoles and orthesis, real time data acquisition, no path limit.
  - ✓ *Disadvantages:* not wireless, very sensitive to temperature and humidity inside the shoe, targeting.

Commercial and DIAFOOT sensors

- DIAFOOT sensors: previous stabilization, durable.
- Other sensors: not stable, short lifetime.



DIAFOOT system

- Advantages
  - ✓ Wireless
  - ✓ Monitoring
  - ✓ No targeting
  - ✓ Massive service
  - ✓ Pressure data of everyday walking
- Components
  - ✓ Sensor insole
  - ✓ Data Logger 1
  - ✓ Data Logger 2
  - ✓ Base Unit (modem or cellular)
  - ✓ Central Unit

State of the art

Diagnosis systems

Monitoring systems

DIAFOOT

State of the art

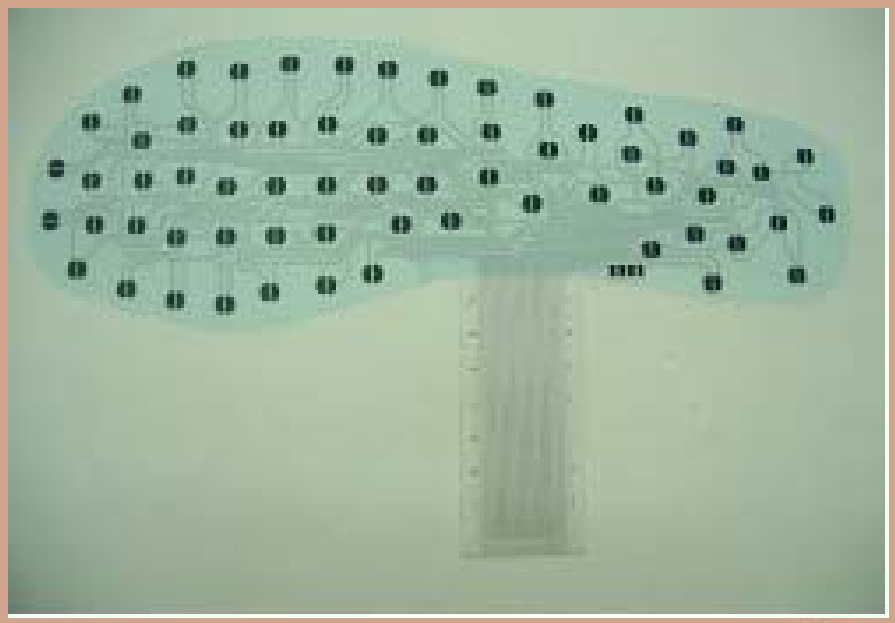
Diagnosis systems

Monitoring systems

DIAFOOT

SENSORS INSOLE

- 64 sensors/insole
- Max-detection threshold: 3 kg/cm^2
- Resolution:1/50 or better (minimum division: 200 g)
- Diameter of 6mm
- Hermetic and perfectly guarded from humidity



Sensors calibration

- ✓ Absolute pressure
- ✓ Pneumatic chamber
- ✓ Linearization matrix (255x64)
- ✓ Each sensor calibrated individually

64 columns: one for each sensor

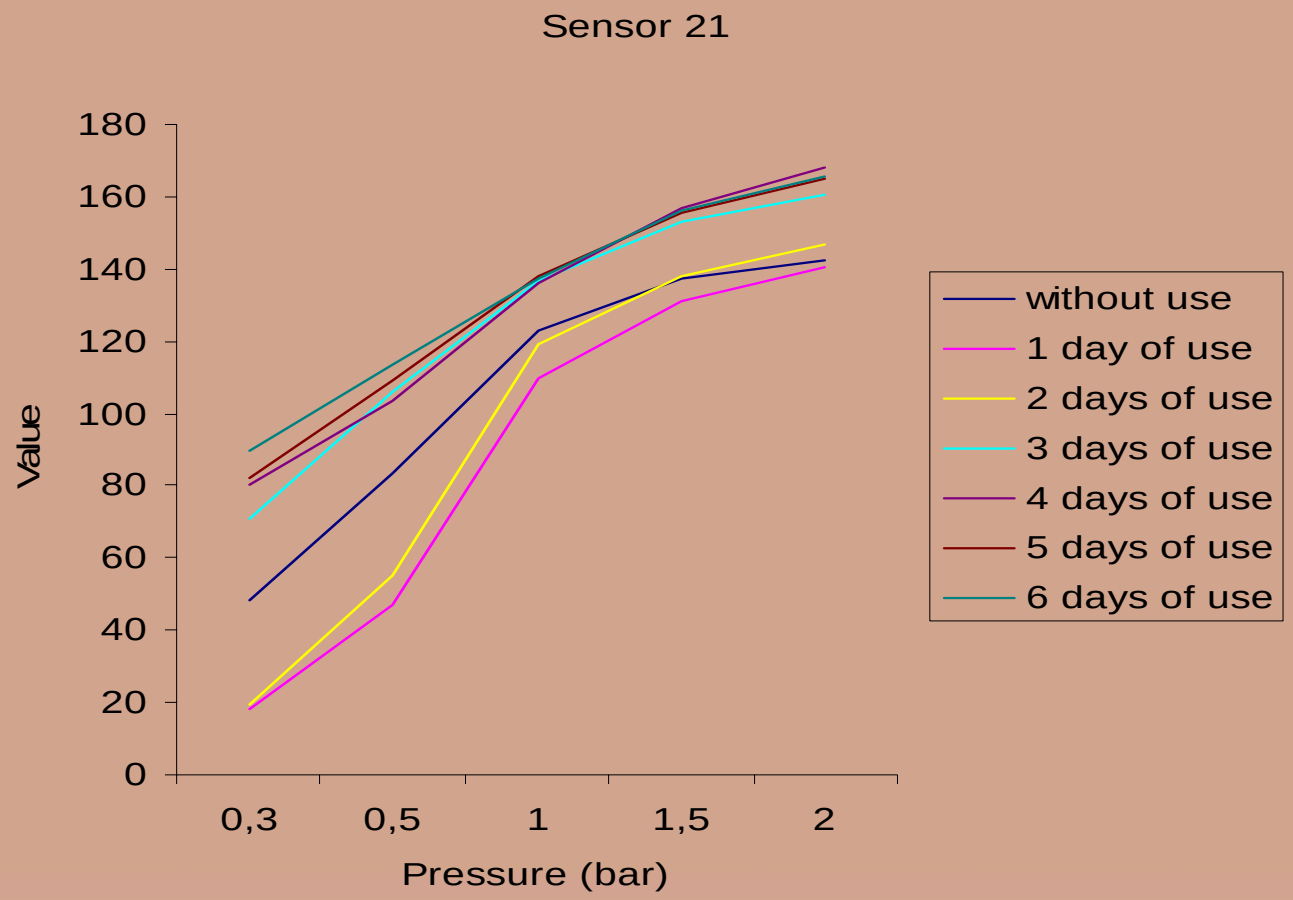
255 rows: one for each output

	1	2	3	4	.	.	61	62	63	64
1	10	33	18	3	.	.	4	10	17	21
2	48	35	24	30	.	.	19	39	31	22
3	57	42	27	35	.	.	24	40	58	33
4	195	163	168	163	.	.	197	195	194	198
.	.	.	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	.	.	.
253	199	180	196	182	.	.	197	203	222	217
254	216	189	240	188	.	.	205	243	224	228
255	218	190	243	202	.	.	238	244	233	234

Real value of the variable

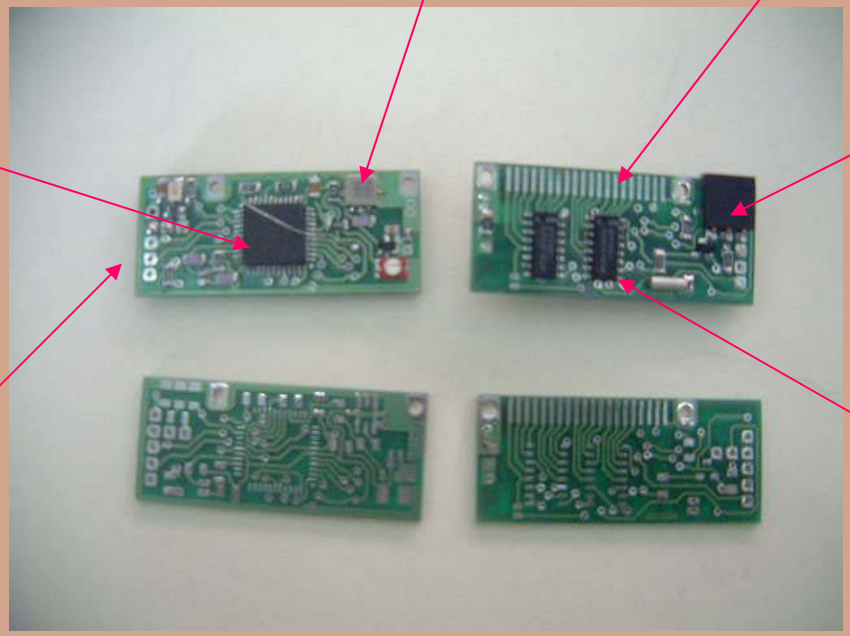
Linearity

- Different days of use
- Different pressures (2; 1.5; 1;0.5; 0.3 bar)



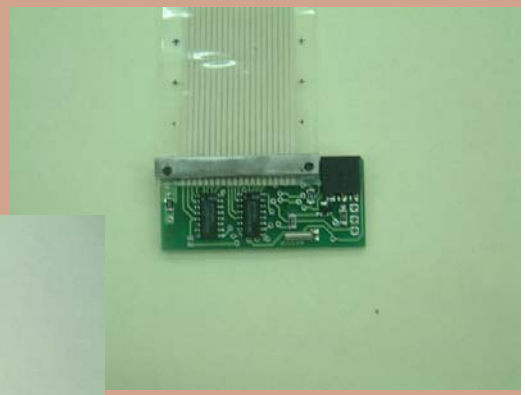
DATA LOGGER 1

- ✓ Conditioning of the signals
- ✓ Analogical ➡ Digital
- ✓ Transmission to Data logger 2
- ✓ 20 x 45 x 5 mm



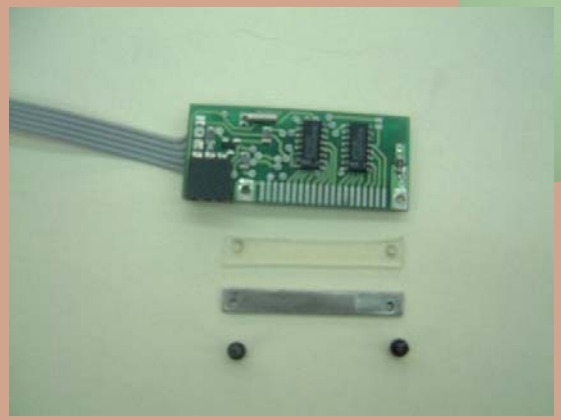
Components of DL 1

- **Analogical-8-channel-multiplexor**
  - 8 analogical signals ➡ 8x8 multiplexor ➡ 64 signals
  - 20 tie lines: 16 for pressure, 4 for temperature
  - CMOS low resistance, SMD format



B. Connector

- sensors-DL 1 connection
- Good electric contact
- High reliability
- Metal sheet + elastic band



Components of DL 1

C. Microcontroller

- FLASH memory, Sequence programming
- Analogical/Digital converter included
- SMD format, Eeprom memory

D. Transmitters

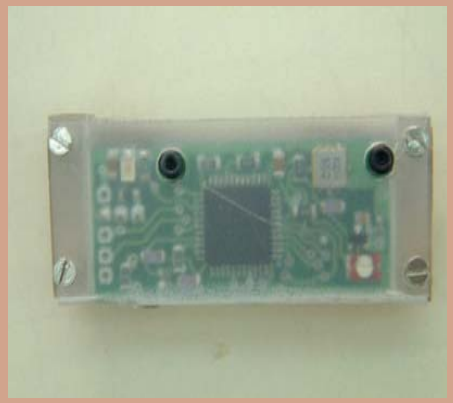
- 433,92 MHz band (free emission)
- SAW (Superficial Acoustic Wave) resonators and a transistor
- 1200 baud
- PDM modulation type

E. Power supply

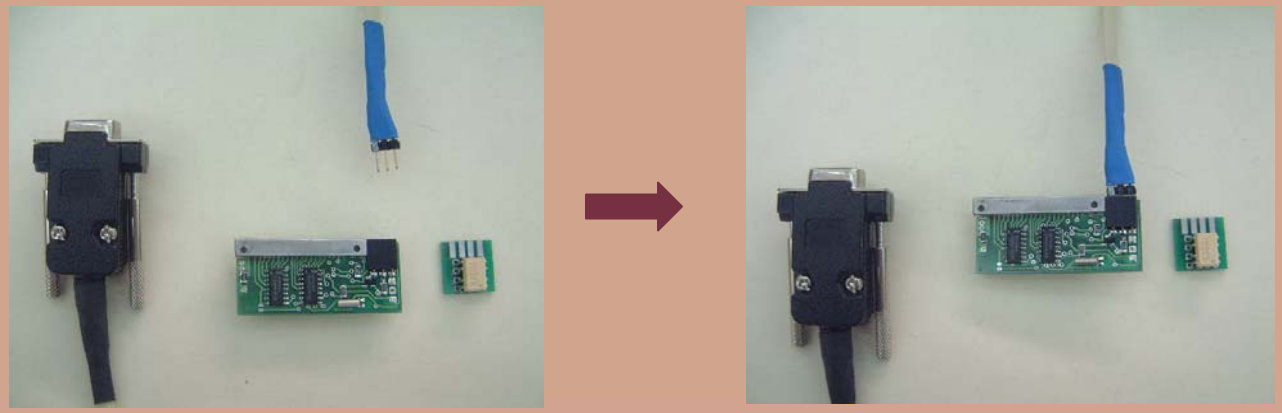
- Lithium battery 3V, 100mAh: 1 transmission ➡ some weeks

Components of DL 1

F. **Protection Box**



G. **Programming connection and RS232 connection.**



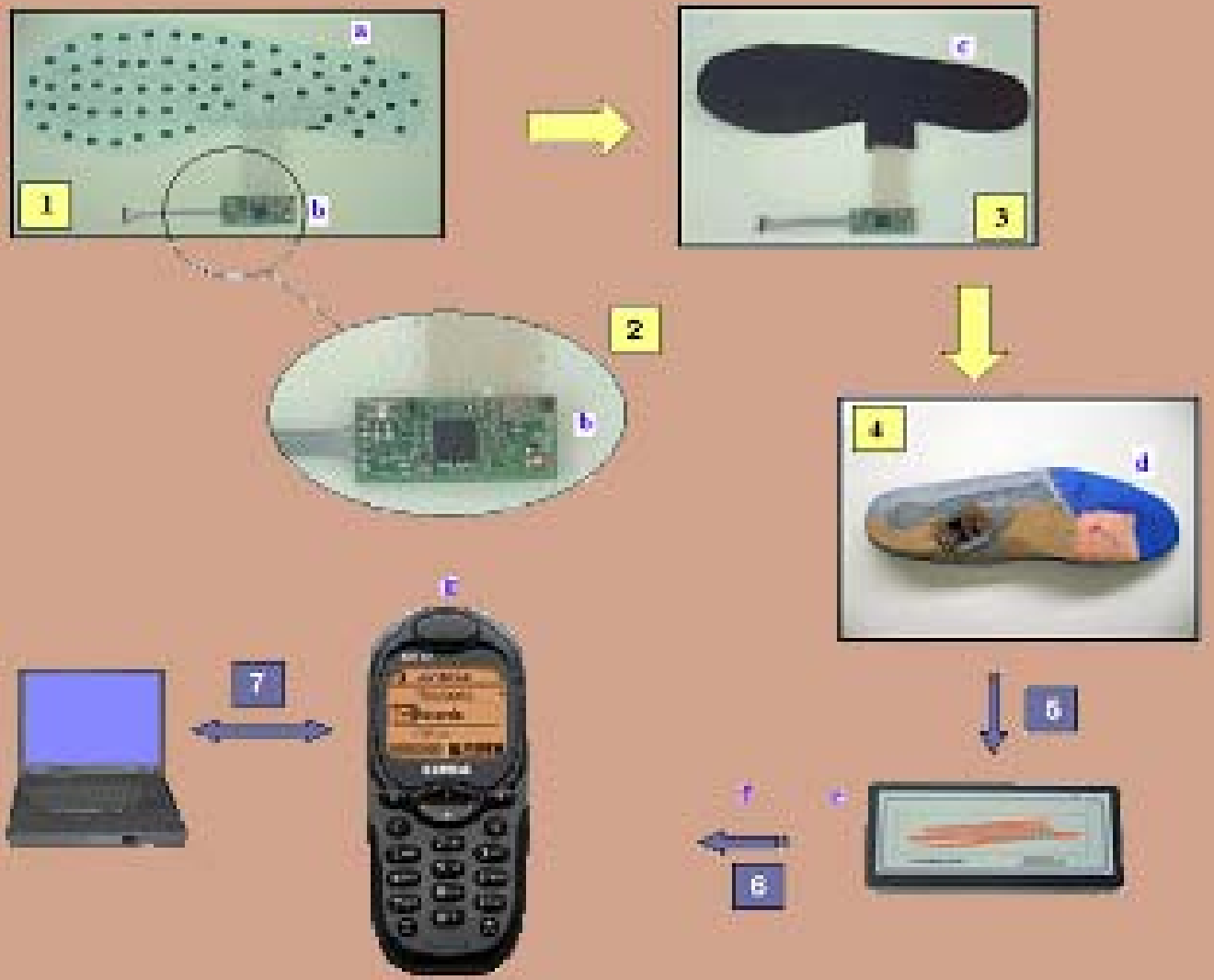
DATA LOGGER 2

- Temporary storage unit
- RS232 connection (speed 19600 Baud).
- Size:130x60x30mm.
- Capacity: 4 Mb
- Minimum range: 1 week
- Tx: 432.92 Mhz transmitter, 50 mW/min
- Rx: 432.92 Mhz receptor, sensitiveness: 2uV/min
- Signal configuration (64+17 bytes)

FF	FF	ID (high)	ID (Low)	FN	1ª	2ª	3ª	4ª	5ª	6ª	7ª	8ª	Values	Year-Month

Day	Hour	Minute	Second	C.S

DIAFOOT system assembling

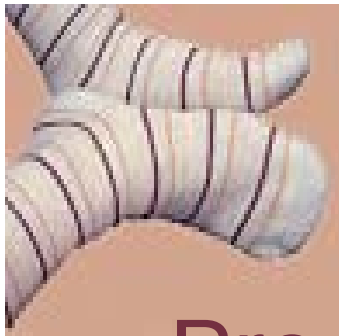


DIAFOOT flexibility

- ✓ Individually connection of sensors
- ✓ Personalized distribution of sensors
- ✓ Individual sensors

Clinical evaluation protocols

- Status
  - ✓ Selected patients (30 Spain+30 Italy)
  - ✓ Evaluation at laboratory (new specifications from medical team)
- Patient selection criteria
  - ✓ General criteria: Age, sex, weight, height, time suffering the illness
  - ✓ Inclusion criteria: insulin-dependence, ulcers for no more than 4 weeks and no infection, neuropathy
  - ✓ Exclusion criteria: deep or multiple ulcers, amputations, serious feet deformity, gait pains



Pre-clinical protocols

- ✓ Comparison: 10 control subjects-10 non neuropathic diabetic patients
  - Bipedestrian standing
  - Walking at normal speed
  - Walking at fixed speed
- ✓ Repeatability: evaluation 3 times
- ✓ Effectiveness in detecting hyper-pressures
- ✓ Reliability of remote-recording and transmission

Clinical protocols

- ✓ Normal volunteers
- ✓ Diabetic with high risk of foot ulcers
- ✓ Diabetic with low risk of foot ulcers

-Total activity (n° of steps/24 h)
-Mean pressure in 24 h
-Mean area in 24 h
-The same parameters/time actually spent of foot. (TASF)
-Pressure/area/24 h
-Pressure/area/TASF
-Pattern of activity

Orthopaedic Insoles Materials

- ✓ Materials' status
  - Great variety
  - Little technological information
  - Lack of objective criteria on uses
  - Low durability
  - High costs
- ✓ Objectives
  - Establish criteria of materials selection for orthopaedic insoles
  - Develop or adapt new materials in order to obtain:
    - High durability
    - Low costs

Characterization of materials

- Materials tested
  - Polyurethane (PUR)
  - Ethylene vinyl acetate (EVA)
  - Polyethylene (PE)
  - Polyvinyl chlorate (PVC)
  - Rubber
  - Polyester Resin

Characterization of materials

- Tests
  - Bulk density
  - Hardness
  - Stiffness
  - Remanent deformation
  - Resilience
  - Compression fatigue
  - Sweat resistance
  - Steam permeability
  - Steam absorption
  - Martindale abrasion

0,2 J

- Shore A
- Asker C
- Asker C2

Dissemination activities

- ✓ Project-presentation CD-video and brochures
- ✓ Articles in journals (leather, footwear, medicine)
- ✓ Publications in national and regional press
- ✓ Local TV reports (VHS format)

- 25 January 2002: “First National Meeting of Specialised Care Units in Diabetic Foot”
- 19-21 April 2002: “II Course of Diabetic Foot”
- 20 July 2002: Seminar DIAFOOT in University Miguel Hernández
- 2 October 2002: Seminar DIAFOOT in Aziende Ospedalaria Pisana

Calendar of activities

WP1: STUDY PHASE 100%

A: Bibliographic study about diabetic foot and treatment protocols

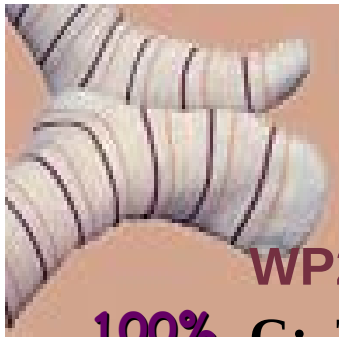
B: Analysis of the information transmission procedure from patients to Hospital

C: Training needs analysis, by direct interviews to medical team and patients

D: Evaluation and harmonisation of protocols for diabetic feet treatment between participating Hospitals

E: State of the art of sensors and other possible variables to be measured

F: Initial cost-benefit analysis



WP2: TECHNOLOGY IMPLEMETATION

100% **G:** To identify potential obstacles to the use of proposed sensor and communications systems in relation to internal procedures, external procedures and patients requirements

100% **H:** Definition of reference parameters for clinical trials

80% **I:** Technology implementation and integration Hospitals-patients

WP3: PATIENT TRIALS

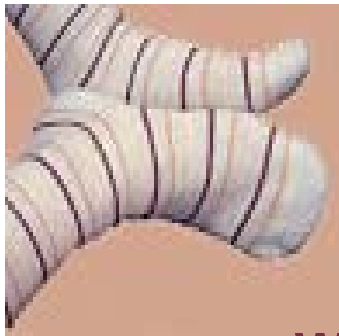
90% **J:** selection of 60 patients between Spain and Italy

40% **K:**clinical tests (30 tests/Hospital) showing the advantages of the technology implemented (dynamic Hospital-patient communication mechanism through electronic data exchange and remote monitoring)

WP4: ASSESSMENT PHASE

0% **L:** Evaluation of results/benefits

0% **M:** preparation of an exploitation plan for each participant of the project



WP5: DISSEMINATION ACTIVITIES AND EXPLOITATION PLAN

100%

N: Definition of a communication and diffusion plan (addressees, "message" and strategy)

90%

O: Execution of diffusion activities (leaflets, seminars, fairs, publication of articles in magazines, press and internet, videos, workshops, etc)

0%

P: Analysis of the possibilities of implementing the results in other health areas

75%

Q: Analysis of mechanisms of knowledge transfer inside the consortium

0%

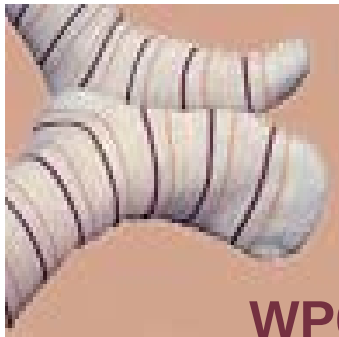
R: Elaboration and execution of an exploitation plan

50%

S: Complete definition of business plan

0%

T: carry out the activities of market prospective and commercialisation of the new products



WP6: TRAINING AND SUPPORT TO COMMERCIALIZATION ACTIVITIES

80% **U:** Elaboration of training material for medical team (management and technical aspects) and patients

80% **V:** Development of training courses

WP7: PROJECT MANAGEMENT

100% **W:** Establishment of management, co-ordination and organisation elements of the project

75% **X:** Definition of mechanisms for conflict resolution

75% **Y:** Project control: short term (each 6 months) and medium term (each 12 months), with the edition of the corresponding progress report

75% **Z:** Quality assurance plan during the development of the project

Deliverables

- D1.1: Integration requirements (28/02/02)
- D1.2: Benchmarking of sensor systems (May 02)
- D1.3:Preliminary analysis of medical and sensor issues (24/02/02)
- D6.1:Training materials (24/02/02)
- D2.1:Demonstration of technology implemented at lab.level (20/07/02)
- D2.2:Dissemination and use plan (02/09/02)
- D3.1:Patient trials. Patient compliance and user acceptance (02/09/02)

D1.1:Integration requirements

Study report consisting of overall design of the system:

- ✓ Developed system features
- ✓ Possible architecture of the system
- ✓ Analysis of already existing products in market
- ✓ Detailed description of integration elements of built system

D1.2:Benchmarking of sensors systems

Study report consisting of the state of the art of pressure sensor technology

- ✓ Fundamentals of pressure sensor technology
- ✓ Pressure sensitive inks
- ✓ Results of laboratory trial (INESCOP) with pressure sensitive ink

D1.3: Preliminary analysis of medical and sensor issues

Survey of available medical issues for pressure measurement

- ✓ Survey of commercial forms in pressure measurement issues
- ✓ Commercial available platform issues
- ✓ Commercial available in-shoe issues
- ✓ DIAFOOT issue under building

D6.1: Training materials

Focused on the skills requires in medical team and patients in order to proper deal with the system

- ✓ Relevance of pressure measurement
- ✓ Features of technology involved
- ✓ User general advice
- ✓ Advantages in treatment protocol when new system implementation

D2.1: Demonstration of technologies implemented and integrated at laboratory level

- ✓ Public demonstration: DIAFOOT seminar in Elche (Alicante-Spain)

D2.2: Dissemination and use plan

- ✓ Definition of elements for the dissemination and exploitation of the technology system.

D3.1: Patient trials.Patient compliance and user acceptance

- ✓ Trials under development: deliverable reviewed after prolongate use of the system by patients

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