A MULTI-PARAMETER LABORATORY-IN-A-PILL DEVICE WITH REAL-TIME DATA PROCESSING

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INRODUCTION

There has been considerable interest in the development of a miniature radio pill and a portable data receiver for non-invasive gastrointestinal monitoring.

In Glasgow, we prototyped a system comprising a Laboratory-in-a-pill device and a base station being capable of real-time pH, temperature and location information acquisition and data processing.

SYSTEM ARCHITECTURE AND ASIC INTEGRATION

A compact ASIC 20 mm in size.
Based on AMS 0.6 μm via Europractice.
Core limited design 9 mm.
Double pad rings for wire bonding.
Encoded data (Manchester coding).

DISCRETE LIAP COMPONENT

- The LIAP component list:
  - Magnetic
  - On-off-keying transmitter (choice 1)
  - Reference electrode (optional)
  - Temperature and pH sensor chip
  - Battery cells
  - On-off-keying transmitter (choice 2)
  - Test port connector

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Access channel  ASIC  Magnet  Battery cells  Test port

COMPLETE LIAP

The LIAP measures 44 mm x 12 mm

The LIAP weighs 8 grams.

Sensor chip  Transmitter (beneath the ASIC)

Encapsulation material using PDMS.

Encapsulation process takes approx. 1 week

5 of 6 encapsulations were successful.

A LIAP and the encapsulation model

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SYSTEM TEST

The LIAP was powered connected into one test solution.

Parameter
Buffered pH solutions  Artificial GI solutions  Artificial GI solutions (high viscosity)

<table>
<thead>
<tr>
<th>pH channel resolution (pH)</th>
<th>0.1</th>
<th>0.4</th>
<th>0.3</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH channel response time (s)</td>
<td>5.5</td>
<td>15.8</td>
<td>2400</td>
</tr>
<tr>
<td>On-capule compression rate</td>
<td>2.9</td>
<td>3.5</td>
<td>2.8</td>
</tr>
</tbody>
</table>

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TEMPERATURE AND pH TEST

Parameter

<table>
<thead>
<tr>
<th>Temperature (°C)</th>
<th>0</th>
<th>5</th>
<th>10</th>
<th>15</th>
<th>20</th>
<th>25</th>
<th>30</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>7</td>
<td>7.5</td>
<td>7.2</td>
<td>7.5</td>
<td>7.8</td>
<td>8</td>
<td>8</td>
</tr>
</tbody>
</table>

Blue curve: temperature channel.
Red curve: pH channel.

- Artificial gastric solution pH 1.2, artificial intestinal solution pH 6.8, environmental temperature 25°C.
- Readings in intestinal solution averaged at pH 5.6 that was lower than the true pH – the deep access and deposit stock of the access channel.

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• ASIC power consumption: 3.9 mW @ 3.0 V.
• Transmitter peak power (ON state): 15 mW.
• An on-capule data compression: 70% power reduction.
• Two SR48 cells => 10h (no compression) => 50h lifetime.
• Detailed tests included the immersion of the LIAP in different solutions over a wide temperature range:
• pH buffer solutions pH 1, 4, 7 & 10.
• Artificial gastric & intestinal solutions.
• Artificial (high viscosity) GI solutions.
• PBS & RO water.
• Temperature ranged 10°C – 50°C using a feedback controllable hotplate.
LOCATION TRACKING TEST

The magnet was moved at approximately 10 cm/min and 150 cm/min, respectively, and the position information from Zortrax was presented below.

The test also showed a location accuracy of ±1 cm was achieved within 25 cm distance. For distance less than 10 cm, better accuracy of ±0.5 cm was achieved.

Since the LIAP is expected to travel in the small intestine at an average speed of 2 cm/min - 5 cm/min, the response time of the location tracking would be sufficient.

CONCLUSION

- Outputs from the 8-month Laboratory-in-a-pill feasibility project:
  - Sensors: proven functionality within buffered and simulated GI environment.
  - ASIC: self-timed, low power consumption, more functionalities could be added.
  - LIAP: low cost encapsulation, size needs further reduction.
  - Base station: being capable of real-time data processing, need to be hardwired.
  - Location tracking: there is a potential (location tracking due to a permanent magnet), but more research are required, e.g. earth field effects when ambulatory.
  - Wireless link: an easy and cheap way to achieve a 10 kbps data link.
  - In the future:
    - Validation of the system performance in real GI tract.
    - Demonstration the safety for ingestion.
    - In vivo trials on animals.