Development of the Silicone-Based *B-FIT* Microfluidic Platform
(A Bio-Flips Integrable Transdermal Microsystem)

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Abstract

The early stages of the body's physiological response to either health or environmental trauma can be a useful diagnostic measure for the early detection of stress and a method for determining the appropriate "first response" for the maintenance of well-being. However, current diagnostic tools are typically large, expensive, and laboratory intensive for monitoring an individual's state of health. Recent advances in microfabrication technologies will allow the creation of novel chip-scale devices capable of non- or minimally invasive, real time sensing of biomedical conditions. The development of the Bio-Flips Integrable Transdermal Microsystem, or B-FIT, will be a major advance in this direction providing an enabling technology for transdermal sampling of molecules that do not normally diffuse across the skin. B-FIT will serve as a prototype for biomedical monitoring and is foreseen to be used by individuals with high health risk such as those exposed to environmental hazards, have predisposed health conditions, or need to be monitored following illness. Additionally, the device is envisioned for use by soldiers who, under extreme environmental conditions, can act as mobile early-warning sensing units. The prototype microsystem will be demonstrated for safety and efficacy by sampling glucose as a stress indicator. However, the platform being developed will be applicable to a large variety of applications, limited only by the identification of proper biological markers and the ability to sample them transdermally.

The B-FIT Microsystem is a micro-fluidic sampling system coupled with a thermal ablation microdevice enabling body analyte sampling at the Stratum Corneum (SC)/Viable Epidermis (VE) interface without invasive extraction of interstitial fluid. The thermal micro-heaters will be used to create pores in the dead skin layer (SC) while perfusion of the bio-molecules will be used as the non-inflammatory collection strategy. The device will be in the form of a patch comprising the transdermal transfer system (TTS) that forms the core component of B-FIT. The TTS is formed by two sub-component systems: 1. the microfluidic subsystem (MFS) that includes a fluid reservoir for perfusion and a capillary path for fluid transfer, and 2. the thermal perforation subsystem (TPS) including micro-ablation heaters and capillary seals/valves. The complete integrated microsystem includes the TTS sandwiched by the glucose detector patch (GDP) on top, and the adhesive dermal interface (ADI) on the bottom, allowing attachment of B-FIT to the skin. The B-FIT microsystem incorporates colorimetric detection allowing fast information transfer to a health care provider or individual user. These components have been illustrated in Fig. 1, showing the 3 major states of transdermal transfer operations.

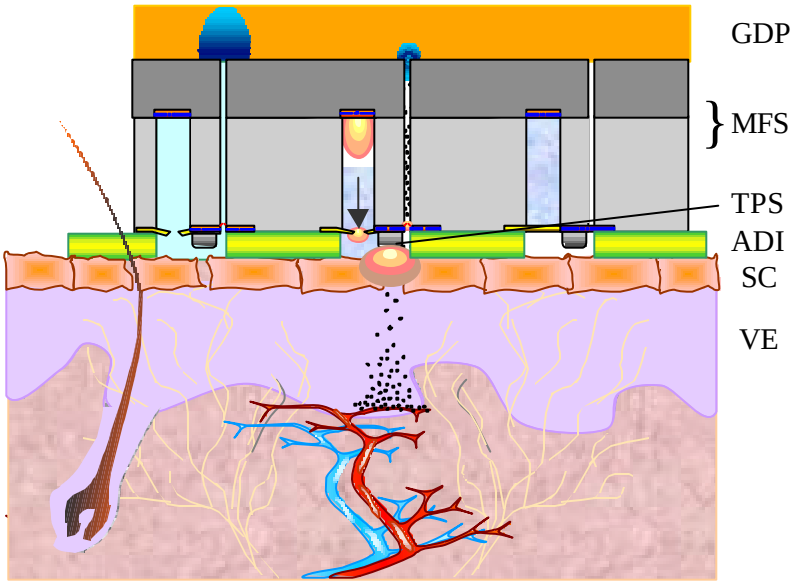

Fig. 1. *The B-FIT mSystem shown on the skin, including the stratum corneum and viable epidermis.*