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MEDICAL DEVICES MANAGEMENT SYSTEM BASED ON BLOCKCHAIN TECHNOLOGY

BY

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Abstract. The recent use of digital Distributed Ledger Technology (DLT) in the healthcare domain can surpass the existing limitations in the centralized IT systems, such as the lack of security, access control or immutability of the electronic health information. If we discuss about clinical information, this innovative informatics advance gives back the control to the data owner. In decentralized environments, smart contracts allow trustable agreements grounded by irreversible transactions, which permit transparency and traceability. Moreover, smart contracts are the living heart of the decentralized applications that run on DTL. In this work, our attention is focused on medical equipments that helps health staff to diagnose and treat patients keeping much of their clinical data taken in dynamics. Hence, we propose a smart contract-based decentralized application framework for the management of devices, targeting also medical services, meant to facilitate the interaction of the involved entities. Our testing environment is the Ethereum platform, extensively used recently in the healthcare domain, being itself a smart operating system that allows decentralized applications to run on it.

Keywords: blockchain, medical devices, management system, smart contract.

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1. Introduction

Digitalization is a must for the current healthcare approach and a step forward is interoperability which empowers the medical assets integration and data sharing a standardized way. It is well known that medical data may take different patterns depending on the vendor framework and clinical information core application models used to format and store the information. Moreover, the lack of integration of all clinical tools shows an increased level of complexity overburdening the medical personnel finally creating serious workflows roadblocks. Therefore, the adoption of well-known healthcare standards must be dealt with uniformly to ensure information exchange between entities in an appropriately structured data format. Here, it is worth to say that Health Level 7 Fast Healthcare Interoperability Resources standard (HL7 FHIR) (https://www.hl7.org/fhir/) brings closer all the necessary resources that all these reasons be possible. Moreover, to make things easier, an application programming interface is made available to facilitate the access to data interchange formats (www.ncbi.nlm.nih.gov/books/NBK22862/#).

Recently, blockchains and digital smart contracts (SC) in the context of FHIR standards, have stirred a great interest in the healthcare ecosystems, mainly for enabling new possibilities for clinical data dispensing and control (Zhang *et al.*, 2018). If is to think in terms of a traditional clinical data distribution systems, this innovative technology approach bring significant advantages for all the involved parties: patients, personnel and healthcare providers, companies from the supplier chains, or insurance agencies in terms of safety of the access and control of the medical information, claims and management of processes.

Moreover, in our days the digitalization of healthcare institutions is a fact, requiring transparency of medical data storage transactions (Omar *et al.*, 2021).

2. Related Works

The advantages of SC have been acknowledged and there are many reasons to include them in the whole chain of processes in the medical field. Firstly, the blockchain business logic ensure a safe and secure connectivity between actors (*i.e.*, patients, medical personnel, institutions, etc.). For that, the field of digital services has been extensively explored from a electronic medical records (EMR) point of view. It is the case for MedRec a blockchain-based architecture using smart contracts designed to tackle the safe access of the patients to their medical clinical data The patient is in direct relationship with healthcare providers and his agreement to access the clinical data is mandatory. The method considers the interoperability principles for data exchange from different sources reveling the advantages of decentralization (Azaria *et al*., 2016). In the same time efforts have been made to handle medical records keeping at the same time flexible the full information availability regarding the medical

workflows. In this way they have been shaped various clinical procedures from the consultation process, issuing medical prescription, tackling the formalities in the closed source pharmacy chain to the surgical decision algorithm (Khatoon, 2020; Aleksandr *et al.*, 2019).

At the same time keeping safe the healthcare data has been a concern of many research initiatives. Different approaches consider the degree of trust between different actors in regards of sharing clinical information. Hence, progressive provisional progressive blockchain and attribute-based access control solutions have been proposed (Jagtap *et al.*, 2021; Zaidi *et al.*, 2021). Not the least, incentive mechanisms having the patient centric frameworks have been proposed starting from the patient device link and finalizing with the medical prescription process (Litchfield *et al.*, 2021). However, at the medical processes scale, blockchain-based approach has proven its well-known attributes. Recently attempts have been made to store the clinical information history using the blockchain network operated cloud storage (Quasim *et al.*, 2020). The approach is particularly effective with the perspective of have large volumes of sensitive medical records and device generated patient data warehoused in a decentralized management environment. On the other hand, different studies had a different approach for the application of the blockchain in the healthcare field storing genomic, pharmacologic effects or Covid-19 patient information providing in the same time scalable solutions for querying the data (Gürsoy *et al.*, 2020; Rimsan *et al*., 2020).

Nevertheless, many of the studies regarding the application of the blockchain in healthcare field are following somehow the same pattern, namely: mainly regarding clinical information protection, clinical data storage on the blockchain proposing various frameworks or DApps (decentralized Applications) or medical workflow management based on the 29 evelopmentt of smart contracts (Omar *et al.*, 2021; Jagtap *et al.*, 2021; Quasim *et al.*, 2020; Quasim *et al.*, 2020; Kumar *et al.*; Chen *et al.*, 2018; Yu *et al.*; Radhia, 2020). All these works are sharing mainly the great attributes of the medical blockchain which can include the following:

– functioning as a decentralized database, the blockchain is providing an easy way to make the patient is the only owner of the clinical data;

– the blockchain can provide a storage security and privacy medical data protection;

– the patient in in the center of the medical scene. It the only one which can authorize the use of his clinical informations.

Considering that many of the clinical patient data reside in the medical device, our work resonates in this respect and for this purpose we have developed a blockchain-based medical device management system (MDMS) in the form of a decentralized application, taking advantage of SC business logic. It is known that in 2019 IEEE Standards Committee has approved the IEEE 11073 SDC Standard addressing the interoperability of medical devices which define the

manner different medical devices exchange data. The standard has been also adopted and mapped by FHIR specifications. SDC comes to unify the communication between a multitude of proprietary technologies ensuring a bidirectional data transport between equipments and hospital infrastructure. Data sets have a standardized structured format being available for further manipulations. Therefore, this solution can overcome the existing drawbacks of traditional services contracts for medical devices being at the same time a system with a reliable data sharing, storing and retrieval capabilities. Furthermore, we used the Interplanetary Files System (IPFS), a content-based peer to peer storage network for device logs and functional parameters which significantly improves the response times for servicing biomedical engineers in the case of systems errors or malfunctions.

3. MDMS design and development tools

The MDMS implementation is mainly a decentralized application which runs over a public blockchain along with a storage solution for data files using IPFS. Ethereum Platform (EP), an open-source network for running the smart contracts has been chosen with a proof-of-work (PoW) consensus algorithm. MDMS has been designed to run on EP which acts like a distributed state machine.

All the process of development has employed Ethereum Virtual Machine (EVM) along with Ganache, a local blockchain, targeted on Ethereum and Corda of choice, easy to use for fast code business logic testing and deployment. Ganache comes with both command line and desktop versions, offering 10 Ethereum accounts with 100 ether balance. The friendly interface allows the assessment of the entire local blockchain activity and computational complexity of the transactions. Furthermore, Ganache is as a part of Truffle suite, a development and testing framework that we have used, with all the necessary tools for migration of the contracts on blockchain. The environment has a lot of features being widely preferred in the world of decentralized applications.

Firstly, for MDMS development we have used Remix IDE, a JavaScript development tool made available on the EP which permits fast coding of smart contracts directly in the web browser. The user has the possibility to use the compiler for the code in the desired version and the deployment was chosen for fast coding to JVM. The Web3 provider endpoint to Ganache was made to deploy and monitor smart contracts on local node and to use also the Metamask extension for virtual wallet. To build the smart contracts we have used a Solidity, a high-level programming language, which perform static verification at the code compilation time. The compiled bytecode is executed allowing to perform stack operation in any network on the EP.

Figure 1 shows the MDMS workflow and is straightforward. The EP blockchain is used as a repository for device profiles and at the same time is

handling the log datafiles. The access of operators, admins and FSE is made through the user portal. The log hashes retrieved from the IPFS are managed directly by the SC and stored directly in the blockchain to be accessed only by engineers.

Further, the DApp has been initiated using the truffle suite with two main components. A front-side client application for the operators, technical staff administrators and field service engineer's (FSE) portal where the users interact with the following main elements: HTML pages and JavaScript libraries. In our case is Web3.js and ReactJs components. The Web3 library allows to retrieve the data from the blockchain through RPC (remote procedures calls).

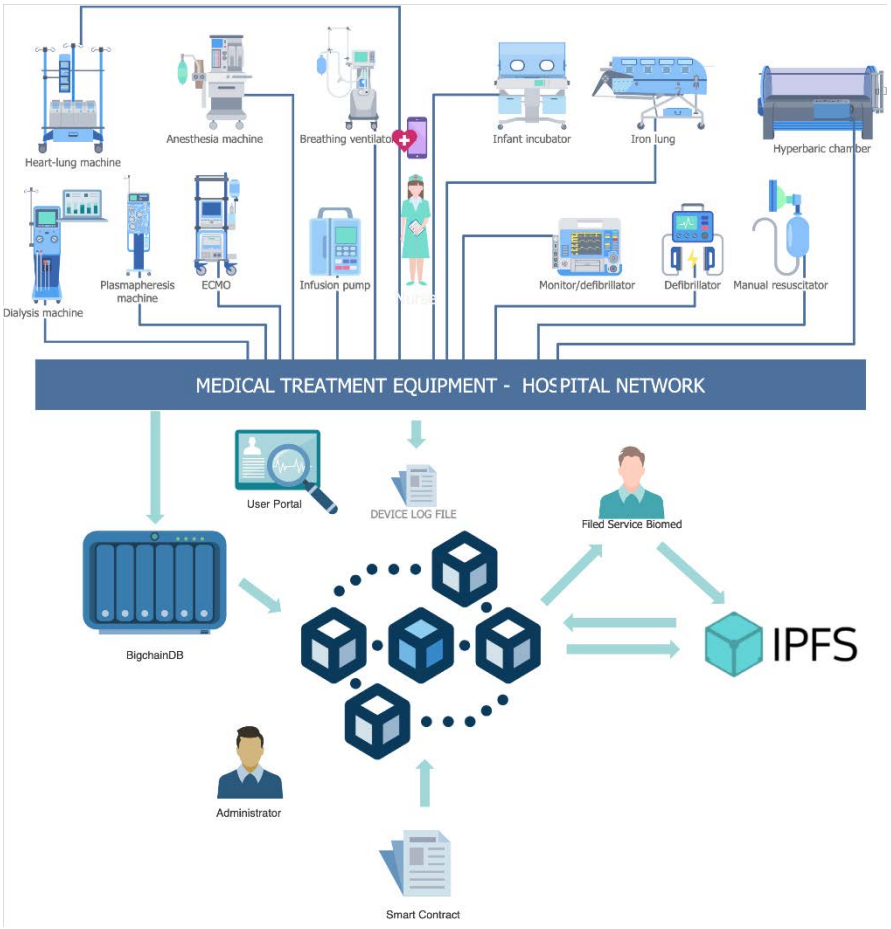


Fig. 1 – Proposed blockchain workflow for MDMS.

Figure 2 shows the SC with all the mappings constructed for a Point of Care medical device system. It worth to mention that both blockchains exchange

only relevant informations such as patient or operator ID's as defined in the FHIR MDS profile.

```
contract Devman {

    //Definig URL http://hl7.org/fhir/uv/pocd/StructureDefinition/MdsDevice
    //StructureDefinition for Device resources that represent a Medical Device System (MDS)
    //only strictly needed profile elements, except MDS parent

    struct mds {
        uint workingHours;
        uint operatingCycles;
        Code[] operatingMode;
        Status[] status;
        StatusReason[] statusReason;
        mapping(uint => patient) patients;
        mapping(uint => operator) operators;
        mapping(uint => mdsString) mdsStrings;
        mapping(uint => location) locations;
        bool isActive;
    }
```

Fig. 2 – Screenshot of the MDMS smart contract written in Solidity and loaded in truffle suite.

Another SC is handling the IPFS storage log data files being instantiated in the main contract allowing a device profile to have its own log history. The implemented SC provide control over the management system data giving the possibility to store medical equipments profiles in the blockchain network using a simplified FHIR schema. At the same time, we have used the BigchainDB to keep the full profile of equipment. The main advantages of using a consortium decentralized database in a hospital environment are the following:

– Each department (*i.e.*, ICU, CSSD, OR's, etc.) is a node and can create digital image (assets) of devices described as immutable with no possibility the change, modify, or delete the data for other entities. The blockchain is replicating the information in different locations and all the transaction are verified having the cryptographical signature (*i.e.*, private keys, etc). The platform that BigchainDB is using is Tendermint which performs a Byzantine Fault Tolerant state machine replication.

– Each department biomed responsible can create its own security. At the same time the admin is using the EP to be functioning as a lightweight backup keeping only the absolutely needed data for serviceman to create the activity reports.

– The local nodes are using a powerful mongoDB instance on the background which gives a huge advantage over the other blockchain architecture regarding the data storage.

For this matter, we have used the Structure Definition for a Medical Device System resource as foreseen in the HL7 FHIR specifications. Moreover, the patient data history is represented as a digital asset and stored in the BigchainDB, proof of concept database. Nevertheless, a lightweight profile of devices is kept in the EP, along with the algorithm for the IPFS log data.

The client application permits for admins the access to all log files and a method to upload data to IPFS (Fig. 4). The data saved for each device profile can be accessed and on both blockchains. Moreover, the log files are stored in tab delimited text files to be easily accessed by FSE directly from a web browser or command line without any other tool. Obviously, the MDMS limitation are for the equipments which are not connected on the hospital network. In that case, the operators can upload through the user portal, photos of the displays with the working parameters and device status. Same is happening with the errors occurred during operation.

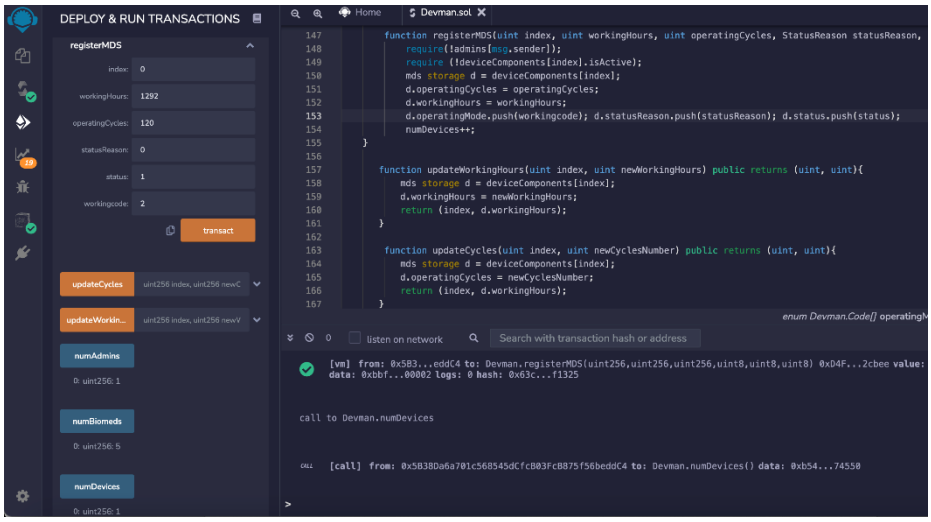


Fig. 3 – Registration on the blockchain and storing the relevant working information for a medical device

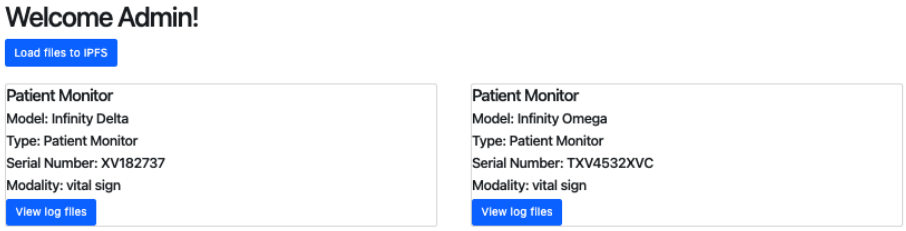


Fig. 4 – Screenshot of the client application admin page interface showing medical device data loaded from the blockchain network.

4. Discussion

Regarding the blockchain technology, several advantages for healthcare providers and maintenance services companies can be brought into attention. First of all, blockchain is a decentralized database. All the profiles of the installed

base devices are stored in the chain-connected blocks by hashes with a mechanism of integrity (*i.e.*, Merkle tree) and lives in the network as long as the deployed smart contract is available.

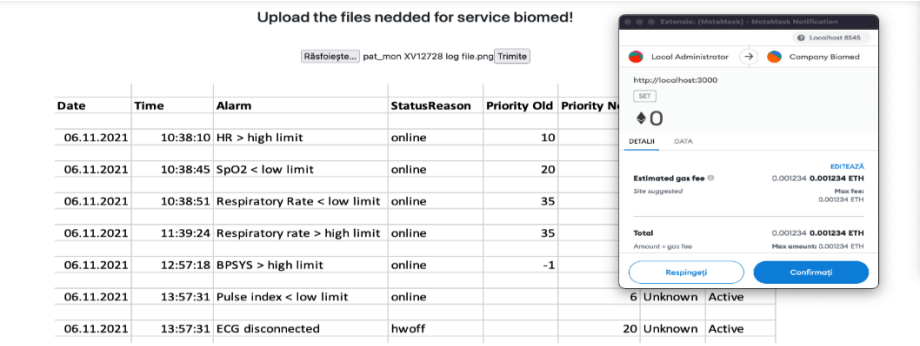


Fig. 5 – Screenshot of the client application page interface showing medical device data loaded from the blockchain network.

MDMS gives healthcare administrator the possibility to orchestrate the MD installed base in a new safe and accessible way. As well, the device errors log files and alarms history and become an effective way to exchange information with third party by a simple electronic transaction, decreasing the time of intervention and less contact with externalized services for repair and maintenance of equipments as it can be seen in Fig. 4. For the sake of simplicity, we have demonstrated the visualization in the browser of a PNG extension file of a log error from a patient monitor. The permission defined rules on the blockchain enable the administrator to keep auditable evidence of interaction of a field service biomed with each MD. Moreover, blockchain acts as a safe database storing all relevant information regarding the profiles, in such a way that Point of Care HL7 structure definition for medical devices are respected. Our work has also involved an improvement phase of SC using the oracle service which has added the easy way to fetch clinical data (heart rate or respiration rate for example) by queries from external HL7 public test server (HAPI FHIR) with no modification of data format only by accessing the API through Ethereum bridge application which gives the path to transfer assets to EVM network. In our scenario the HIS has been a FHIR server which can be easily installed on any department with the BigchainDB along. In this way it can be imagined an integration of external data storages and blockchain technology, just following the FHIR schema. In a real case scenario, considering the huge number of clinical proprietary applications, to reformat the data is not an easy task, but in the decentralized environments starting with a standardization of clinical information might be a correct approach.

5. Conclusion

MDMS has been designed having in mind to provide a safe platform to share equipments functional status and their logs. Our DApp built on blockchain technologies stands for one for decentralized storage of MDS HL7 FHIR profile along with error and devices logs in the IPFS and one using BigchainDB, the blockchain database to store full equipment information along with the patient history with a simplified Vital Sign Panel FHIR profile.

Our framework stands as a base for future developments. We also intent to develop a real case scenario for ICU department considering an integration of clinical data engine and central monitoring station along with the gateway for vital signs export system.

It is clear that the advantage of deploying SC on the blockchain can bring a lot of improvements regarding the way an electronic contract is executed with the other additional authentication and intruder detection benefits. Sharing data in a controlled manner has also opened the way for smart contract and blockchain technology to enter into automation of medical processes. The deterministic behavior, the low cost for implementation and the well-known stability may lead soon to the management of a series of medical events or procedures, and why not, with the help of artificial intelligence in the therapy assist or clinical decision-making field, finally all leading to the improvement of the patient outcome.

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SISTEM DE MANAGEMENT AL DISPOZITIVELOR MEDICALE BAZAT PE TEHNOLOGIE DE BLOCKCHAIN

(Rezumat)

Utilizarea recentă a tehnologiei de tip registru digital distribuit (DLT) în domeniul asistenței medicale poate depăși limitările existente în sistemele IT centralizate, cum ar fi lipsa de securitate, controlul accesului sau imutabilitatea informațiilor electronice privind sănătatea. Dacă discutăm despre informațiile clinice, acest avans informatic inovator oferă înapoi controlul asupra datelor proprietarului de drept, si anume pacientului. În mediile descentralizate, contractele inteligente permit acorduri de încredere bazate pe tranzacții ireversibile, care permit transparența și trasabilitatea acestora. În plus, contractele inteligente reprezintă nucleul viu al aplicațiilor descentralizate pe baza cărora funcționează DTL. În această lucrare, atenția noastră se concentrează asupra echipamentelor medicale care ajută personalul medical să diagnosticheze și să trateze pacienții păstrând o mare parte din datele lor clinice luate în dinamică. Prin urmare, propunem o arhitectură descentralizată pe bază de contracte inteligente pentru gestionarea dispozitivelor, care vizează și serviciile medicale, menite să faciliteze interacțiunea entităților implicate în sănătate. Mediul nostru de testare este platforma Ethereum, utilizată pe scară largă recent în domeniul asistenței medicale, fiind în sine un sistem de operare inteligent, care permite implementarea aplicațiilor descentralizate în blockchain.