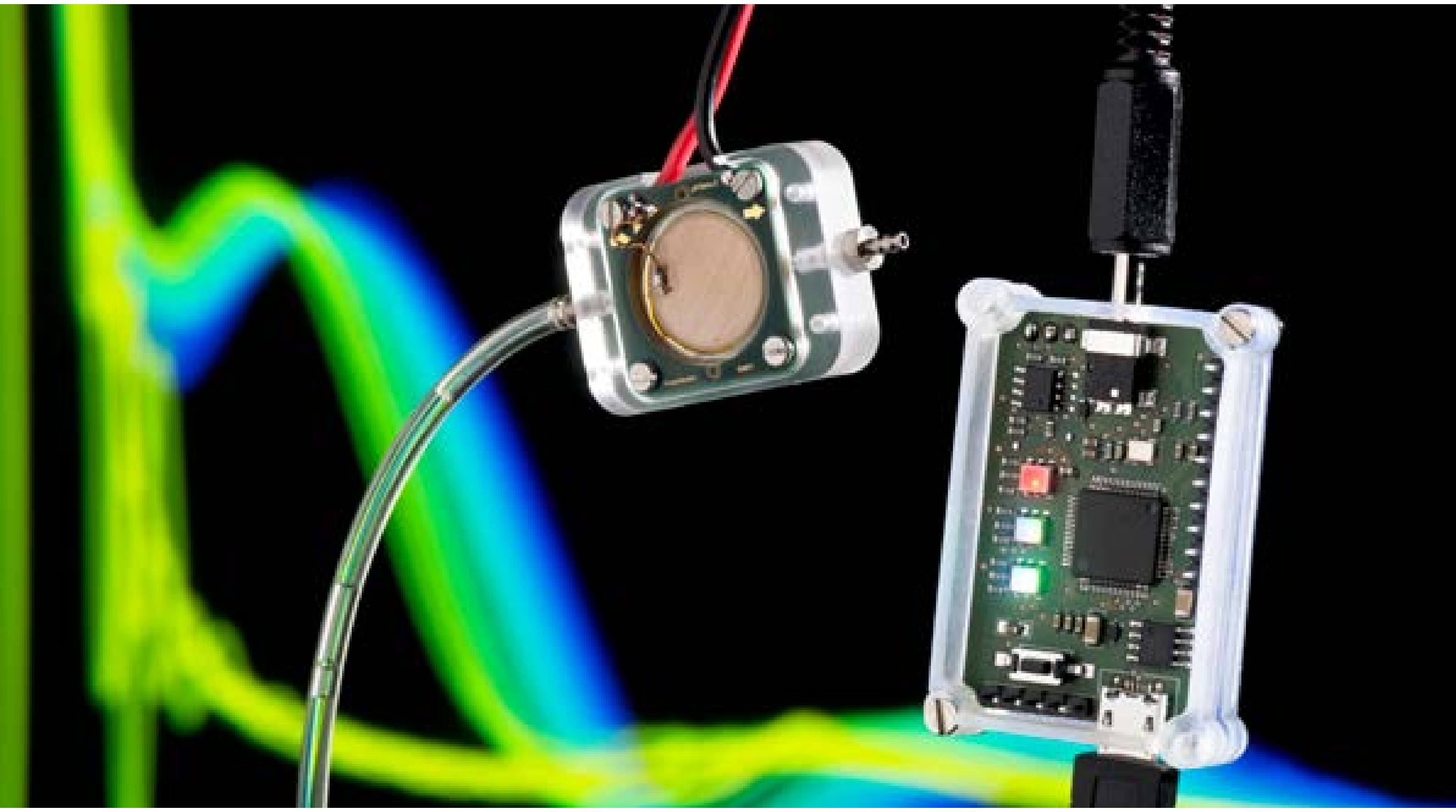

WHITEPAPER

Micropump with Self-Sensing Technology

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For the sake of better readability, gender-neutral spelling has been largely dispensed with in this report. Terms such as employees, customers, partners, etc. naturally always refer to all grammatical genders.

CONTENTS

PART 1 - INTRODUCTION

Challenges of Micropump-based Dosing

Many analysis and processing tasks in medical technology, biotechnology or the chemical industry require the handling of extremely small quantities of liquids. The precise dosing of liquids or gases is a demanding task. Therefore, micropumps are used for these dosing tasks.

To ensure high dispensing accuracy and reliability, it is important to monitor possible malfunctions and failures. One of the main disturbances in microdosing technology are small gas bubbles, which are unavoidable in practical operation. These disturbances can lead to dosing errors or even endanger the safety of patients during drug dosing If the required amount of drugs is not dosed correctly.

There are various options for monitoring microdosing and detecting malfunctions and anomalies, such as bubble detection. However, these require additional external sensors, which makes the dosing system more complex and expensive. This represents a challenge and a broad field of research for scientists who are always looking for innovative solutions.

In this white paper, the Fraunhofer Institute EMFT for Electronic Microsystems and Solid State Technologies presents a new self-sensing technology that will be of great importance for the future of microdosing in medical technology.

Micropump with Self-sensing Technology

Experts at the Fraunhofer Institute EMFT have developed an self-sensing for a piezoelectronic micropump that improves dosing accuracy and reliability and drives the development of new products and technologies.

The pump monitors its own status without additional external sensors and detects anomalies during operation. It provides the status of the dosing system in real time and also offers new savings potential in terms of installation space and manufacturing costs - particularly important for disposable products and small, portable dosing systems. The basis for this innovation is the “piezo micropump” developed by RAPA and Fraunhofer EMFT, which is already successfully ready for series production and available on the market.

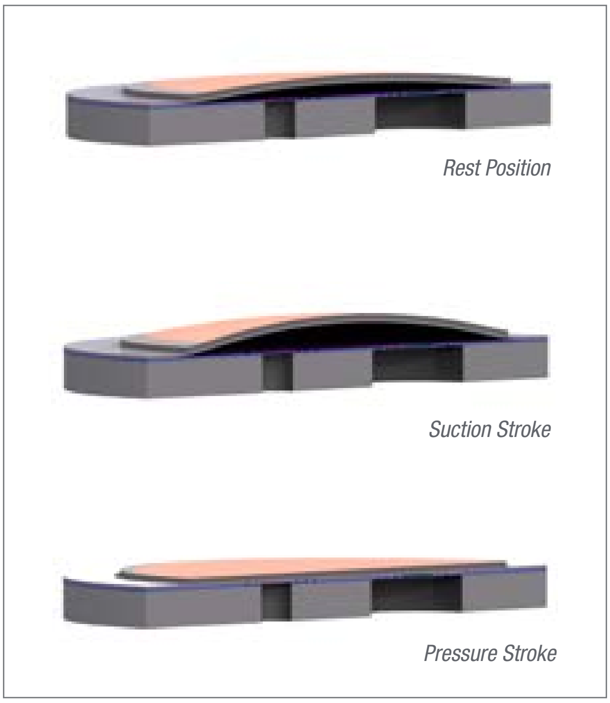
The new self-sensing technology now creates a further customer benefit and increases safety in the application. Artificial intelligence and the piezoelectric effect are used to detect and evaluate the control signal of the micropump. As a result, any gas bubbles that occur and their size can be reliably detected. In addition to bubble detection, this technology has the potential to detect other disturbance variables such as backpressure detection, catheter occlusion or long-term fatigue of the micropump.

The micropump presented was specially developed to comply with the framework conditions. Overall, it can be stated that the present intrinsic sensor concept successfully demonstrates feasibility and provides a solid basis for the practical implementation of specific lead projects. It is planned that RAPA will take over the transfer of this groundbreaking concept to series production readiness as well as the manufacturing.

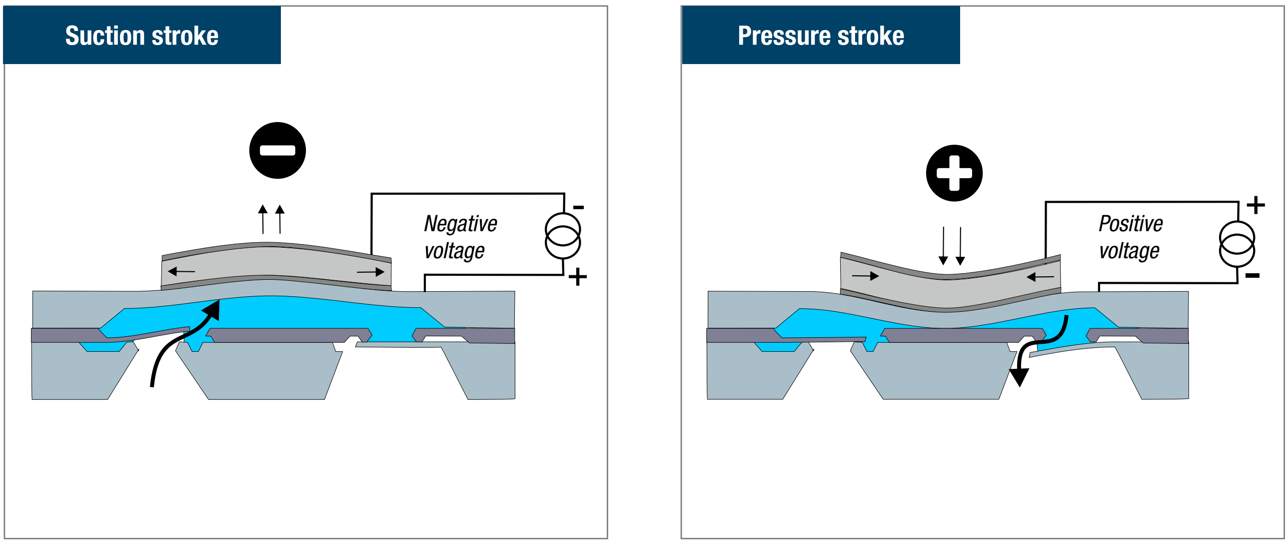
PART 2 - SKIN PART

Fundamentals of the Operating Principle of a Piezoelectrically Driven Micropump

Piezoelectrically driven micropumps consist of several structured layers that form a pump chamber. While the top layer is the drive diaphragm, to which a piezoceramic is bonded at the top, the lower layers form passive check valves, an inlet valve and an outlet valve.



Structure of the RAPA micropump made of stainless steel foils



Operating principle of a piezoelectrically driven micropump consisting of suction stroke and pressure stroke

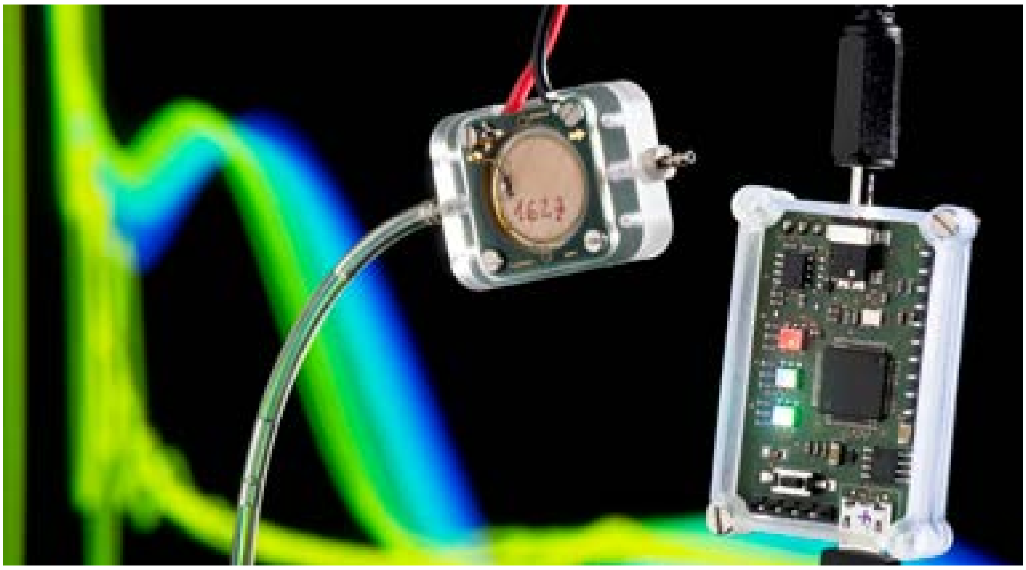
State of the Art for Monitoring Micropumps

One way to monitor a microdosing system or detect malfunctions is to use flow sensors such as anemometers, which can measure pressure differences or changes in capacitance. Flow or pressure sensors can also be used to detect malfunctions. However, one disadvantage is that separate components must be integrated into the microdosing system.

Another approach to detecting faults is the use of sensors in the actuator diaphragm. Special sensors are integrated directly into the diaphragm of the micropump in order to determine, among other things, the stress state of the diaphragm. Alternatively, additional electrodes can be attached to the piezo ceramic. The disadvantages here are that additional contacting is required, that the overall manufacture becomes more complex, and that no direct information about the pneumatic or hydraulic state can be determined. In addition, the sensor technology must be accommodated in critical areas of the micropump where high electrical and high mechanical stresses or tensions prevail.

Another possibility for detecting malfunctions or fault conditions is to use two micropumps connected in series with a piezoelectric element. The two piezoelectrically driven micropumps are connected in such a way that one of the two pumps is in operation while the other is inactive. The effect of the fluidic signal of the active micropump is now detected by the sensor characteristics of the piezo element of the switched off second micropump.

In this case, too, an additional sensor element is required in addition to the micropump, in this case in the form of a second micropump. Furthermore, the fluidic signal of the micropump is influenced by the fluid tubing between the two micropumps and no longer represents the process in the pump chamber of the active micropump. It would therefore be desirable to improve existing systems for fault detection and condition monitoring of micropumps so that no additional sensors or electrodes are required. It would also be desirable that the micropump does not have to be specially controlled, but that condition monitoring can take place during regular operation.



Prototype of a piezoelectric diaphragm pump with the driver circuit on the bottom and the intelligent control unit on the top.

Solution Approach Self-Sensing

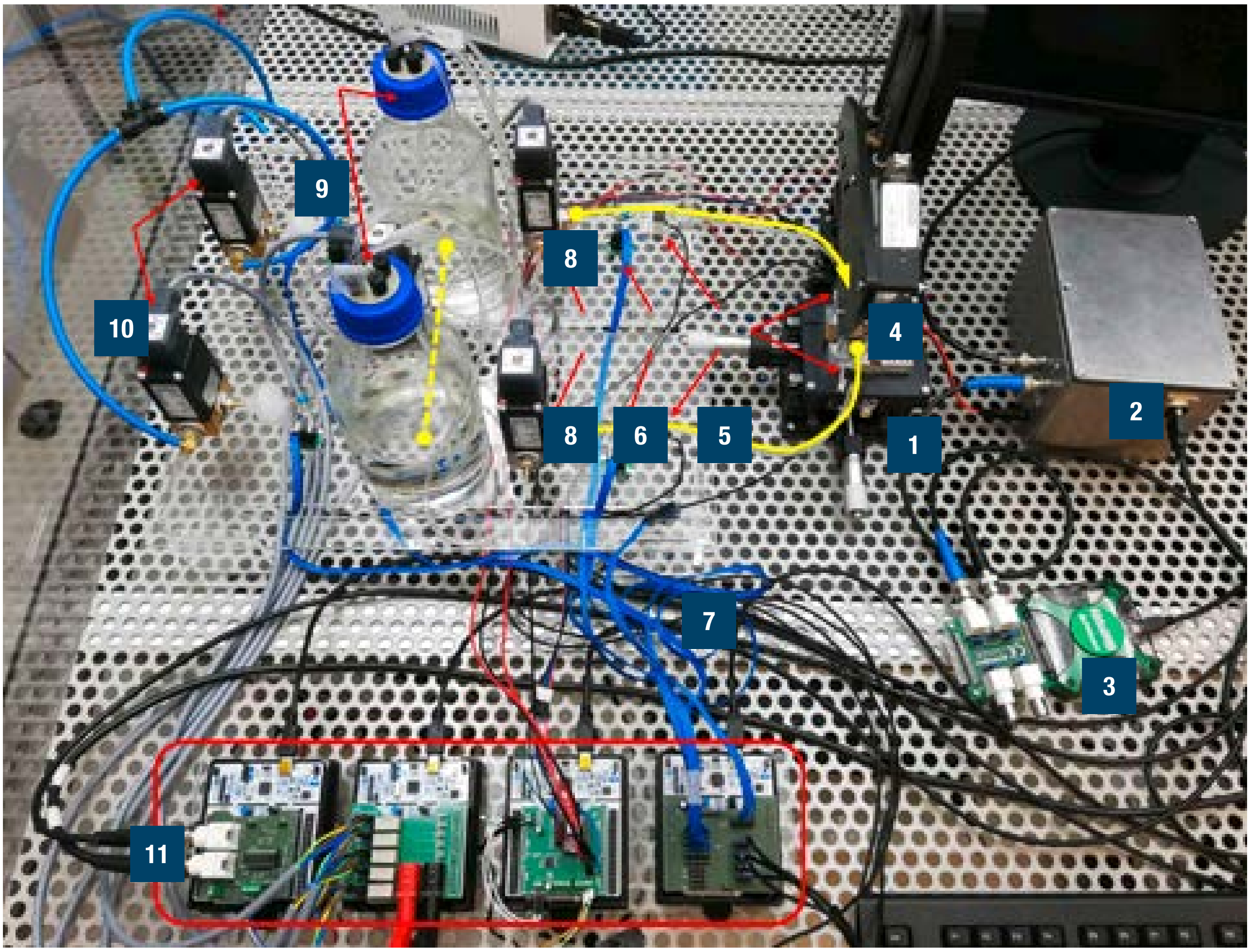
Classic piezoelectric actuators use the indirect piezoelectric effect to cause a mechanical deflection induced by an electrical control signal. In contrast, piezoelectric sensors use the direct piezoelectric effect to obtain an electrical signal from a mechanical deformation. In addition to the indirect piezoelectric effect (actuator), the Fraunhofer EMFT smart pump also uses the direct piezoelectric effect (sensor) in the same pump to achieve the desired self-sensing capabillity.

Due to the fluid-mechanical couplings of the system, the sensor current modulates the charging current in a variety of ways so that various system states produce a characteristic “fingerprint” in the “self-sensing” signal. To obtain this additional information, the self-sensing signal is measured by a load-free amplifier circuit. ML algorithms are used to analyze and evaluate the diverse and complex signal shapes. These are integrated directly onto the driver circuit of the piezoelectric diaphragm pump, minimizing the increase in footprint of the entire circuit. Furthermore, additional pressure and air bubble sensors can be omitted, which further reduces the size and system costs.

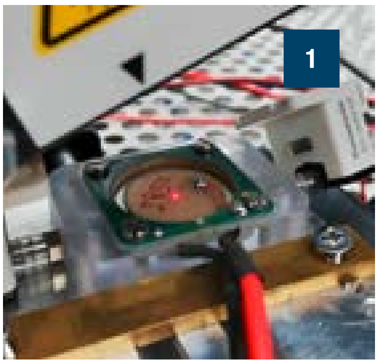
For application-oriented use of the self-sensing property, the ML algorithms are trained with suitable measurement data. This training data is generated at a measuring station at Fraunhofer EMFT that was developed specifically for this purpose. In this way, various fault conditions, such as a change in viscosity, air bubbles, changes in system pressures, clogging and electronic faults, can be specifically generated and clearly assigned to the measurement signal.

The ML algorithms are trained with the data obtained in this way on a high-performance computer and optimized for runtime and memory utilization. The original driver circuit of the micropump is extended with these ML algorithms and is thus able to recognize complex system states and react accordingly.

Due to the controlled production process of RAPA, the scatter of the pumps is so low that an ML algorithm generated once is also used for pumps of the same generation produced later.



AI training station for micropumps



1	Piezoelectric diaphragm pump
2	Self-Sensing Electronic
3	Oscilloscope for measuring the sensor current
4	Optical distance sensor for measuring the diaphragm deflection
5	Air bubble sensors
6	Pressure sensors
7	Temperature sensor
8	3/2 way valve for changing the pumped medium
9	Inlet and outlet reservoir
10	3/2 way valve for changing between ambient pressure and pressure controller
11	Electronics for controlling the actuators, sensors of the measuring station
12	Not shown: function generator, piezo amplifier, pressure controller, DC power supply, desktop PC

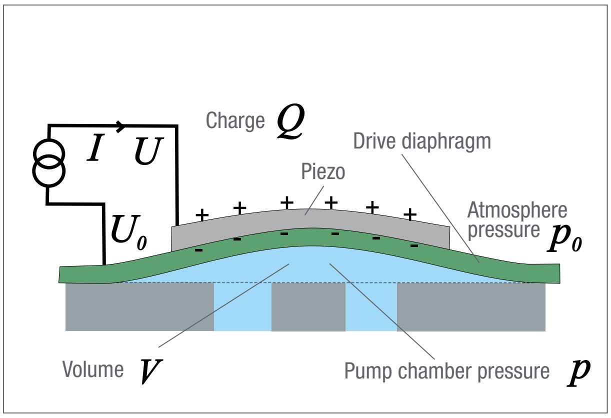
Theory of Electromechanical Coupling of Micropumps

The time-dependent signal of interest is already inherent in the piezo drive and has been extracted from the drive signal by a suitable measurement circuit and signal evaluation, without the need to change the micropump or the voltage amplitudes.

The piezoelectric diaphragm of the micropump exploits the indirect piezoelectric effect *(equation 1)*. By applying an electrical voltage *U*, a volume *V* is displaced, the scaling factor is the volume coupling coefficient C_E*. At the same time, there is also the direct piezoelectric effect *(equation 2)*.

A change in voltage *U* changes the charge *Q* on the piezoceramic, scaled by the electrical capacitance C_{el}. The pump chamber pressure *p* under the diaphragm influences both equations: in the indirect piezoelectric effect, a change in pump chamber pressure shifts additional volume *V* (scaling factor here is the fluidic capacitance C_p), whereas in the direct piezoelectric effect, a pump chamber pressure change additionally leads to a change of charges *Q*, which is scaled by the volume coupling coefficient C_E*.

The figure on the following page shows an example of a transient current signal for the suction stroke as it occurs in a metal micropump. Since this current signal *I (p,U)* represents the simple derivative of *Q (p,U)* with respect to time *(equation 3)*, it contains a lot of information about disturbances. The following parameters influence the time-dependent pump chamber pressure *(equations 4 and 5)*.



This signal occurs during each pump cycle, both during the suction stroke and the pressure stroke. The rather "uninteresting" charging current I_U, by far the largest component (amplitude approx. 100 mA), disappears within one millisecond with the electrical time constant $\tau = R_{el}\, C_{el}$. After that the "interesting" intrinsic sensor term I_p , superimposed on the piezo big signal current $I_{piezo,1} + I_{piezo,2}$. For this reason, the electronics truncate all current amplitudes above one mA to accurately amplifies the interesting part of the sensor current.

When the micropump is operated at 10 Hz per second, 20 "fingerprints" of the processes in the pump chamber are obtained, one each for the suction and pressure strokes. In the following, the "fingerprints" of a gas bubble located in the fluidic system are discussed. Between the individual curves there is a time of 100 ms in which a pump stroke with a stroke volume of 6 µl was performed.

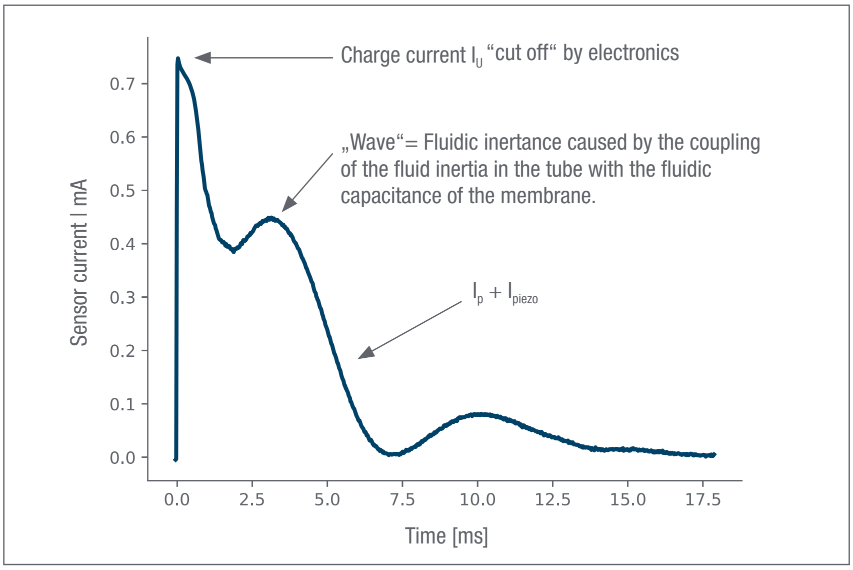
1
$$Q(p,U) = C_{el}(U - U_0) + C_E^*(p - p_0)$$

2
$$V(p,U) = C_p(p - p_0) + C_E^*(U - U_0)$$

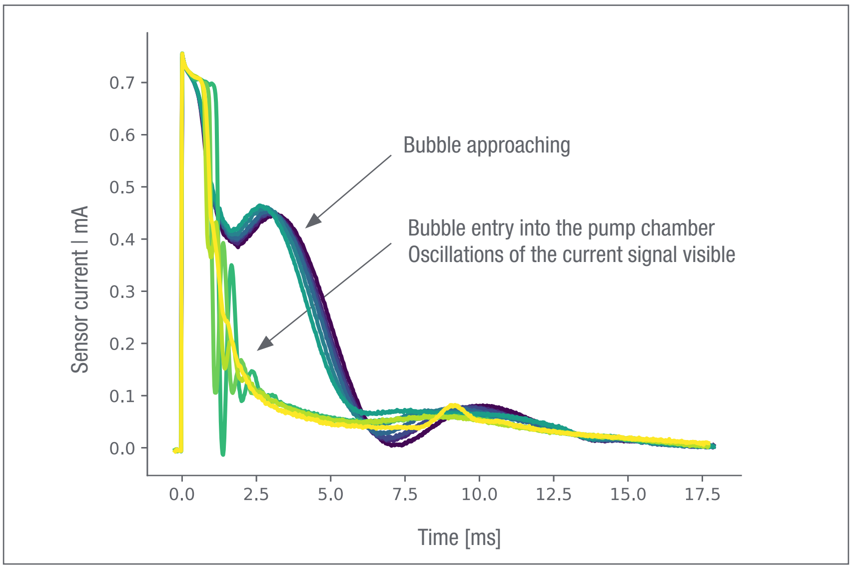
3
$$I(p,U) = \frac{Q(p,U)}{dt}$$

4
$$I(p,U) = C_{el}\frac{d(U-U_0)}{dt} + (U - U_0)\frac{dC_{el}}{dt} + (p - p_0)\frac{dC_E^*}{dt} + C_E^*\frac{d(p-p_0)}{dt}$$

5
$$I(p,U) = I_U + I_{Piezo,1} + I_{Piezo,2} + I_P$$



Transient current signal for the suction stroke: characteristic signal curve of a metal micropump during the pressure stroke when pumping water with the operating frequency 10 Hz.



Several waveforms of the intrinsic sensor signal during the passage of an air bubble through the micropump during the pressure stroke when pumping water at the operating frequency of 10 Hz. It can be seen that due to the coupling of fluid inertia in the tubing and fluidic capacity, the bubble is detected by the intrinsic sensor system before it reaches the pump chamber. After entering the pump chamber, the signal changes significantly, oscillations occur. In this case, these rapid changes were measured for three pump cycles before the bubble leaves the pump chamber.

> Cooperations between companies and science generate added value for both sides in order to develop a marketable product from applied research.
>
> *Dr. Martin Richter*

Concept of Micropump Monitoring

Time-dependent fluidic and mechanical processes in a pump chamber can be measured by precisely measuring the drive signal of the piezoelectric actuator, which is required for the regular drive of the piezoelectric actuator anyway. This makes the concept extremely advantageous, since no changes have to be made to either the components of the micropump or the actuation itself. It is sufficient to simply integrate the corresponding measurement function into the driver electronics of the micropump in order, in combination with the above-described data acquisition and -evaluation to obtain relevant data.

With this concept, information can be extracted from the regular actuation signal, purely electrically and without any additional sensors, and in real time, which shows how the piezo actuator interacts with its environment. From this information, further relevant fluidic changes can be read. For example, a change in backpressure allows conclusions to be drawn about clogging and/or external mechanical effects on the dosing system.

The status of the micropump can therefore be monitored on the basis of a signal evaluation of the temporal course of the control signal. This means that the micropump can monitor itself during operation, and in particular during regular operation, without individual calibration of the individual pumps.

Dr. Martin Richter, Head of the Department for Microdispensing Systems at Fraunhofer EMFT in Munich, concludes: “With this system extension, we are entering new areas of accuracy and application functions such as operation monitoring or data logging. Together with RAPA Healthcare, we want to quickly transfer the new technology into application”.

PART 3 - RAPA PIEZO-MICROPUMP

Technology and Performance Data

The micropump was developed and manufactured in close collaboration between the Fraunhofer Institute EMFT and the company Rapa Healthcare. The Fraunhofer Instute EMFT contributed its in-depth expertise and many years of experience in microsystems technology and sensor technology and developed the original concept of the micropump. Rapa Healthcare, as an experienced development and supply company in the field of medical technology, has taken the necessary steps to further develop the concept and make the micropump ready for series production. The result is a high-quality micropump that meets the requirements of various industries and is available on the market. RAPA Healthcare ensures that the micropump is produced reliably and in high quality.

The micropump is based on advanced piezo technology and features outstanding characteristics:

- Extremely durable
- Excellent back pressure characteristics
- Large bubble tolerance

Another major advantage of the micropump is its adaptability to customers' specific requirements. The technological parameters such as metering accuracy, counter-pressure stiffness, size, energy consumption, particle resistance, bubble tolerance and "free flow" protection can be flexibly adapted to individual requirements.

The fields of application of the micropump extend to both the medical and industrial sectors, making it an extremely flexible solution.

Fields of Application in Medicine

- Dosing of "biologicals" such as monoclonal antibodies, also with higher viscosity
- Patch pumps for biologicals in home care applications
- Negative Pressure Wound Therapy (negative pressure therapy for wound treatment)
- Portable blood pressure monitors
- Pharmacology, for example drug dosing systems
- Diagnostics
- Pain therapy with PCA systems (patient-controlled analgesia)
- Lab-on-chip systems
- Dosing of rinsing liquids
- Intelligent inhalation systems

Fields of Application in Industry

- Sample feeding for gas sensor systems
- Fragrance metering systems (olfactometers, training systems, consumer, automotive)
- Microcooling systems
- Metering modules for fuel cells
- Laboratory technology (e.g. air cushion pipetting, microplate dispensing))
- Dosing systems for aroma mixtures

For more information and the technical data of the micropump, visit www.rapa.com

> **The application-specific development adaptation of the micropump is inevitable in most cases. As a specialist for valves and fluid technology, RAPA Healthcare's expertise lies particularly in transferring concepts to product and series maturity.**
>
> *Jörg Manzer, Managing Director RAPA Healthcare*

Conclusion

The new intrinsic sensor concept shows that the integration of this innovative technology into the micropump brings numerous advantages. To this end, RAPA Healthcare is actively working with interested companies to establish concrete development projects in which the enhanced functionalities and disruptive properties of the micropump's intrinsic sensor technology can be used.

Philipp Höllein, project manager in the development of the micropump at RAPA Healthcare, emphasizes the established procedures and processes for cost-effective manufacturing of pumps with high accuracy and quality to realize both small and large volumes. The control electronics were designed by Rapa Healthcare, made ready for series production, and can now be easily expanded to include the few components needed for intrinsic sensor technology. The new developments from Fraunhofer perfectly complement RAPA Healthcare's existing micropump portfolio. By integrating the intrinsic sensor concept, expensive components such as separate sensors can be saved.

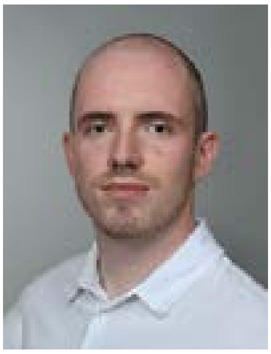
At this stage, many applications of the new technologies are difficult to predict. One thing is certain, however: they will offer our customers many opportunities and benefits. The innovative solution enables early detection and reporting of malfunctions. The micropump can transmit more detailed operating parameters and messages to the device electronics. The integration of the self-monitoring concept thus opens up a wide range of applications in micropump technology.

Outlook Microdosing Systems

The trend towards miniaturization and microtechnology in medical technology will continue in the coming years, driven by the increasing demand for personalized therapies and the need to reduce costs. Micropumps in particular play an important role in drug dosing by enabling precise and controlled delivery. The applications of micropumps are diverse, ranging from microfluidics, microanalytics and microreaction technology to pain management and the development of new drugs and therapies.

One challenge in the development of microdispensing systems is adapting to different customer requirements and flexibility to meet the current trend of cost-saving in the healthcare industry. Nevertheless, the industry is expected to make great strides in the coming years, and innovative microdispensing systems are expected to open up new opportunities for improved therapy management and reduced treatment costs. Overall, miniaturization and the targeted application of microtechnologies will revolutionize medical technology, and the development of microdispensing systems will remain a driving force for the industry.

AUTHOR TEAM



Dr. Martin Richter
Head of the Department
for Microdispensing Systems
Fraunhofer EMFT

T +49 89 54759-455
martin.richter@emft.fraunhofer.de

Kristjan Axelsson, M.Sc.
Research Associate
Fraunhofer EMFT

T +49 89 54759-454
kristjan.axelsson@emft.fraunhofer.de

Philipp Höllein
Product Developer R&D
RAPA Healthcare

T +49 9287 884-530
phoellein@rapa.com

GET IN TOUCH

We hope that this white paper has helped to give you an insight into the world of microdispensing systems and in particular micropumps in medical technology. If you have any further questions or need a specific application for your microfluidic challenge, our experts are here to help.

Contact us today to find a solution together. If you are interested in the micropump and working with Rapa Healthcare, please feel free to contact us as well. We look forward to hearing from you and discussing your requirements.

HELPFUL LINKS

On the following pages you will find further helpful and interesting information.

Explainer video micropump
www.emft.fraunhofer.de/de/forschung-entwicklung/mikropumpen.html
https://youtu.be/lb_7_MpV5Jo
Data sheet micropump
www.rapa.com/de/wp-content/uploads/Datenblatt_Mikropumpe_A4_10_2021_DE_Web.pdf

CORPORATE INFORMATION

About Fraunhofer EMFT

The Fraunhofer Institute for Electronic Microsystems and Solid State Technologies (EMFT) specializes in the precise metering of gases and liquids in the nanolitre range in its Micro-Dispensing Systems business unit. In doing so, the institute has developed outstanding expertise in the design of micropumps, which is unique worldwide. Technological parameters such as dosing accuracy, backpressure stiffness, size, energy consumption, particle resistance, bubble tolerance and "free flow" protection are adapted to specific requirements. This expertise is used to develop new key components in various fields such as medical technology, industry and the consumer market. Fraunhofer EMFT offers a portfolio of silicon, stainless steel and titanium micropumps for various application areas. One focus is on the miniaturization of silicon micropumps, with the aim of reducing manufacturing costs and facilitating access to mass markets. The institute has developed the world's smallest silicon micromembrane pump with dimensions of 3.5 x 3.5 x 0.6 mm^3.

In addition to micropumps, Fraunhofer EMFT's R&D portfolio also includes a wide variety of microdispensing components and the team has extensive systems expertise. Microdispensing technology as a cross-sectional technology requires broad knowledge in various fields such as fluid mechanics and surface physics or chemistry to ensure smooth interaction of all components.

Fraunhofer EMFT München
Hansastrasse 27d
D-80686 München
T +49 89 54759-0
F +49 89 54759-100
contact@emft.fraunhofer.de
www.emft.fraunhofer.de

About RAPA Healthcare

RAPA Healthcare is a wholly owned subsidiary of the RAPA group of companies based in Selb (Bavaria), which has subsidiaries in the USA and China. The medical technology division produces application and customer-specific components or complete assemblies for the international medical technology market, such as solenoid valves and fluidic systems. However, RAPA Healthcare not only acts as a supplier to well-known manufacturers, but also participates in innovations as a development partner.

RAPA products play an important role in the manufacture of medical technology and analytical equipment as well as biomedicine or in pneumatic and hydraulic integration solutions. The fluid technology components are used, among other things, in fluid control to precisely control gases and liquids, meter the flow or regulate the pressure. All components can be adapted to specific customer requirements.

RAPA Healthcare operates internationally and is headed by Jörg Manzer as Managing Director. All necessary accreditations and certifications for the medical market are available - including the important EU-harmonized standard ISO 13485. For more than 20 years, RAPA has already been a supplier for media-separated valves used in dialysis machines of the market leader Fresenius Medial Care.

RAPA Healthcare GmbH & Co.KG
Albert-Pausch-Ring 1
D-95100 Selb
T +49 9287 884-0
F +49 9287 884-223
healthcare@rapa.com
www.rapa.com/healthcare

Fraunhofer EMFT München
Hansastrasse 27d
80686 München | Germany
www.emft.fraunhofer.de

RAPA Healthcare
Albert-Pausch-Ring 1
95100 Selb | Germany
www.rapa.com